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DEPARTMENT OF AGRICULTURE

7 CFR Part 3201 and 3202

Rural Business-Cooperative Service

7 CFR Part 4270

[Docket No. RBS–22–BUSINESS–0004]

RIN 0570–AB05

Biobased Markets Program

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Final rule.

SUMMARY: The Rural Business-Cooperative Service (RBCS or the Agency), an agency of the Rural Development (RD) mission area within the U.S. Department of Agriculture (USDA), is issuing a final rule to adopt changes from the Agriculture Improvement Act of 2018 (2018 Farm Bill) that apply to the Biobased Markets (BioPreferred) Program. These changes include the merger of the Guidelines for Designating Biobased Products for Federal Procurement and the Voluntary Labeling Program for Biobased Products into one streamlined regulation, Biobased Markets (BioPreferred) Program.

DATES: This final rule is effective January 8, 2025.

ADDRESSES: Information regarding the BioPreferred® Program is available at *biopreferred.gov.*

FOR FURTHER INFORMATION CONTACT: Vernell Thompson, Procurement Analyst, USDA RD, 1400 Independence Avenue SW, Washington, DC 20250–1522, STOP 3250; email: *vernell.thompson@usda.gov;* phone (202) 720–4145.

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Authority

The USDA Biobased Markets Program, called the BioPreferred® Program, is established under the authority of Section 9002 of the Farm Security and Rural Investment Act (FSRIA) of 2002 (Pub. L. 107–171) (the 2002 Farm Bill), as amended by the Food, Conservation, and Energy Act of 2008 (Pub. L. 10–246) (the 2008 Farm Bill), the Agricultural Act of 2014 (Pub. L. 113–79) (the 2014 Farm Bill), and the Agriculture Improvement Act of 2018 (Pub. L. 115–334) (the 2018 Farm Bill). Section 9002 of the 2002 Farm Bill, as amended by the 2008, 2014, and 2018 Farm Bills, is referred to in this rule as section 9002 of FSRIA.

II. Background

On January 24, 2024, the Agency published a proposed rule, 89 FR 4770, with request for comments for the purpose of implementing the amendments made to section 9002 of FSRIA by the 2018 Farm Bill by combining the Guidelines for Designating Biobased Products for Federal Procurement (7 CFR part 3201) and the Voluntary Labeling Program for Biobased Products (7 CFR part 3202), the legacy rules of the BioPreferred Program, into one regulation, 7 CFR part 4270, and making amendments to streamline and improve the BioPreferred Program's rules.

The legacy rules established the two core initiatives of the BioPreferred Program. Part 3201 of title 7 of the Code of Federal Regulations detailed the rules for the procurement of Biobased Products by Federal Agencies and their contractors, established the process for designating categories of Biobased Products for preferred Federal procurement, maintained the list of Designated Product Categories, and outlined the requirements for Biobased Products to qualify for preferred Federal procurement. Part 3202 of title 7 of the Code of Federal Regulations established the rules for manufacturers and vendors of Biobased Products to become certified to use the USDA Certified Biobased Product Label (Label) and provided rules for maintaining certification and utilizing the Label. With this rulemaking, the Agency is merging the legacy rules into one streamlined regulation that will facilitate the objective of the BioPreferred Program, which is to encourage the increased use of Biobased Products in all market sectors. Additionally, the Agency believes these changes will benefit BioPreferred Program Stakeholders by implementing process improvements and tying the two initiatives more closely together, making it easier to qualify for both initiatives.

III. Discussion of Public Comments

Sixteen respondents submitted comments on the proposed rule. The Agency reviewed the public comments in the development of the final rule. A discussion of the comments is provided as follows.

A. Definitions

a. Three respondents expressed support for the inclusion of Renewable Chemicals in the definition of the term Biobased Product.

Agency Response: The Agency thanks the respondents for their support of the change to the definition of Biobased Product.

b. One respondent recommended establishing the BioPreferred Program's definition of biobased as the uniform definition throughout the federal government.

Agency Response: The Agency agrees that it is important to have a uniform definition of biobased throughout the federal government. The requirements

established by the BioPreferred Program apply to all federal agencies, and therefore, the definitions established by the BioPreferred Program apply to all federal agencies as well. The Agency will continue efforts to educate federal agencies and their contractors about Biobased Products and the requirements associated with the BioPreferred Program.

B. Criteria for Eligibility

a. Three respondents expressed support for establishing a single participation process under which all products must undergo Biobased Content Testing using ASTM D6866.

Agency Response: The Agency thanks the respondents for their support in establishing a single participation process. For reader clarification, ASTM D6866 is the American Society for Testing and Materials (ASTM) International standard test methods for determining the Biobased Content of solid, liquid, and gaseous samples using radiocarbon analysis.

b. Two respondents expressed concern regarding the added requirements for all products to undergo Biobased Content Testing. The respondents noted that, through collaboration with USDA Forest Service Forest Products Lab (FPL), the Agency has established guidelines for testing wood products, under which specific types of wood and engineered wood products are exempt from testing. The respondents recommended that the Agency continue to uphold these guidelines under this final rule. The respondents asserted that changing the testing requirements for products that fall under the exemption guidelines established with FPL would add unnecessary cost to manufacturers (and therefore purchasers) and hinder the efficiency of the BioPreferred Program.

Agency Response: The Agency agrees that the guidelines for testing wood products that have been established in collaboration with FPL should be maintained. The Agency is not intending to change these guidelines with the implementation of this final rule. Products that are eligible to be exempt from testing under the guidelines established in collaboration with FPL will be exempt from testing as described by § 4270.7(d)(1) in this final rule.

c. Two respondents expressed support for maintaining the raw material sourcing innovative criterion that allows participants to demonstrate that their Biobased Product is innovative if the raw material is sourced from responsible sources according to standards such as ASTM Standard D7612—Standard Practice for Categorizing Wood and Wood-Based Products According to Their Fiber Sources.

Agency Response: The Agency thanks the respondents for their support.

d. One respondent expressed support for the addition of the raw material sourcing innovative criterion that allows participants to demonstrate that their Biobased Product is innovative if the raw material is grown, harvested, manufactured, processed, sourced, or applied in other sustainable and ethically sourced ways as determined by the Agency.

Agency Response: The Agency thanks the respondent for their support.

e. One respondent recommended that Biobased Products should never be grown, sold, or used as an energy source and strongly recommended against establishing any rules, requirements, or funding opportunities related to biofuels.

Agency Response: The Agency notes that biofuels, including motor vehicle fuels, heating oil, and electricity, are specifically excluded from the BioPreferred Program as mandated by section 9002 of FSRIA, and as such, this is outside the scope of the request for comment on the proposed rule.

C. Procurement Programs

a. One respondent would like to see increased enforcement of the requirements for federal agencies and their contractors to purchase Qualified Biobased Products. The respondent noted that the U.S. Government is the single largest purchaser of consumer goods in the world, yet this is not reflected in the reported levels of Biobased Products purchases.

Agency Response: The Agency appreciates this comment and agrees that increased education and enforcement of the requirements to purchase Qualified Biobased Products is needed. The Agency is actively trying to increase awareness of these requirements through outreach efforts such as hosting trainings for federal agencies as requested, reminding federal agencies and their contractors about reporting requirements near the end of each fiscal year, and reviewing solicitations for compliance. These efforts have led to an increase of 1,000% in reporting of Biobased Product purchases in recent years. While this increase is encouraging, the Agency acknowledges that more is needed and hopes to see this trend continue with the implementation of Executive Order (E.O.) 14081, which requires federal agencies to report their Biobased Product purchasing to the Office of Management and Budget.

b. One respondent expressed concerns with section 6 of E.O. 14081, Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. The respondent asserted that E.O. 14081 has a very narrow window of improving the procurement by federal agencies for Renewable Chemicals and Biobased Products by 2024, and by the time staff are trained on the E.O., it may be rescinded by the next administration. The respondent requested that the concepts described in section 6 of E.O. 14081 be incorporated in the reauthorization of the next Farm Bill. The respondent asserted that the guidelines on procuring Biobased Products provided in section 6 of E.O. 14081 need to be codified in legislation as agencies have not been given direction in the implementation of the BioPreferred Program since its inception in the 2002 Farm Bill.

Agency Response: While the contents of E.O. 14081 and legislative changes to the Farm Bill are outside the scope of the request for comment on the proposed rule, the Agency agrees that efforts are needed to ensure federal agencies and their contractors are aware of and understand the requirements for purchasing Qualified Biobased Products.

D. Category Designation

a. Two respondents expressed support for the revised category designation process included in the proposed rule. The respondents noted that the revised process will encourage transparency and timeliness in the procurement of Biobased Products by federal agencies. One of the respondents further noted that the rapid advancement of sophisticated fermentation techniques is leading to the development of Biobased Products and Renewable Chemicals at an increasing rate and a timely response to these advancements will be necessary for the BioPreferred Program to keep pace with industry advancements. Thus, the respondent supported the changes to the category designation process.

Agency Response: The Agency thanks the respondents for their support for the revised category designation process.

b. Two respondents recommended maintaining the category designation process established in the legacy rules. The respondents noted that the process established in the legacy rules is transparent and provides clear guardrails regarding procedural steps for designating product categories. Specifically, the respondents were concerned that without going through

the regulatory process, the revised process may not allow for the collection and evaluation of Stakeholder feedback on category additions and updates. Further, the respondents were concerned that the revised process would lead to a loss of clear requirements to provide Stakeholders with adequate notice and opportunity to comment, and in turn, the requirement for the Agency to consider and respond to all comments would be lost. The respondents strongly encouraged the Agency to establish similar, robust procedures for notice, comment, and Stakeholder feedback should the Agency move forward with the revised process.

Agency Response: The Agency strongly agrees with maintaining the transparency and robustness of the category designation process, and the Agency intends to ensure that the revised designation process provides Stakeholders with opportunities to review and provide input equal to those provided by the process established by the legacy rules. Under the revised category designation process, the Agency intends to notify Stakeholders of potential updates and additions to designated product categories. While these updates will no longer be made through the formal rulemaking process, the Agency acknowledges that many Stakeholders have become accustomed to learning about designated category changes through **Federal Register** notices. As such, the Agency intends to notify Stakeholders of changes to designated product categories through **Federal Register** notices that will direct them to view and submit comments on the changes through the BioPreferred Program's website. Similarly, the Agency intends to maintain the process for considering and responding to public comments on designated product categories; this process will take place on the BioPreferred Program's website rather than as a step in the formal rulemaking process. The Agency believes that the revised process will create a balance between proposing and implementing changes in a timely manner and maintaining the transparency of the process established by the legacy rules.

E. Determining Biobased Content

a. One respondent urged the Agency to require Biobased Content Testing for products to qualify for the federal procurement preference. The respondent asserted that without required testing, there is a heightened risk for greenwashing and fraud. The respondent also recommended establishing Biobased Content audit procedures for products that are qualified to receive the federal procurement preference.

Agency Response: The Agency appreciates these comments. The Agency notes that under section 9002 of FSRIA, any Biobased Product that meets the requirement of one or more designated product category is qualified to receive a federal procurement preference. This means that Biobased Products may be qualified to receive a federal procurement preference even if they do not participate in the BioPreferred Program. Qualified Biobased Products that participate in the BioPreferred Program will be required to undergo the same Biobased Content Testing and auditing procedures as certified products according to this final rule. While the Agency is unable to establish requirements for products that do not participate in the BioPreferred Program, the Agency believes it is important for federal buyers to be aware of Biobased Content requirements and ask for validation of Biobased Content claims when making purchasing decisions. To that end, the legacy rules included a stipulation that required manufacturers and vendors to provide federal agencies information to verify Biobased Content claims for Qualified Biobased Products upon request. The Agency realized this stipulation was unintentionally left out of the proposed rule language and is revising the final rule to include it.

b. One respondent strongly supported the continued use of ASTM D6866 to measure Biobased Content. The respondent also recommended specifying the use of ASTM D6866 Method B when conducting Biobased Content Testing, rather than also allowing the use of ASTM D6866 Method C as the instruments used for Method C tend to be less accurate than those used in Method B. The respondent stated that the results produced by ASTM D6866 Method B are easily understood by regulators, policy makers, corporate officers, and the public, and the overwhelming advantage of this test method is that it is an independent and standardized laboratory measurement that produces highly accurate and precise values. This means that the test results can be easily reproduced to verify the value if the results are challenged. The respondent specifically supported the use of ASTM D6866 Method B over the test method EN 16785–2 and mass balance measurements. The respondent asserted that calculation-based approaches, such as mass balance calculations, are difficult to audit and could lead to greenwashing of Biobased Content claims.

Agency Response: The Agency thanks the respondent for their support of the continued use of ASTM D6866 to validate Biobased Content claims. The Agency agrees with the use of ASTM D6866 Method B when products undergo Biobased Content Testing for certification and notes that this is current practice. The Agency feels that specifying the use of Method B in the final rule is unnecessary but will refer to Method B in informational materials on the BioPreferred Program's website and in information sent to participants prior to testing.

c. Two respondents strongly encouraged the Agency to include an additional certification pathway that utilizes mass balance methods to verify content claims, a recommendation that was included in the Conference Report that accompanied the 2018 Farm Bill. The respondents stated that while the ASTM D6866 test method is adequate for determining the amount of traceable Biobased Content present in a finished product, it is unable to account for renewable feedstocks attributed under the mass balance approach. The respondents asserted that modernizing the BioPreferred Program to include the mass balance approach as one of the approved methods to qualify for the BioPreferred Program would advance the program's goals of furthering the bioeconomy and providing new markets for farm commodities. The respondents also stated that incorporating the mass balance method to approve products to qualify for the BioPreferred Program would substantially lower the barrier to entry for Participating Organizations and further incentivize U.S. production of mass balance Biobased Products and their related markets.

Agency Response: The Agency appreciates the comments. The Agency notes that it is required to follow the specifications included within the 2018 Farm Bill itself; some of the recommendations in the accompanying Conference Report were not included in the 2018 Farm Bill, and establishing a certification pathway using mass balance approaches is one such recommendation. The Agency acknowledges that industry use of the mass balance approach can help advance the BioPreferred Program's goals of furthering the bioeconomy and providing new markets for farm commodities. However, the Agency believes that further consideration is needed before including an additional certification pathway that utilizes mass balance methods to verify content claims. The Agency also acknowledges

that the mass balance process may make it easier for manufacturers to transition to more sustainable feedstocks because segregated production pathways are not needed. The Agency notes that products produced by mass balance methods are not Biobased Products as defined by this final rule. To maintain the integrity of the Label and to prevent diluting public understanding of what the Label means, it is important that the Agency maintain a consistent definition of what it means for a product to be biobased. The Agency feels that allowing alternative methods that certify claims other than Biobased Content as defined by this final rule would cause confusion about what the Label is reporting. The Agency believes that including the mass balance approach as one of the approved methods to participate in the BioPreferred Program would require establishing a separate Label and certification process with separate requirements to those established for Biobased Products, which would require significant resources. The Agency will continue to stay informed of any advancements in the use of the mass balance approach and will coordinate with program Stakeholders and the program's Technical Advisory Committee to evaluate these advancements as resources allow.

d. Two respondents recommended allowing alternative test methods in addition to the use of ASTM D6866 to validate Biobased Content claims. The respondents stated that the ASTM D6866 test method essentially discounts the relative weight of the non-carbon biobased components in products as ASTM D6866 only measures the weight of carbon content in a product. The respondents noted that certain types of products, such as wood products, contain a significant amount of molecular oxygen, and failing to account for molecular oxygen substantially underrepresents the proportion of ''biobased'' materials. The respondents recommended amending the final rule to allow for the use of alternative, more accurate methodologies for measuring Biobased Content as future industry consensus standards are developed and adopted.

Agency Response: The Agency appreciates the comments. The Agency believes it is important to maintain a consistent definition of Biobased Content across all types of materials to maximize understanding of what the Label means. At this time, the Agency defines Biobased Content as the amount of recent, biologically derived organic carbon in the material or product expressed as a percent of weight (mass) of the total organic carbon in the material or product. The Agency feels that allowing alternative test methods that measure attributes other than Biobased Content as defined by this final rule would cause confusion about what the Label is reporting.

e. One respondent recommended adding a certification attribute that quantifies the carbon intensity of a given product.

Agency Response: This is outside the scope of the request for comment on the proposed rule, which seeks to implement the amendments made to section 9002 of FSRIA by the 2018 Farm Bill.

f. Two respondents recommended allowing testing exemptions for products that have been certified to industry consensus standards that are substantively equivalent to the third-party requirements set out in the proposed rule. The respondents noted that doing so would avoid duplicative costs and compliance burdens.

Agency Response: The Agency appreciates these comments. The Agency agrees that, where possible, efforts should be made to minimize burdens associated with participating in the BioPreferred Program. To that end, the Agency allows testing exemptions in specific situations where the Biobased Content of an exempt product has been demonstrated using the alternative methods specified in § 4270.7(d)(1) of this final rule. Maintaining the integrity of the BioPreferred Program and the Label is of upmost importance, and the Agency believes that accepting testing that has been done outside of the Agency's oversight could erode that integrity.

g. One respondent expressed support for allowing testing exemptions for Biobased Product Ingredients with the same formulation as other, already-approved products. The respondent noted that allowing these exemptions reduces the cost and time burdens associated with participating in the BioPreferred Program, which is important as many potential participants already have tight margins as they work to scale their operations.

Agency Response: The Agency thanks the respondent for their support.

h. Two respondents recommended specifying that Biobased Content Testing must be done by a laboratory that is ISO/IEC 17025 accredited by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body.

Agency Response: For reader clarity, International Organization for Standardization (ISO) is an independent, non-governmental, international standard development organization composed of representatives from the national standards organizations of member countries. International Electrotechnical Commission (IEC) is an organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

The Agency agrees that ISO accreditation is important to maintain the integrity of the certification process. While the final rule does not specify that testing facilities must be ISO/IEC 17025 accredited, the Agency does require laboratories that are approved to perform testing for the BioPreferred Program to maintain ISO/IEC 17025 accreditation. The Agency believes it is not necessary to specify in the final rule that laboratories must be ISO/IEC 17025 accredited since the Agency verifies accreditation before laboratories are approved to perform testing for the BioPreferred Program.

i. One respondent recommended specifying that laboratories that are approved to perform testing for the BioPreferred Program be carbon-14 tracer-free facilities.

Agency Response: The Agency agrees that it is important for laboratories that are approved to perform testing for the BioPreferred Program be carbon-14 tracer-free facilities to minimize the potential for contamination of certification samples. Laboratories that are approved to perform testing for the BioPreferred Program sign an agreement with the Agency; the Agency believes the tracer-free stipulation would be better suited to be included in the laboratory agreement rather than in this final rule.

F. Initial Approval Process/Oversight and Monitoring

a. One respondent recommended reducing the time period between recertification requirements (referred to by the respondent as audits) from every 5 years to every 2 to 3 years. The respondent emphasized that these requirements must include retesting using ASTM D6866 rather than allowing a self-declaration attesting that the formulation has not been altered. The respondent asserted that, given the frequency of supply chain and formulation changes required in the Biobased Products industry, a 5-year sampling period does not guarantee that products displaying the USDA Certified Biobased Product Label will contain the Biobased Content their companies receive certification for. The respondent also recommended establishing a blind auditing procedure to randomly select products for testing in between recertification periods. The respondent

stated that coupling blind audits with more frequent recertification requirements is the best way to ensure accurate, fair validation.

Agency Response: The Agency appreciates these comments. The Agency notes that under the revised requirements, participants will be required to participate in an annual informational audit, during which they will self-verify that their company and product information remains up to date, as well as have their products recertified by undergoing ASTM D6866 testing every 5 years. Under the legacy rules, informational audits and retesting audits both took place every 6 years. The Agency believes that establishing an annual information audit during which participants must confirm or update their company and product information will be frequent enough to remind participants to notify the Agency of supply chain changes that may affect their product formulations. While the Agency agrees that more frequent retesting requirements, including the addition of a blind auditing procedure, would better ensure that the Biobased Content of certified products remain valid, the Agency must consider the burden associated with maintaining certification on program participants. The Agency believes that combining annual informational audits with 5-year recertification requirements balances the need to obtain updated information from participants while minimizing the burdens associated with retesting. However, the final rule does allow the Agency to request that a product be retested outside of the 5-year certification period if concerns about the validity of the product's Biobased Content are raised.

b. One respondent recommended reducing the window of time allowed to conform to the updated requirements for participants with products that are qualified but not certified or products that have been certified for more than 5 years. The respondent asserted that a 3-year window to conform to the final rule is too much time and recommended reducing this to 6 months to a year maximum and any product that does not conform within that timeframe should be removed from the BioPreferred Program.

Agency Response: The Agency appreciates these comments. The Agency agrees that allowing a 3-year window to conform to the final rule is a generous amount of time. However, given the large number of products that will be required to undergo Biobased Content Testing to conform to the updated requirements, the Agency believes that a grace period of this length is needed to minimize the burden that may be placed on program resources in undertaking these activities. The Agency notes that all participants will be required to participate in annual informational audits during the grace period and may be removed from the BioPreferred Program's website if they fail to participate in such audits.

c. One respondent noted that the success for this type of certification is dependent on its universality and flexibility.

Agency Response: The Agency thanks the respondent for their comment.

G. Miscellaneous/General

a. Five respondents expressed support for the Agency's efforts to streamline the BioPreferred Program's rules.

Agency Response: The Agency thanks the respondents for their support.

b. One respondent expressed support for streamlining the BioPreferred Program's rules but expressed concern that this final rule does not do enough to streamline the program for participants. The respondent stated that streamlining does not improve important issues within the BioPreferred Program, such as improving the procurement initiative. To further assist in the implementation and enforcement of Biobased Product purchasing and reporting requirements, the respondent requested that procurement officers be identified for the BioPreferred Program.

Agency Response: The Agency appreciates the comments. The Agency believes the efforts to streamline the BioPreferred Program will have positive impacts for participants and potential participants by establishing a single, efficient process through which products are determined to be qualified for a federal procurement preference and eligible to use the Label. The changes to the category designation process will also streamline the program for participants by making it quicker and easier to designate new categories, allowing more products to qualify for the federal procurement preference. The Agency notes that the BioPreferred Program does not itself procure products, and therefore, procurement officers are not needed within the BioPreferred Program. The Agency will continue its efforts to educate federal agencies (including procurement officers) and their contractors on the requirements for purchasing Qualified Biobased Products and reporting such purchases.

c. One respondent expressed general support for the BioPreferred Program. The respondent noted that the BioPreferred Program presents a significant opportunity to promote sustainability, innovation, and economic growth. The respondent also noted that the BioPreferred Program parallels the success of the National Organic Program, and by providing a clear framework for the certification and labeling of Biobased Products, the final rule will enhance consumer awareness of and confidence in Biobased Products in a similar manner to what the National Organic Program has done for organic products. The respondent further noted that the BioPreferred Program has the potential to create new avenues for job growth and economic development, particularly in rural communities. Additionally, the respondent noted that by incentivizing investment in Biobased Product research, production, and manufacturing, the BioPreferred Program can help bolster rural economies.

Agency Response: The Agency thanks the respondent for their support.

d. Three respondents recommended establishing North American Industry Classification System (NAICS) codes for Biobased Products with this final rule.

Agency Response: While establishing NAICS codes are outside the scope of the request for comment on the proposed rule, the Agency strongly agrees that it is necessary to establish NAICS codes for Biobased Products and will share these comments with the Department of Commerce. The Agency will continue its efforts to encourage the Department of Commerce to establish NAICS codes for Biobased Products and will continue to offer support as needed to advance these efforts.

e. One respondent recommended making updates to the BioPreferred Program website to make it more consumer friendly.

Agency Response: The Agency appreciates this comment. While this is outside the scope for the proposed rule request for comment, the Agency agrees that the BioPreferred Program's website is in need of updates to make information easier to find and understand. The Agency is currently working to refresh the BioPreferred Program's website to make these changes.

f. One respondent recommended that the BioPreferred Program be incorporated into the Coordinated Framework established by section 8 of E.O. 14081.

Agency Response: This is outside the scope of the proposed rule request for comment.

g. One respondent requested the proposed rule plain language summary.

Agency Response: The Agency provided the appropriate information for locating the plain language summary at *regulations.gov*.

h. One respondent inquired whether there would be an interagency review of the proposed rule.

Agency Response: The proposed rule did not require official interagency review because the rulemaking was designated as non-significant.

IV. Summary of Changes

The final rule will not include revisions based on the public comments received in response to the proposed rule. The final rule will include two technical amendments summarized below.

a. In the final rule, § 4270.7(a) is being revised to include the last sentence from 7 CFR 3201.7(a). While reviewing the public comments, the Agency determined that this stipulation was unintentionally excluded from the proposed rule language. This requirement is being added to the final rule language to clarify that manufacturers and vendors of Qualified Biobased Products may be asked to prove their Biobased Content claims regardless of whether they participate in the BioPreferred Program.

b. In addition, § 4270.7(c)(2)(i) is being revised to correct the notation used in the Complex Assemblies equation. The proposed rule used ''of the nth component'' and the final rule is being revised to correct this to ''of the ith component.''

V. Executive Orders/Acts

A. Executive Order 12866—Classification

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

B. Executive Order 12372—Intergovernmental Consultation

This program is not subject to the requirements of Executive Order 12372, Intergovernmental Review of Federal Programs, as implemented under 2 CFR part 415.

C. Paperwork Reduction Act

The information collection and recordkeeping requirements contained in this final rule will not be effective until approved by OMB, subject to the submission of a paperwork package submitted to OMB pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

D. National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, Public Law 91–190, this final rule has been reviewed in accordance with 7 CFR part 1970. The Agency has determined that (i) this action meets the criteria established in 7 CFR 1970.53(f); (ii) no extraordinary circumstances exist; and (iii) the action is not ''connected'' to other actions with potentially significant impacts, is not considered a ''cumulative action,'' and is not precluded by 40 CFR 1506.1. Therefore, the Agency has determined that the action does not have a significant effect on the human environment, and therefore neither an Environmental Assessment nor an Environmental Impact Statement is required.

E. Regulatory Flexibility Act

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

F. Administrative Pay-As-You-Go-Act of 2023

The Administrative Pay-As-You-Go-Act of 2023 (Act) (See Fiscal Responsibility Act of 2023, Pub. L. 118–5, 137 Stat 31, div. B, title III) requires the U.S. Government Accountability Office (GAO) to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. The Act does not apply to this final rule because it does not increase direct spending.

G. Executive Order 12988—Civil Justice Reform

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

H. Unfunded Mandates Reform Act (UMRA)

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

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

I. Executive Order 13132—Federalism

The policies contained in this final rule do not have any substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Nor does this final rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with the States is not required.

J. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the

Federal Government and Indian tribes. Consultation is also required for any regulation that preempts Tribal law or that imposes substantial direct compliance costs on Indian Tribal governments and that is not required by statute.

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

K. E-Government Act Compliance

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

L. Civil Rights Impact Analysis

RD has reviewed this final rule in accordance with USDA Regulation 4300–4, Civil Rights Impact Analysis, to identify any major civil rights impacts the final rule might have on program participants on the basis of age, race, color, national origin, sex, disability, marital or familial status. Based on the review and analysis of the final rule and all available data, issuance of this final rule is not likely to negatively impact low and moderate-income populations, minority populations, women, Indian tribes or persons with disability, by virtue of their age, race, color, national origin, sex, disability, or marital or familial status. No major civil rights impact is likely to result from this final rule.

M. USDA Non-Discrimination Statement

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

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; or the 711 Relay Service.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *usda.gov/sites/default/files/documents/ad-3027.pdf* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

a. *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or

b. *Fax:* (833) 256–1665 or (202) 690–7442; or

c. *Email: program.intake@usda.gov.*

N. Severability

It is USDA's intention that the provisions of this final rule shall operate independently of each other. In the event that this final rule or any portion of this final rule is ultimately declared invalid or stayed as to a particular provision, it is USDA's intent that the final rule nonetheless be severable and remain valid with respect to those provisions not affected by a declaration of invalidity or stayed. USDA concludes it would separately adopt all of the provisions contained in this final rule.

List of Subjects in 7 CFR Parts 3201, 3202, and 4270

Biobased products, Business and industry, and Government procurement.

For the reasons stated in the preamble, USDA amends chapters XXXII and XLII of title 7 of the Code of Federal Regulations as follows:

CHAPTER XXXII—OFFICE OF PROCUREMENT AND PROPERTY MANAGEMENT

PART 3201 [REMOVED AND RESERVED]

■ 1. Under the authority of 7 U.S.C. 8102, remove and reserve part 3201.

PART 3202 [REMOVED AND RESERVED]

■ 2. Under the authority of 7 U.S.C. 8102, remove and reserve part 3202.

CHAPTER XLII—RURAL BUSINESS-COOPERATIVE SERVICE

■ 3. Add part 4270, consisting of §§ 4270.1 through 4270.99, to read as follows:

PART 4270—USDA BIOBASED MARKETS PROGRAM: FEDERAL PROCUREMENT AND VOLUNTARY LABELING

Sec.

Authority: 7 U.S.C. 8102.

§ 4270.1 Purpose and scope.

(a) This part sets forth the procedures and guidelines for the implementation of the USDA Biobased Markets Program, called the BioPreferred® Program, established by section 9002 of the Farm Security and Rural Investment Act of 2002 (FSRIA) as amended by the Food, Conservation, and Energy Act of 2008, and further amended by the Agricultural Act of 2014, and the Agriculture Improvement Act of 2018 (Pub. L. 107–171, 116 Stat. 476, 7 U.S.C. 8102).

(b) The guidelines in this part establish:

(1) A process for designating categories of products that are, or can be, produced with biobased Intermediate Ingredients or feedstocks and whose procurement by procuring agencies and other relevant Stakeholders will carry out the objectives of section 9002 of FSRIA;

(2) The criteria for eligibility and the process through which Biobased Products can participate in the BioPreferred Program, be subject to preferred Federal procurement, and be eligible to display the USDA Certified Biobased Product Label;

(3) Specifications for the correct and incorrect uses of the USDA Certified Biobased Product Label and Certification Icon, which apply to Participating Organizations and Other Entities; and

(4) Actions that constitute noncompliance with this part.

§ 4270.2 Definitions

Agricultural materials. Plant, animal, and marine matter, raw materials or residues used in the manufacturing of a commercial or industrial product excluding food, feed, motor vehicle fuel, heating oil, and electricity.

Applicable minimum biobased content. The required Biobased Content level set by USDA that a product must meet or exceed to qualify for the Federal procurement preference and use of the USDA Certified Biobased Product Label.

ASTM International (ASTM). A nonprofit organization, formerly known as American Society for Testing and Materials, that provides an international forum for the development and publication of voluntary consensus standards for materials, products, systems, and services.

Biobased content. The amount of recent, biologically derived organic carbon in the material or product expressed as a percent of weight (mass) of the total organic carbon in the material or product.

Biobased content testing. The testing that is performed to verify a product's Biobased Content. For products participating in the BioPreferred Program, the Biobased Content is to be determined using ASTM Method D6866, Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis.

Biobased product(s). (1) A product determined by USDA to be a commercial or industrial product (other than food or feed) that is:

(i) Composed, in whole or in significant part, of Biological Products, including renewable domestic Agricultural Materials, Renewable Chemicals, and forestry materials; or

(ii) An Intermediate Ingredient or Feedstock.

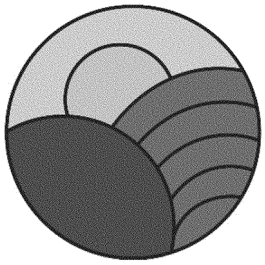
(2) The term Biobased Product includes, with respect to forestry materials, Forest Products that meet Biobased Content requirements, notwithstanding the market share the product holds, the age of the product, or whether the market for the product is new or emerging. For the purposes of the BioPreferred Program, the term Biobased Product does not include motor vehicle fuels, heating oils, or electricity.

Biodegradability. A quantitative measure of the extent to which a material is capable of being decomposed by biological agents, especially bacteria.

Biological products. Products derived from living materials.

Certification icon. The distinctive image, as shown in figure 1 (note that actual size will vary depending on application), that depicts the symbols of the sun, the soil, and the aquatic environments to be used with USDA's permission to identify Certified Biobased Products. The icon will be used in materials including, but not limited to, advertisements, catalogs, procurement databases, websites, and promotional and educational materials. The colors used in the Certification Icon can be found in the USDA BioPreferred Program Brand and Marketing Guidelines available on the BioPreferred Program website (*biopreferred.gov*).

Figure 1 to Definition of Certified Icon—Certification Icon



Certified application. An application for a Biobased Product to participate in the BioPreferred Program that has completed all steps of the certification process, including an initial Prequalification review and Biobased Content Testing as required, and has received a notice of certification.

Certified biobased product. A Biobased Product that is eligible for preferred Federal procurement because it meets the definition and Applicable Minimum Biobased Content criteria for one or more Designated Product Categories as specified in the Register of Designated Categories, and for which the Participating Organization has received approval from USDA to utilize the USDA Certified Biobased Product Label.

Complex assembly. A system of distinct materials and components assembled to create a finished product with specific functional intent where some or all of the system components contain some amount of biobased material or feedstock.

Days. As used in this part means calendar Days.

Defined product category. Any product category that has been established for a specified grouping of Biobased Products with similar characteristics and intended uses. A Defined Product Category includes a description of the product characteristics that fall within the category. The other product category is not a Defined Product Category.

Designated product category. A grouping of Biobased Products, including finished products, Intermediate Ingredients or Feedstocks, and Complex Assemblies, identified in the Register of Designated Categories on the BioPreferred Program website (*biopreferred.gov*). Certified or Qualified Biobased Products that meet the criteria for at least one designated category are eligible for the procurement preference established under section 9002 of FSRIA.

Designated representative. An entity authorized by a Participating Organization to act on their behalf to obtain certification or to affix the USDA Certified Biobased Product Label to the Participating Organization's Certified Biobased Product or its packaging or perform other marketing functions.

Federal agency. Any executive agency or independent establishment in the legislative or judicial branch of the Government (except the Senate, the House of Representatives, the Architect of the Capitol, and any activities under the Architect's direction).

Forest product. A product made from materials derived from the practice of forestry or the management of growing timber. The term Forest Product includes:

(1) Pulp, paper, paperboard, pellets, lumber, and other wood products; and

(2) Any recycled products derived from forest materials.

Formulated product. A product that is prepared or mixed with other Ingredients, according to a specified formula and includes more than one Ingredient.

FSRIA. The Farm Security and Rural Investment Act of 2002, Public Law 107–171, 116 Stat. 134 (7 U.S.C. 8102).

Ingredient. A component, or a part of a compound or mixture, that may be active or inactive.

Innovative criteria. Benchmark for demonstrating new and emerging approaches in the growing, harvesting, sourcing, procuring, processing, manufacturing, or application of the Biobased Product. Biobased Products must meet one of the Innovative Criteria

as defined by USDA to be eligible for preferred Federal procurement and to display the USDA Certified Biobased Product Label.

Intermediate ingredient or feedstock. A material or compound made in whole or in significant part from Biological Products, including renewable Agricultural Materials (including plant, animal, and marine materials) or forestry materials that have undergone value added processing (including thermal, chemical, biological, or a significant amount of mechanical processing), excluding harvesting operations, offered for sale by a Participating Organization and that is subsequently used to make a more complex compound or product.

ISO. The International Organization for Standardization, a network of national standards institutes working in partnership with international organizations, governments, industries, business, and consumer representatives.

ISO 9001 conformant. An entity that meets all the requirements of the ISO 9001 standard, but that is not required to be ISO 9001 certified. ISO 9001 refers to the ISO's standards and guidelines relating to quality management systems. Quality management is defined as what the manufacturer does to ensure that its products or services satisfy the customer's quality requirements and comply with any regulations applicable to those products or services.

Other entity. Any person, group, public or private organization, or business other than USDA or Participating Organizations that may wish to use the USDA Certified Biobased Product Label or Certification Icon in informational or promotional material related to a Certified Biobased Product.

Parent product. The Certified Biobased Product in a test exempt relationship that was originally tested for certification. A test exempt product references the Certified Application of its Parent Product.

Participating organization. An entity that has completed the steps required to have a Certified and/or Qualified Biobased Product under the BioPreferred Program. Participants can include entities that perform the necessary chemical and mechanical processes to make a Biobased Product, and entities that offer for sale Biobased Products that they do not manufacture but that are marketed and sold under their own brand.

Prequalification. The step during the certification process at which an application is conditionally approved pending the product undergoing Biobased Content Testing.

Procuring agency. Any Federal Agency that is using Federal funds for procurement or any business contracting with any Federal Agency with respect to work performed under the contract.

Qualified biobased product(s). A product that is eligible for preferred Federal procurement because it meets the definition and Applicable Minimum Biobased Content criteria for one or more Designated Product Categories as specified in the Register of Designated Categories.

Register of Designated Categories. The list of product categories that are eligible for the procurement preference established under section 9002 of FSRIA, including the category name, description, required minimum Biobased Content, and date of finalization. The Register of Designated Categories can be found on the BioPreferred Program website at *biopreferred.gov*.

Renewable chemical. A monomer, polymer, plastic, Formulated Product, or chemical substance produced from renewable biomass.

Secretary. The Secretary of the United States Department of Agriculture.

Stakeholder. Individuals or officers of State or local government organizations, private non-profit institutions, or organizations, and private businesses or consumers.

USDA. The United States Department of Agriculture.

USDA Certified Biobased Product label. A combination of the Certification Icon (as defined in this part); one of three statements identifying whether the USDA certification applies to the product, the package, or both the product and package; and the letters ''FP'' to indicate that the product is within a Designated Product Category and eligible for preferred Federal procurement. The distinctive image, as shown in figures 2, 3, and 4 (note that actual size will vary depending on application), identifies products as USDA Certified Biobased Products. The colors used in the USDA Certified Biobased Product Label can be found in the USDA BioPreferred Program Brand and Marketing Guidelines available on the BioPreferred Program website (*biopreferred.gov*). The USDA Certified Biobased Product Label is owned and its use is managed by USDA (standard trademark law definition applies).

Figure 2 to Definition of USDA Certified Biobased Product Label—USDA Certified Biobased Product Label

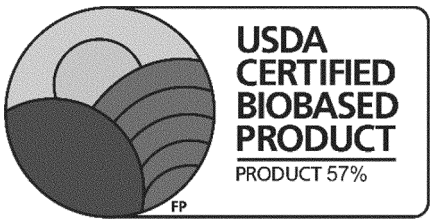


Figure 3 to Definition of USDA Certified Biobased Product Label—USDA Certified Biobased Package Label

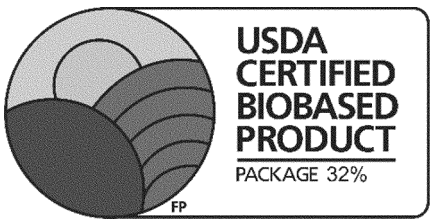
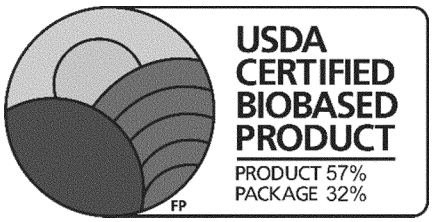


Figure 4 to Definition of USDA Certified Biobased Product Label—USDA Certified Biobased Product & Package Label



§ 4270.3 Applicability.

(a) *Applicability to Federal procurements*—(1) *Applicability to procurement actions.* The guidelines in this part apply to all procurement actions by Procuring Agencies involving product categories designated by USDA in this part, where the Procuring Agency makes purchases of $10,000 or more of one of these products during a fiscal year, or where the quantity of such products or of functionally equivalent products purchased during the preceding fiscal year was $10,000 or more. The $10,000 threshold applies to Federal Agencies as a whole rather than to agency subgroups such as regional offices or subagencies of a larger Federal department or agency.

(2) *Exception for procurements subject to Environmental Protection Agency (EPA) regulations under the Solid Waste Disposal Act.* For any procurement by any Procuring Agency that is subject to regulations of the Administrator of the EPA under section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976 (40 CFR part

247), these guidelines do not apply to the extent that the requirements of this part are inconsistent with such regulations.

(3) *Procuring products composed of the highest percentage of Biobased Content.* Section 9002(a)(2) of FSRIA (7 U.S.C. 8102(a)(2)) requires Procuring Agencies to procure Qualified Biobased Products composed of the highest percentage of Biobased Content practicable. Procuring agencies may decide not to procure such Qualified Biobased Products if they are not reasonably priced or readily available or do not meet specified or reasonable performance standards.

(4) *Incidental purchases.* This part does not apply to purchases of Qualified Biobased Products that are unrelated to or incidental to Federal funding (*i.e.,* purchases that are not the direct result of a contract or agreement with persons supplying products to a Procuring Agency or providing support services that include the supply or use of products).

(5) *Exemptions.* The following applications are exempt from the preferred procurement requirements of this part:

(i) Military equipment: Products or systems designed or procured for combat or combat-related missions.

(ii) Spacecraft systems and launch support equipment.

(b) *Applicability to Participating Organizations and Other Entities*—(1) *Participating Organizations.* The requirements in this part apply to all prospective Participating Organizations who wish to participate in the BioPreferred Program. Those wishing to participate in the BioPreferred Program are required to obtain and maintain product certification. USDA will allow only one owner or Designated Representative of a branded product to participate. Participating Organizations may not obtain product certification for a product using a brand name owned by a separate organization unless they are acting on behalf of the brand owner, with their approval, as a Designated Representative.

(2) *Other Entities.* The requirements in this part apply to Other Entities who wish to use the USDA Certified Biobased Product Label or Certification Icon in promoting the sales or the public awareness of Certified Biobased Products.

§ 4270.4 Criteria for eligibility.

A product must meet each of the criteria specified in paragraphs (a) through (c) of this section to be eligible to participate in the BioPreferred Program.

(a) *Biobased Product.* The product for which certification is sought must be a Biobased Product as defined in § 4270.2. Products must undergo Biobased Content Testing as described in § 4270.7 of this part to confirm the products meet or exceed the applicable minimums.

(1) *Products that are qualified for preferred Federal procurement but not certified as of the date of publication of this rule.* If the product is qualified for preferred Federal procurement through the BioPreferred Program as of January 8, 2025, the product will remain eligible under the legacy rules, which can be found on the BioPreferred Program website (*biopreferred.gov*), until the product is reformulated, discontinued, or until December 9, 2027, whichever comes first. These products must follow the procedures described in § 4270.9 before December 9, 2027 to remain eligible.

(2) *Exclusions.* Motor vehicle fuels, heating oil, and electricity are excluded by statute from this Program. For the purposes of this Program, food, animal feed, and products intended to be ingested or inhaled such as pharmaceuticals or nutraceuticals are also excluded.

(b) *Minimum Biobased Content.* The Biobased Content of the product must be equal to or greater than the Applicable Minimum Biobased Content, as described in paragraphs (b)(1) and (2) of this section.

(1) *Products that fall under one or more Defined Product Categories*—(i) *Product is within a single product category.* If the Biobased Product is within a single Defined Product Category that, at the time the application for certification is submitted, has been designated by USDA for preferred Federal procurement, the Applicable Minimum Biobased Content requirement for the product is the minimum Biobased Content specified for the Defined Product Category as found in the Register of Designated Categories on the BioPreferred Program website at *biopreferred.gov.*

(ii) *Product is within multiple product categories.* If the Biobased Product is marketed within more than one Defined Product Category identified for preferred Federal procurement at the time the application for certification is submitted and uses the same packaging for each use, the product's Biobased Content must meet or exceed the specified minimum Biobased Content for each of the applicable product categories, as found in the Register of Designated Categories on the BioPreferred Program website at *biopreferred.gov,* to become certified in each category. If the product's Biobased Content does not meet the specified minimum Biobased Content for the category that most closely matches the product's primary intended use, the product is not eligible to participate.

(2) *Products that do not meet the definition of at least one Defined Product Category.* If the Biobased Product does not meet the definition of a Defined Product Category that has been designated by USDA at the time the application for certification is submitted, the Applicable Minimum Biobased Content is 30 percent. USDA will evaluate such products as described in § 4270.6 to determine the viability of designating a new product category. If a new category is subsequently designated for preferred Federal procurement, the Applicable Minimum Biobased Content will become, as of the effective date indicated in the Register of Designated Categories, the minimum Biobased Content specified for the newly Defined Product Category.

(c) *Innovative Criteria.* In determining eligibility for certification under the BioPreferred Program, USDA will consider as eligible only those products that use innovative approaches in the growing, harvesting, sourcing, procuring, processing, manufacturing, or application of the Biobased Product. USDA will consider products that meet one or more of the criteria in paragraphs (c)(1) through (4) of this section to be eligible for certification. USDA will also consider other documentation of innovative approaches in the growing, harvesting, sourcing, procuring, processing, manufacturing, or application of Biobased Products on a case-by-case basis. USDA may deny or revoke certification for any products whose manufacturers are unable to provide USDA with the documentation necessary to verify claims that innovative approaches are used.

(1) *Product applications.* (i) The Biobased Product or material is used or applied in applications that differ from historical applications; or

(ii) The Biobased Product or material is grown, harvested, manufactured, processed, sourced, or applied in other innovative ways; or

(iii) The Biobased Content of the product or material makes its composition different from products or material used for the same historical uses or applications.

(2) *Manufacturing and processing.* (i) The Biobased Product or material is manufactured or processed using renewable, biomass energy or using technology that is demonstrated to increase energy efficiency or reduce

reliance on fossil-fuel based energy sources; or

(ii) The Biobased Product or material is manufactured or processed with technologies that reduce waste and ensure high feedstock material recovery and use.

(3) *Environmental Product Declaration.* The product has a current Environmental Product Declaration as defined by International Standard ISO 14025, Environmental Labels and Declarations—Type III Environmental Declarations—Principles and Procedures.

(4) *Raw material sourcing.* (i) The raw material used in the product is sourced from a Legal Source, a Responsible Source, or a Certified Source as designated by ASTM D7612 (Standard Practice for Categorizing Wood and Wood-Based Products According to Their Fiber Sources); or

(ii) The raw material used in the product is 100% resourced or recycled (such as material obtained from building deconstruction or agricultural wastes); or

(iii) The raw material used in the product is acquired as a result of activities related to a natural disaster, debris clearing, right-of-way maintenance, tree health improvement, or public safety; or

(iv) The raw material used in the product is grown, harvested, manufactured, processed, sourced, or applied in other sustainable and ethically sourced ways as determined by USDA. Examples include but are not limited to rainforest and habitat conservation, wildlife protection, ethical workplace practices, and adherence to environmental management systems, such as ISO 14001.

§ 4270.5 Procurement programs.

(a) *Integration into the Federal procurement framework.* The Office of Federal Procurement Policy, in cooperation with USDA, has the responsibility to coordinate this policy's implementation in the Federal procurement regulations. These guidelines are not intended to address full implementation of these requirements into the Federal procurement framework. This will be accomplished through revisions to the Federal Acquisition Regulation.

(b) *Federal Agency preferred procurement programs.* (1) Each Federal Agency will maintain and implement a procurement program that will assure that Qualified Biobased Products are purchased to the maximum extent practicable and that is consistent with applicable provisions of Federal procurement laws. Each procurement program will contain:

(i) A preference program for purchasing Qualified Biobased Products;

(ii) A training program to educate the Federal Agency and its contractors on the requirements for purchasing Qualified Biobased Products;

(iii) Provisions for the annual review and monitoring of the effectiveness of the procurement program;

(iv) Provisions for reporting quantities and types of Biobased Products purchased by the Federal Agency and its contractors through the BioPreferred Program Portal in the System for Award Management (*https://sam.gov*) as required by 48 CFR 52.223–2; and

(v) Provisions for reviewing and eliminating specifications that prohibit the purchasing of Qualified Biobased Products.

(2) In developing their preference program, Federal agencies will adopt one of the following options, or a substantially equivalent alternative, as part of the procurement program:

(i) A policy of awarding contracts on a case-by-case basis to the vendor offering a Qualified Biobased Product composed of the highest percentage of Biobased Content practicable except when such products:

(A) Are not available within a reasonable timeframe;

(B) Fail to meet performance standards for their intended use, or the reasonable performance standards of the Federal Agency; or

(C) Are not available at a reasonable price.

(ii) A policy of setting minimum Biobased Content specifications in such a way as to assure that the required Biobased Content of Qualified Biobased Products is consistent with section 9002 of FSRIA and the requirements of the guidelines in this part.

(iii) A policy of documenting and reporting cases where it is not possible to award contracts and set specifications in such a way that is consistent with section 9002 of FSRIA and the requirements of this part.

(3) In implementing the preference program, Federal agencies will treat as eligible for the preference Biobased Products from designated countries, as that term is defined in 48 CFR 25.003 (Federal Acquisition Regulation), provided that those products otherwise meet all requirements for participation in the preference program.

(4) Each Federal Agency will continue to establish an annual targeted biobased-only procurement requirement under which the Procuring Agency will issue a certain number of biobased-only contracts when the Procuring Agency is purchasing products, or purchasing services that include the use of products, that are included in a Biobased Product category designated by the Secretary.

(c) *Procurement specifications.* Federal agencies that have the responsibility for drafting or reviewing specifications for products procured by Federal agencies will ensure that their specifications require the use of Qualified Biobased Products, consistent with the guidelines in this part. These specifications must be put in place no later than six months after a designated category of products is finalized and added to the Register of Designated Categories. USDA will identify the allowable time frame for specifications to be put in place in the Register of Designated Categories found on the BioPreferred Program website at *biopreferred.gov*. The Biobased Content of Qualified Biobased Products within a Designated Product Category may vary considerably from product to product based on the mix of Ingredients used in its manufacture. In procuring Qualified Biobased Products, the percentage of Biobased Content should be maximized, consistent with achieving the desired performance for the product.

§ 4270.6 Category designation.

(a) *Procedure.* Designated Product Categories are found in the Register of Designated Categories on the BioPreferred Program website (*biopreferred.gov*).

(1) *General.* In designating product categories, USDA will designate categories composed of generic groupings of specific products, Intermediate Ingredients or Feedstocks, or Complex Assemblies and will identify the minimum Biobased Content for each listed category or subcategory. As product categories are designated for procurement preference, they will be added to the Register of Designated Categories on the BioPreferred Program website at *biopreferred.gov.*

(i) *Adding new product categories to the Register of Designated Categories.* If a product does not fall within a Defined Product Category that has been designated by USDA at the time the application for certification is submitted, the Applicable Minimum Biobased Content is 30 percent, and it will be listed in the other product category. USDA will evaluate the viability of designating new product categories to categorize products in the other product category more appropriately, following the procedure described in paragraphs (a)(1)(i)(A) through (D) of this section.

(A) New Defined Product Categories that are identified during the category evaluation process will be added to the Register of Designated Categories on the BioPreferred Program website (*biopreferred.gov*). Using the data gathered during the certification process, USDA will establish a provisional category name, definition, and minimum Biobased Content for each new product category based on the product(s) that fall within the new category.

(B) The provisional minimum will be in place for a period of six months following the addition of the new Defined Product Category to the Register of Designated Categories. During that time, any product that falls within the category based on the category definition and has a Biobased Content that is either at least 30 percent or within 30 percentage points of the provisional minimum, whichever is higher, will be considered for inclusion.

(C) After a period of six months following the addition of the new product category to the Register of Designated Categories, USDA will re-evaluate the provisional category name, description, and minimum Biobased Content based on the data gathered during the year. At that time, USDA will make final the product category name, description, and minimum Biobased Content, and the category will no longer be considered provisional.

(D) Procuring agencies, in accordance with this part, are encouraged to give a procurement preference for Qualified Biobased Products that falls within provisionally designated categories and are required to give a procurement preference for Qualified Biobased Products that falls within designated categories no later than six months after the finalized product category is added to the Register of Designated Categories. By that date, Federal agencies responsible for products to be procured will ensure that the relevant specifications require the use of Biobased Products that fall within the designated categories.

(ii) *Revising Defined Product Categories on the Register of Designated Categories.* USDA will periodically evaluate the need to update the product categories included in the Register of Designated Categories by reviewing items including, but not limited to, the category names, definitions, minimum Biobased Contents, subcategories, and the need for the category or subcategory. If the data support making updates, USDA will amend the category and publish the updated category to the Register of Designated Categories. No later than six months after the amended category is published to the Register of Designated Categories, procuring agencies, in accordance with this part, will give a procurement preference for Qualified Biobased Products that fall within the amended designated category. By that date, Federal agencies responsible for products to be procured will ensure that the relevant specifications require the use of Biobased Products that fall within the designated categories.

(2) *Public comments.* Interested parties, including manufacturers, vendors, groups of manufacturers and/or vendors, and trade associations may propose an alternative Applicable Minimum Biobased Content for a new, provisional, defined, or Designated Product Category by, in consultation with USDA, developing and conducting an analysis to support the proposed alternative Applicable Minimum Biobased Content. If approved by USDA, the proposed alternative Applicable Minimum Biobased Content would become the Applicable Minimum Biobased Content for products that fall within that category to be certified.

(3) *Continued eligibility.* If the applicable required minimum Biobased Content for a product to be eligible to participate in the BioPreferred Program is revised by USDA, the product will remain certified or qualified, as applicable, only if it meets the new minimum Biobased Content level. In those cases where the Biobased Content of a certified or qualified product fails to meet the new minimum Biobased Content level, USDA will notify the Participating Organization that their certification is no longer valid. Such Participating Organizations must notify USDA of their intent to increase the Biobased Content of their product to a level at or above the new minimum Biobased Content level within 120 Days and must re-apply for certification within an additional 120 Days if they wish to continue to participate in the Program. The affected product's certification will expire if the Participating Organization does not notify USDA of the intent to reformulate within 120 Days or if the Participating Organization does not re-apply within the additional 120 Days. Participating Organizations who have re-applied for certification may continue using the existing USDA Certified Biobased Product Label until they receive notification from USDA on the results of their re-application for certification.

(b) *Considerations.* (1) In designating product categories, USDA will consider the availability of Qualified Biobased Products and the economic and technological feasibility of using such products, including price. USDA will gather information on individual Qualified Biobased Products within a category and extrapolate that information to the category level for consideration in designating product categories.

(2) In designating product categories for the BioPreferred Program, USDA will consider as eligible only those products that use innovative approaches in growing, harvesting, sourcing, procuring, processing, manufacturing, or application of the Biobased Product. USDA will consider products that meet one or more of the criteria in § 4270.4(b)(1) and (2) to be eligible for the BioPreferred Program. USDA will also consider other documentation of innovative approaches in growing, harvesting, sourcing, procuring, processing, manufacturing, or application of Biobased Products on a case-by-case basis.

§ 4270.7 Determining Biobased Content.

(a) *Certification requirements.* For any Biobased Product seeking to participate in the BioPreferred Program, prospective Participating Organizations must submit an application as specified in § 4270.9 and confirm that the product meets the Applicable Minimum Biobased Content requirements and the definition for the Defined Product Category within which the Biobased Product falls. Paragraph (c) of this section addresses how to determine Biobased Content. Upon request, manufacturers and vendors must provide USDA and Federal agencies information to verify Biobased Content claims for Qualified Biobased Products.

(b) *Minimum Biobased Content.* Unless specified otherwise in the designation of a particular product category, the minimum Biobased Content requirements in a specific category designation refer to the organic carbon portion of the product, and not the entire product.

(c) *Determining Biobased Content.* Verification of Biobased Content must be based on third party ASTM/ISO compliant test facility testing using the ASTM Standard Method D6866 (Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis). ASTM Standard Method D6866 determines Biobased Content based on the amount of biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the product.

(1) *General.* Biobased Content will be based on the amount of biobased carbon in the product as a percent of the weight

(mass) of the total organic carbon in the product.

(2) *Complex Assemblies*—(i) *Equation.* The Biobased Content of a Complex Assembly product, where the product has n components whose Biobased Content and organic carbon content can be experimentally determined, may be calculated using the following equation:

$$Biobased\ Content\ of\ Product = \frac{\sum_{i=1}^{n} M_i * BBC_i * OCC_i}{\sum_{i=1}^{n} M_i * OCC_i}$$

Where:

M_i = mass of the ith component

BCC_i = biobased carbon content of the ith component (%)

OCC_i = organic carbon content of the ith component (%)

(ii) *Proportional sampling.* The Biobased Content of an Assembly product may be determined by sub-sampling (by weight) each organic constituent in a proportion representative of its content within the assembly and combining the sub-samples into a measurable quantity so that a single ASTM D6866 analysis of the combined sub-samples is representative of the assembly.

(d) *Products and Intermediate Ingredients or Feedstocks with the same formulation.* In the case of products and Intermediate Ingredients or Feedstocks that are essentially the same formulation but marketed under more than one brand name, Biobased Content test data may be shared as specified in paragraphs (d)(1) and (2) of this section.

(1) *Test exemptions.* In situations where a new product for which certification is sought is composed of the same Ingredients and has the same Biobased Content as a product that has already been certified and tested by a company that the interested party has a direct relationship with, the interested party may apply for a test exemption by referencing the Certified Application of the certified Parent Product in lieu of having the new product undergo Biobased Content Testing using ASTM D6866.

(2) *Families.* In situations where a Participating Organization is seeking certification for two or more products that are composed of the same Ingredients and have the same Biobased Content but are marketed for different uses or under more than one brand name, the products may be grouped in a family. Biobased Content test data must only be obtained for one of the products in the family, and the test data will apply to all products within the family.

§ 4270.8 [Reserved]

§ 4270.9 Initial approval process.

(a) *Application.* Prospective Participating Organizations seeking USDA approval to use the USDA Certified Biobased Product Label and to become qualified for preferred Federal procurement for an eligible Biobased Product must submit an application for each Biobased Product or product family. USDA has developed a standardized application form that must be used. The standardized application form and instructions are available on the BioPreferred Program website (*biopreferred.gov*). The contents of an acceptable application are as specified in paragraphs (a)(1) and (2) of this section.

(1) *General content.* The applicant must provide the information as specified in paragraphs (a)(1)(i) though (viii) of this section.

(i) Contact information, including the name, mailing address, email address, and telephone number of the applicant.

(ii) The product's brand name(s) or other identifying information.

(iii) Intended uses of the product.

(iv) The biobased source(s) of the raw materials used in the product.

(v) Information to document that one or more of the Innovative Criteria specified in § 4270.4(c) has been met.

(vi) The corresponding Designated Product Category classification for preferred Federal procurement.

(vii) The estimated Biobased Content of the product.

(viii) A web link directly to the applicant's website (if available).

(2) *Commitments.* The applicant must verify in the application that the product for which use of the USDA Certified Biobased Product Label is sought is a Biobased Product as defined in § 4270.2. The applicant must also agree to statements in the application that commit the applicant to submitting to USDA the information specified in paragraphs (a)(1)(i) through (viii) of this section, some of which USDA will post to the BioPreferred Program website (*biopreferred.gov*), and to providing USDA with up-to-date information on this website.

(b) *Evaluation of applications*—(1) *Initial evaluation.* USDA will evaluate each application to determine if it contains the information specified in paragraph (a) of this section and to determine compliance with the criteria specified in § 4270.4. If USDA determines that the application is incomplete, USDA will contact the applicant via email with an explanation of the application's deficiencies. Once the deficiencies have been addressed, the applicant may respond to USDA with an explanation of how the application's deficiencies were addressed for re-evaluation by USDA, and USDA will update the application as needed. If the applicant does not provide a response within 90 Days, USDA will make the application inactive.

(2) *Prequalification.* (i) USDA will provide a written response to each applicant as quickly as practicable, but no later than 90 Days after the receipt of a complete application, depending on the responsiveness of the applicant. The written response will inform the applicant of whether the application has been conditionally approved, or prequalified, to move forward to Biobased Content Testing, or has been disapproved. After notification that the application has been conditionally approved, if any of the information specified in paragraphs (a)(1)(i) through (viii) of this section has changed, the applicant must provide updates to USDA (for posting by USDA on the BioPreferred Program website).

(ii) For those applications that are conditionally approved to move forward, Biobased Content Testing must be completed as described in § 4270.7. Test results obtained prior to the application being conditionally accepted or obtained in a manner that does not comply with this part cannot be accepted.

(iii) After Biobased Content Testing has been completed, USDA will evaluate the results and determine if the product meets the criteria described in § 4270.4(b). For those applications that meet the criteria described in § 4270.4(b), USDA will issue a notice of certification, as specified in paragraph (c) of this section. A notice of certification must be issued before the use of the USDA Certified Biobased Product Label can begin.

(iv) For those applications that are disapproved, USDA will inform the applicant in writing of each criterion not met.

(c) *Notice of certification.* Once USDA confirms that the test results document an acceptable Biobased Content, USDA will issue a notice of certification to the applicant that includes the date of certification, name of the product(s) covered by the certification, and certified Biobased Content of the product(s). Upon receipt of a notice of certification, the applicant may begin using the USDA Certified Biobased Product Label on the Certified Biobased Product and may advertise that the product is a Certified Biobased Product. Paragraph (c)(1) of this section presents the procedures for revising the information provided under paragraphs (a)(1)(i) through (viii) of this section after a notice of certification has been issued.

(1) If at any time, during the application process or after a product has been certified, any of the information specified in paragraphs (a)(1)(i) through (viii) of this section changes, the applicant must notify USDA of the change within 30 Days. Such notification must be provided in writing via email to USDA. Failure to notify USDA of any change made to a Certified Biobased Product may result in the violation actions described in § 4270.12.

(2) After receiving the notice of certification, the Participating Organization may request to display a Biobased Content percentage that is lower than the content measured by the ASTM D6866 test results but is greater than or equal to the applicable category minimums. Such requests must be sent in writing via email to USDA and must be approved by USDA.

(3) If, after reviewing the test results, USDA determines that the product does not meet the Applicable Minimum Biobased Content, USDA will issue a notice of denial of certification and will inform the applicant in writing via email of each criterion not met.

(d) *Term of certification*—(1) *General.* The effective date of certification is included in the notice of certification from USDA. Except as specified in paragraphs (d)(1)(iii) and (iv) and (d)(2) through (4) of this section, certifications will remain in effect for five years. The applicant will be notified 90 Days before the certification expires, at which time, the product must be re-tested in accordance with the procedure as specified in § 4270.7.

(i) If the certification is not renewed within the 90 Days, the product certification will expire, the product will no longer be a Certified Biobased Product, and the product information will be removed from the BioPreferred Program website (*biopreferred.gov*).

(ii) If a Participating Organization whose product certification has expired wishes to renew the certification, the participant must follow the procedures required for original certification.

(iii) All certifications are subject to periodic USDA auditing activities, as described in § 4270.15. If a Participating Organization fails to participate in such audit activities or if such audit activities reveal Biobased Content violations, as specified in § 4270.12, the certification will be subject to suspension and revocation according to the procedures specified in § 4270.12(c)(3).

(iv) If USDA discovers that a certification has been issued for an ineligible product as a result of errors on the part of USDA during the approval process, USDA will notify the Participating Organization in writing that the certification is revoked effective 30 Days from the date of the notice.

(2) *Reformulations.* If at any time during the term of certification a Certified Biobased Product is reformulated, the participant must notify USDA of the change. USDA will consider the changes and inform the participant if re-testing is required as specified in paragraphs (d)(2)(i) through (iii) of this section.

(i) If the product formulation or raw materials of a Certified Biobased Product are changed such that the Biobased Content of the product is reduced to a level below that reported in the Certified Application, the existing certification will no longer be valid for the product under these revised conditions and the Participating Organization and its Designated Representatives must discontinue affixing the USDA Certified Biobased Product Label to the product and must not initiate any further advertising of the product using the USDA Certified Biobased Product Label. USDA will consider a product under such revised conditions to be a reformulated product, and the Participating Organization must submit a new application for certification using the procedures specified in paragraph (a) of this section.

(ii) If the product formulation of a Certified Biobased Product is changed such that the Biobased Content of the product is increased from the level reported in the Certified Application, and the raw materials are not significantly changed, the existing certification will continue to be valid for the product.

(iii) If the applicable required minimum Biobased Content for a product to participate in the BioPreferred Program is revised by USDA, Participating Organizations must follow the requirements specified in § 4270.6(a)(3).

(3) *Test exemptions.* For those products that are exempt from Biobased Content Testing as described in § 4270.7, the test exempt certification will expire at the same time as the Certified Application of the Parent Product.

(4) *Special considerations.* (i) For those Participating Organizations who have Qualified Biobased Products that are not certified as of January 8, 2025. USDA will solicit Biobased Content test data obtained using the ASTM D6866 test method. Participants who provide USDA with ASTM D6866 test data that has been obtained within the past five years from January 8, 2025 and whose products meet the requirements as described in § 4270.4 will receive certification for their products covered by the test data. The term of certification as described in paragraph (d)(1) of this section will then apply.

(ii) Participants who have Qualified Biobased Products that are not certified as of January 8, 2025 and do not provide recent ASTM D6866 test results within three years of the publication of this rule will be required to have their products tested and certified as described in § 4270.7. If certification is not completed within three years of the publication of this rule, these Biobased Products will no longer be listed as Qualified Biobased Products on the BioPreferred Program's website (*biopreferred.gov*) and will be removed from the BioPreferred Program's website (*biopreferred.gov*).

(iii) For those participants who have Certified Biobased Products that have been certified for more than five years as of the date of publication of this rule, USDA will require that the certification be renewed as described in paragraph (d)(1) of this section within three years of January 8, 2025. If an application for renewal is not completed within three years, the product certification will expire, the product will no longer be a Certified Biobased Product, and the product information will be removed from the BioPreferred Program website (*biopreferred.gov*).

§ 4270.10 [Reserved]

§ 4270.11 Requirements associated with promotional certification materials.

(a) *How participation in the BioPreferred Program can be promoted.* Guidance on promoting participation in the BioPreferred Program is provided in paragraphs (a)(1) and (2) of this section. USDA will evaluate additional requests for uses of promotional materials or references to the Program and will offer

guidance on the BioPreferred Program website (*biopreferred.gov*).

(1) *Participating Organizations.* Only Participating Organizations that have received a notice of certification, or Designated Representatives of the Participating Organization, may utilize certification materials provided by the BioPreferred Program. A Participating Organization that has received a notice of certification for a product under this part:

(i) May use the USDA Certified Biobased Product Label (in one of the approved variations, as applicable) on the product, its packaging, and other related materials including, but not limited to, advertisements, catalogs, specification sheets, procurement sheets, procurement databases, promotional material, websites, or user manuals for that product, according to the requirements set forth in this section.

(ii) Is responsible for the manner in which the USDA Certified Biobased Product Label is used by its companies, as well as its Designated Representatives, including advertising agencies, marketing and public relations firms, and subcontractors.

(2) *Other Entities.* Other Entities who have entered into a partnership agreement with USDA may use the BioPreferred Program's promotional certification materials to advertise or promote Certified Biobased Products in materials including, but not limited to, advertisements, catalogs, procurement databases, websites, and promotional and educational materials. Other Entities may use:

(i) The Certification Icon;

(ii) The phrase ''USDA Certified Biobased Product/Package/Product & Package,'' as applicable; and

(iii) The BioPreferred Program name in general statements as described in paragraph (b) of this section, as long as the statements do not imply that a non-certified product is certified or endorsed by USDA.

(b) *Correct usage of the USDA Certified Biobased Product Label and other promotional certification materials.* (1) The USDA Certified Biobased Product Label can be affixed only to Certified Biobased Products and their associated packaging.

(2) The USDA Certified Biobased Product Label may be used in material including, but not limited to, advertisements, catalogs, procurement databases, websites, and promotional and educational materials to distinguish certified products from those that are not certified. The USDA Certified Biobased Product Label may be used in advertisements for both Certified Biobased Products and non-certified/labeled products if the advertisement clearly indicates which products are certified/labeled. Care must be taken to avoid implying that any non-certified products are certified.

(3) When educating the public about the USDA Certified Biobased Product Label, the watermarked sample version of the USDA Certified Biobased Product Label may be used without reference to a specific Biobased Product. For example, the following or similar claims are acceptable: ''Look for the 'USDA Certified Biobased Product Label. It means that the product meets USDA standards for the minimum amount of Biobased Content and the manufacturer or vendor has provided relevant information on the product to be posted on the BioPreferred Program website (*biopreferred.gov*).'' This exception allows Participating Organizations or Other Entities to use a sample USDA Certified Biobased Product Label in documents such as corporate reports, but only in an informative manner, not as a statement of product certification.

(4) The USDA Certified Biobased Product Label may appear next to a picture of the Certified Biobased Product(s) or text describing it.

(5) The USDA Certified Biobased Product Label must stand alone and not be incorporated into any other certification mark or logo designs.

(6) The USDA Certified Biobased Product Label may be embossed, stamped, or used as a watermark provided the use does not violate any BioPreferred Program brand standards or usage restrictions specified in this part.

(7) The text portion of the USDA Certified Biobased Product Label must be written in English and may not be translated, even when the certification mark is used outside of the United States.

(c) *Incorrect usage of the USDA Certified Biobased Product Label and other promotional certification materials.* (1) The USDA Certified Biobased Product Label will not be used on any product that has not been certified by USDA as a ''USDA Certified Biobased Product.''

(2) The USDA Certified Biobased Product Label will not be used in a way that does not maintain the integrity of the label and the BioPreferred Program.

(3) The word ''BioPreferred'' will not be used as a descriptor for anything other than the Program, including but not limited to products, categories, and companies. The BioPreferred Program name, the word ''BioPreferred,'' and the phrase ''USDA Certified Biobased Product'' are not interchangeable. For example, certified products may not be referenced as being ''BioPreferred products.''

(4) The USDA Certified Biobased Product Label will not be used on any advertisements or informal materials where both Certified Biobased Products and non-certified products are shown unless it is clear that the USDA Certified Biobased Product Label applies to only the Certified Biobased Product(s).

(5) The BioPreferred Program name and the USDA Certified Biobased Product Label will not be used to imply endorsement by USDA or the BioPreferred Program of any particular product, service, or company.

(6) The BioPreferred Program name and the USDA Certified Biobased Product Label will not be used in any form that could be misleading to the consumer.

(7) The BioPreferred Program name and the USDA Certified Biobased Product Label will not be used by manufacturers or vendors of Certified Biobased Products in a manner disparaging to USDA or any other government body.

(8) The BioPreferred Program name, the word ''BioPreferred,'' the USDA Certified Biobased Product Label, and the Certification Icon will not be altered or incorporated into other label or logo designs.

(9) The USDA Certified Biobased Product Label will not be used on business cards, company letterhead, company stationary, or email signatures.

(10) The BioPreferred Program name, the word ''BioPreferred,'' the USDA Certified Biobased Product Label, and the Certification Icon will not be used in, or as part of, any company name, logo, product name, service, or website, except as may be provided for in this part.

(11) The BioPreferred Program name, the word ''BioPreferred,'' the USDA Certified Biobased Product Label, and the Certification Icon will not be used in a manner that violates any of the applicable requirements contained in this part.

(d) *Imported products.* The USDA Certified Biobased Product Label can be used only with a product that is certified by USDA under this part. The USDA Certified Biobased Product Label cannot be used to imply that a product meets or exceeds the requirements of biobased programs in other countries. Products imported for sale in the U.S. must adhere to the same guidelines as U.S. sourced Biobased Products. Any product sold in the U.S. as a ''USDA Certified Biobased Product/Package/Product & Package'' must have received certification from USDA.

(e) *Elements of the USDA Certified Biobased Product Label.* The USDA Certified Biobased Product Label will consist of the Certification Icon, the Biobased Content percentage, the letters ''FP'' to indicate that the product is qualified for preferred Federal procurement, and one of the three variations of text specified in paragraphs (e)(1) through (3) of this section, as applicable.

(1) USDA Certified Biobased Product: Product.

(2) USDA Certified Biobased Product: Package.

(3) USDA Certified Biobased Product: Product & Package.

(f) *Physical aspects of the USDA Certified Biobased Product Label.* The USDA Certified Biobased Product Label elements may not be altered, cut, separated into components, or distorted in appearance or perspective. The USDA Certified Biobased Product Label must appear only in the colors specified in paragraphs (f)(1) and (2) of this section unless approval is given by USDA for an exception.

(1) A multi-color version of the USDA Certified Biobased Product Label is preferred. The USDA Certified Biobased Product Label colors to be applied will be stipulated in the ''USDA BioPreferred Program Brand and Marketing Guidelines'' document available on the BioPreferred Program website (*biopreferred.gov*).

(2) Black or white outline versions of the USDA Certified Biobased Product Label are acceptable.

(g) *Placement of the USDA Certified Biobased Product Label.* (1) The USDA Certified Biobased Product Label can appear directly on a product, its associated packaging, in user manuals, and in other materials including, but not limited to, advertisements, catalogs, procurement databases, and promotional and educational materials.

(2) The USDA Certified Biobased Product Label will not be placed in a manner that is ambiguous about which product is a Certified Biobased Product or that could indicate certification of a non-certified product.

(3) When used to distinguish a Certified Biobased Product in material including, but not limited to, advertisements, catalogs, procurement databases, websites, and promotional and educational materials, the USDA Certified Biobased Product Label must appear near a picture of the product or text describing it.

(i) If all products on a page are Certified Biobased Products with the same Biobased Content percentage, the USDA Certified Biobased Product Label may be placed anywhere on that page.

(ii) If a page contains a mix of Certified Biobased Products and non-certified Biobased Products, the USDA Certified Biobased Product Label will be placed in close proximity to the Certified Biobased Products. An individual USDA Certified Biobased Product Label near each Certified Biobased Product may be necessary to avoid confusion.

(h) *Minimum size and clear space requirements for the USDA Certified Biobased Product Label.* (1) The USDA Certified Biobased Product Label may be sized to fit the individual application as long as the correct proportions are maintained, and all elements of the USDA Certified Biobased Product Label remain legible.

(2) The USDA Certified Biobased Product Label must be surrounded by a border of clear space that must be of sufficient width to offset it from surrounding images and text to avoid confusion. If a one-color outline version of the USDA Certified Biobased Product Label is used, the USDA Certified Biobased Product Label must appear on a solid background that is a contrasting color.

(i) *Where to obtain copies of the promotional certification materials.* The USDA Certified Biobased Product Label and other associated promotional materials including the USDA BioPreferred Program Brand and Marketing Guidelines are available at the BioPreferred Program website (*biopreferred.gov*).

§ 4270.12 Violations of program requirements.

This section identifies the types of actions that USDA considers violations under this part and the penalties (*e.g.,* the suspension or revocation of certification) associated with such violations.

(a) *General.* Violations under this section occur on a per product basis and the penalties are to be applied on a per product basis. Entities cited for a violation under this section may appeal using the provisions in § 4270.13. If certification for a product is revoked, the Participating Organization whose certification has been revoked may seek re-certification for the product specified under the provisions in § 4270.9.

(b) *Types of violations.* Actions that will be considered violations of this part include, but are not limited to, the examples as described in paragraphs (b)(1) through (4) of this section:

(1) *Biobased Content violations.* USDA reserves the right to request occasional testing of Certified Biobased Products without notice to compare the Biobased Content of the tested product with the product's Applicable Minimum Biobased Content and the Biobased content reported in its Certified Application. Such testing will be conducted using ASTM Method D6866 in accordance with the procedures discussed in § 4270.7.

(i) If the testing shows that the Biobased Content of a Certified Biobased Product is less than its Applicable Minimum Biobased Content, then a violation of this part will have occurred.

(ii) If the testing shows that the Biobased Content is less than that reported in the product's Certified Application but is still equal to or greater than its Applicable Minimum Biobased Content(s), USDA will provide written notification to the Participating Organization. The participant must submit, within 90 Days from receipt of USDA written notification, a new application for the lower Biobased Content. Failure to submit a new application within 90 Days will be considered a violation of this part.

(A) The participant can submit a new application to use the Biobased Content reported to it by USDA in the written notification.

(B) Alternatively, the participant may submit a new application and elect to retest the product in question. If the participant elects to retest the product, it must test a sample of the current product, and the procedures in § 4270.9 must be followed. USDA reserves the right to select the sample that will be submitted for retesting.

(2) *USDA Certified Biobased Product Label violations.* (i) Any usage or display of the USDA Certified Biobased Product Label that does not conform to the requirements specified in § 4270.10.

(ii) Affixing the USDA Certified Biobased Product Label to any product prior to issuance of a notice of certification from USDA.

(iii) Affixing the USDA Certified Biobased Product Label to a Certified Biobased Product during periods when certification has been suspended or revoked.

(iv) Using an image or icon other than the official USDA Certified Biobased Product Label in association with certification claims.

(3) *Application violations.* Knowingly providing false or misleading information in any application for certification of a Biobased Product.

(4) *BioPreferred Program website violations.* Failure to provide USDA with updated information when the information for a Certified Biobased Product becomes outdated or when new information for a Certified Biobased Product becomes available.

(c) *Noncompliance and escalation of actions.* Any identified violations as described in paragraphs (b)(1) through (4) are considered noncompliance with this part. USDA will respond to noncompliance through actions that include, but are not limited to, the examples as described in paragraphs (c)(1) through (4).

(1) *Noncompliance.* USDA will provide the applicable Participating Organization and any Other Entity involved, as known to USDA, written notification of any noncompliance identified by USDA, as well as actions that should be taken to resolve the noncompliance. USDA may remove the product or company information from the BioPreferred Program website (*biopreferred.gov*) until the noncompliance is corrected. If satisfactory resolution of the noncompliance is not reached, USDA will consider the noncompliance to be a violation of this part and may pursue further action as discussed in paragraphs (c)(2) through (4) of this section.

(2) *Violation.* USDA will first issue a notice of violation. Entities who receive a notice of violation for any violation must correct the violation(s) within 30 Days from receipt of the notice of violation. If the entity receiving a notice of violation is a Participating Organization, USDA will also issue notices of suspensions and revocations, as discussed in paragraph (c)(3) of this section. USDA reserves the right to further pursue action against these entities as provided in paragraph (c)(4) of this section. If the entity receiving a notice of violation is an Other Entity (*i.e.,* not a Participating Organization), then USDA may pursue action according to paragraph (c)(4) of this section.

(3) *Suspension and Revocation.* (i) If a violation is applicable to a Participating Organization and the participant fails to make the required corrections within 30 Days of receipt of a notice of violation, USDA will notify the participant, via email and certified mail as appropriate, of the continuing violation, and the certification for that product will be suspended. As of the date that the participant receives a notice of suspension, the participant and their Designated Representatives must not affix the USDA Certified Biobased Product Label to any of that product or associated packaging not already labeled and must not distribute any additional products bearing the USDA Certified Biobased Product Label. USDA will both remove the product information from the BioPreferred Program website (*biopreferred.gov*) and actively communicate the product suspension to buyers in a timely and overt manner.

(ii) If, within 30 Days from receipt of the notice of suspension, the participant whose USDA product certification has been suspended makes the required corrections and notifies the USDA that the corrections have been made, the participant and their Designated Representatives may, upon receipt of USDA approval of the corrections, resume use of the USDA Certified Biobased Product Label. USDA will also restore the product information to the BioPreferred Program website (*biopreferred.gov*).

(iii) If, following the 30-Day period, the participant does not make the required corrections, the certification for that product will be revoked. As of that date, the participant must not affix the USDA Certified Biobased Product Label to any of that product not already labeled. In addition, the participant and their Designated Representatives are prohibited from further sales of the product to which the USDA Certified Biobased Product Label is affixed, and the product will no longer be listed on the BioPreferred Program website (*biopreferred.gov*) as a product qualified for preferred Federal procurement.

(iv) If a participant whose product certification has been revoked wishes to participate in the BioPreferred Program again, the participant must follow the procedures required for the original certification specified in § 4270.9.

(4) *Other remedies.* In addition to the suspension or revocation of the product certification, depending on the nature of the violation, USDA may pursue suspension or debarment of the entities involved in accordance with 2 CFR part 417 and 48 CFR subpart 9.4. USDA further reserves the right to pursue any other remedies available by law, including any civil or criminal remedies, against any entity that violates the provisions of this part.

§ 4270.13 Appeal process.

Participating Organizations whose product certification has been revoked may appeal to USDA.

(a) *Filing an appeal.* (1) Appeals to the Agency must be filed within 30 Days of receipt by the appellant of a notice of suspension and revocation. Appeals must be filed in writing via email to the BioPreferred Program's email address as noted on the BioPreferred Program website (*biopreferred.gov*).

(2) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not made in accordance with the applicable Program regulations, policies, or procedures, or otherwise was not proper.

(b) *Reviewing appeals.* (1) If USDA sustains a Participating Organization's appeal of a notice of suspension and revocation, the participant and its Designated Representative(s) may immediately resume affixing the USDA Certified Biobased Product Label to the Certified Biobased Product and sell and distribute the Certified Biobased Product with the USDA Certified Biobased Product Label. In addition, USDA will reinstate the product's information to the BioPreferred Program website (*biopreferred.gov*).

(2) If USDA denies a participant's appeal of a notice of suspension and revocation, then the notice of suspension and revocation stands.

(c) *Appeals of decisions made on appeals.* Appeals of any of the BioPreferred Program's decisions may be made to the Rural Business-Cooperative Service Administrator. Appeals must be made, in writing, within 30 Days of receipt of USDA's decision and addressed to: Rural Business-Cooperative Service Administrator, 1400 Independence Avenue SW, Washington, DC 20250–1522 STOP 3250. If the Rural Business-Cooperative Service Administrator sustains an appeal, the provisions of paragraph (b) of this section will apply.

§ 4270.14 Reporting and recordkeeping.

(a) *Providing product information to Federal agencies*—(1) *Informational website.* An informational USDA website implementing section 9002 of FSRIA can be found at: *biopreferred.gov.* USDA will maintain a web-based information site for participating originations with Certified Biobased Products and Federal agencies to exchange information, as described in paragraphs (a)(1)(i) through (iv) of this section as applicable.

(i) *Product information.* The website will, as determined to be necessary by the Secretary based on the availability of data, provide the information specified in § 4270.9. USDA encourages Federal agencies to utilize this website to obtain current information on designated categories, contact information for Participating Organizations, and access to information on product characteristics relevant to procurement decisions. In addition to any information provided on the website, participants are expected to provide relevant information to Federal agencies, subject to the limitations specified in paragraph (a)(1)(ii) of this section, with respect to product characteristics, including verification of such characteristics if requested.

(ii) *Providing information on price and environmental and health benefits.* Federal agencies may not require Participating Organizations with Certified Biobased Products to provide procuring agencies with more data than would be required of other manufacturers or vendors offering products for sale to a Procuring Agency (aside from data confirming the Biobased Contents of the products) as a condition of the purchase of Biobased Products from the participant. USDA encourages industry Stakeholders to provide information on environmental and public health benefits based on industry accepted analytical approaches including, but not limited to, material carbon footprint analysis, the International Standards Organization (ISO) 14040, the ASTM International life-cycle cost method (E917) and multi-attribute decision analysis (E1765), and the British Standard Institution PAS 2050. USDA will make such Stakeholder-supplied information available on the BioPreferred Program website (*biopreferred.gov*).

(iii) *Industry standards test information.* The product information will include any relevant industry standard test information as supplied by the participant. In assessing performance of a Certified Biobased Product, USDA requires that procuring agencies rely on results of performance tests using applicable ASTM, ISO, Federal or military specifications, or other similarly authoritative industry test standards. Such testing may be conducted by a laboratory compliant with the requirements of the standards body. The procuring official will decide whether performance data must be brand-name specific in the case of products that are essentially of the same formulation.

(iv) *Biodegradability information.* If Biodegradability is claimed by a participant with a Certified Biobased Product as a characteristic of that product, USDA requires that, if requested by procuring agencies, these claims be verified using the appropriate, product-specific ASTM Biodegradability standard(s). Such testing must be conducted by an ASTM/ISO-compliant laboratory. The procuring official will decide whether Biodegradability data must be brand-name specific in the case of products that are essentially of the same formulation. ASTM Biodegradability standards include:

(A) D5338 (Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials Under Controlled Composting Conditions);

(B) D5864 (Standard Test Method for Determining the Aerobic Aquatic Biodegradation of Lubricants or Their Components);

(C) D5988 (Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil);

(D) D6006 (Standard Guide for Assessing Biodegradability of Hydraulic Fluids);

(E) D6400 (Standard Specification for Compostable Plastics) and the standards cited therein;

(F) D6139 (Standard Test Method for Determining the Aerobic Aquatic Biodegradation of Lubricants of Their Components Using the Gledhill Shake Flask);

(G) D6868 (Standard Specification for Biodegradable Plastics Used as Coatings on Paper and Other Compostable Substrates); and

(H) D7081 (Standard Specification for Non-Floating Biodegradable Plastics in the Marine Environment).

(2) *Advertising, labeling, and marketing claims.* Participating Organizations are reminded that their advertising, labeling, and other marketing claims, including claims regarding health and environmental benefits of the product, must conform to 16 CFR part 260 (Federal Trade Commission Guides for the Use of Environmental Marketing Claims). For further requirements on marketing claims associated with the BioPreferred Program, refer to the ''USDA BioPreferred Program Brand and Marketing Guidelines'' found on the BioPreferred Program website (*biopreferred.gov*).

(b) *Records.* Participating Organizations will maintain records documenting compliance with this part for each product that has received a notice of certification, as specified in paragraphs (b)(1) through (3) of this section.

(1) The results of all tests, and any associated calculations, performed to determine the Biobased Content of the product.

(2) The notice of certification from USDA, the dates of changes in formulation that affect the Biobased Content of Certified Biobased Products, and the dates when the Biobased Content of Certified Biobased Products were tested.

(3) Documentation of analyses performed by participants to support claims of environmental or human health benefits, life cycle cost, sustainability benefits, and product performance made by the participant.

(c) *Record retention.* For each Certified Biobased Product, records kept under paragraphs (a) and (b) of this section must be maintained for at least three years beyond the end of the certification period (*i.e.,* three years beyond the date the product's term of certification expires). Records may be kept in either electronic format or hard copy format. All records kept in electronic format must be readily accessible and/or provided by request.

§ 4270.15 Oversight and monitoring.

(a) *General.* USDA will conduct oversight and monitoring of Participating Organizations, Designated Representatives, and Other Entities involved with the BioPreferred Program to ensure compliance with this part. This oversight may include, but not be limited to, conducting facility visits to Participating Organizations that have Certified Biobased Products and their Designated Representatives. Participating Organizations are required to cooperate fully with all USDA audit efforts for the enforcement of the BioPreferred Program requirements.

(b) *Biobased Content Testing.* USDA will conduct Biobased Content Testing of Certified Biobased Products as described in § 4270.12(b)(1) to ensure compliance with this part.

(c) *Inspection of records.* Participating Organizations must allow Federal representatives access to the records required under § 4270.14 for inspection and copying during normal business hours.

(d) *Audits.* USDA will conduct an annual desk audit on an ongoing basis to verify that the product and company information supplied by Participating Organizations remain valid. Through the BioPreferred Program website (*biopreferred.gov*), Participating Organizations will be asked to confirm that they still manufacture the product, that the formulation remains the same, and that the information described under § 4270.9(a)(1) remains valid. Participants may also be asked for additional supplemental information.

(1) If a Participating Organization indicates that their product or company information needs to be updated during an annual desk audit, these updates will be incorporated into the BioPreferred Program website (*biopreferred.gov*). If it is indicated that a product is no longer manufactured, the product information will be removed from the BioPreferred Program website (*biopreferred.gov*).

(2) If a Participating Organization fails to complete an annual desk audit, the participant will be considered to be in noncompliance with this part, and the Participating Organization and associated product information will be removed from the BioPreferred Program website (*biopreferred.gov*). USDA reserves the right to revoke product

certification for failure to participate in an audit.

§§ 4270.16–4270.98 [Reserved]

§ 4270.99 OMB control number.

The information collection requirements in this part are approved by the Office of Management and Budget (OMB) and assigned OMB control number 0570–0083.

Xochitl Torres Small,

Deputy Secretary, United States Department of Agriculture.

[FR Doc. 2024–28431 Filed 12–6–24; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Rural Housing Service

Rural Business-Cooperative Service

7 CFR Part 5001

[Docket No. RUS–19–Agency–0030]

RIN 0572–AC56

OneRD Guaranteed Loan Regulation

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, USDA.

ACTION: Final rule, correction and correcting amendments.

SUMMARY: On September 30, 2024, Rural Development's Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service, agencies of the United States Department of Agriculture (USDA), published a final rule with comment for the OneRD Guarantee Loan Program (OneRD). The final rule made necessary revisions to the policy and procedures that strengthened the oversight and management of the growing Community Facilities, Water and Waste Disposal, Business and Industry, and Rural Energy for America guarantee portfolios. The final rule had a misspelled subject heading in the preamble. The final rule also contained information in an instruction that was not ultimately in the final rule, an incomplete definition of affiliate, and a misstatement regarding protective advances. This document corrects the final regulation.

DATES: This rule is effective December 9, 2024.

ADDRESSES: Address all comments concerning this correction to Susan Woolard, Regulations Management Division, Rural Development Innovation Center, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Washington, DC 20250; telephone (202) 720–9631; email *susan.woolard@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Woolard, Regulations Management Division, Rural Development Innovation Center, U.S. Department of Agriculture, 1400 Independence Ave. SW, Stop 1522, Washington, DC 20250; telephone (202) 720–9631; email *susan.woolard@usda.gov.*

SUPPLEMENTARY INFORMATION: Rural Development's Rural Business-Cooperative Service, Rural Housing Service, and Rural Utilities Service are issuing corrections to the final rule that published September 30, 2024, at 89 FR 79698.

List of Subjects in 7 CFR Part 5001

Business and industry, Community facility, Energy efficiency improvement, Loan programs, Renewable energy, Rural areas, Rural development, Water and waste disposal.

In FR Doc. 2024–21920 published September 30, 2024, beginning on page 79698, make the following corrections:

■ 1. On page 79699, in the third column, item 11, the title is corrected to read ''*11. § 5001.116 Ineligible CF Projects*''.

■ 2. On page 79702, in the third column, item 39a, is corrected to read:

■ a. § 5001.516(c) is updated to inform lenders that payment of real estate taxes is considered a protective advance but does not require advanced Agency approval.

■ 3. On page 79704, in the third column, Instruction 4 for § 5001.3, is corrected by removing the words ''commercially available''.

■ 4. On page 79711, in the second column, Instruction 14 is corrected to read:

■ 14. Amend § 5001.106 by revising the first sentence of the introductory text, paragraphs (d)(2), (e)(2) and (e)(3) introductory text to read as follows:

For the reasons discussed in the preamble, 7 CFR 5001 is corrected by making the following correcting amendments:

PART 5001—GUARANTEED LOANS.

■ 1. The authority citation for part 5001 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 1926(a); 7 U.S.C. 1932(a); and 7 U.S.C. 8107.

■ 2. Amend § 5001.3 by revising the definition of ''affiliate'' to read as follows:

§ 5001.3 Definitions.

* * * * *

Affiliate means a person that is connected with or controlled by another organization. Factors such as ownership, management, current and previous relationships with or ties to another person, and contractual relationships, may be considered in determining whether affiliation exists. Affiliation is determined using the principles outlined in 13 CFR 121.301(f).

* * * * *

■ 3. Amend § 5001.516 by revising paragraph (c) to read as follows:

§ 5001.516 Protective advances.

* * * * *

(c) A lender must obtain written Agency approval for any protective advance that will cumulatively amount to more than $200,000, or 10 percent of the aggregate outstanding balance of principal and interest, whichever is less, to the same borrower. Payment of real estate taxes by the lender is considered a protective advance, subject to the requirements of this section, and does not require Agency advance approval.

Basil I. Gooden,

Deputy Under Secretary, Rural Development.

[FR Doc. 2024–28031 Filed 12–6–24; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2129; Project Identifier MCAI–2024–00066–T; Amendment 39–22889; AD 2024–23–10]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. This AD was prompted by a report that for airplanes converted from passenger to cargo configuration using certain supplemental type certificates, no height limitation for the cargo, when loaded in the cargo compartment, is defined, and that as a consequence, cargo might be loaded up to the ceiling of the cargo compartment. This AD

requires modification of the cargo compartment and implementation of updated cargo loading procedures. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2129; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Sabena Technics material identified in this AD, contact Sabena Technics BGC, Le Galilée, 9 Bd Henri Ziegler, 31700 Blagnac France; telephone 33 (0)1 56 54 42 30; email *airworthiness.office@sabenatechnics.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2129.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. The NPRM published in the **Federal Register** on August 22, 2024 (89 FR 67908). The NPRM was prompted by AD 2024–0025, dated January 24, 2024, issued by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union (referred to after this as the MCAI). The MCAI states that it was identified that for airplanes converted from passenger to cargo configuration using EASA Supplemental Type Certificate (STC) 10069551, Revision 1 (EASA STC 10069551, Revision 0, corresponds to FAA STC ST04602NY), or the previous EASA STC 2004–2872 (which corresponds to FAA STC S116–004NM, Revision 1), no height limitation for the cargo, when loaded in the cargo compartment, is defined. Consequently, operators of such airplanes may load the cargo up to the ceiling of the cargo compartment and, therefore, potentially affect the proper functioning of the smoke detectors. This condition, if not corrected, could lead to smoke not being detected in time, possibly resulting in an uncontrolled fire.

In the NPRM, the FAA proposed to require modification of the cargo compartment and implementation of updated cargo loading procedures. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–2129.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Sabena Technics Airworthiness Technical Instructions 0110–09–A–ATI–F01–R00, and 0110–11–A–ATI–F01–R00, both dated September 19, 2023. This material describes procedures for modifying the cargo compartment (installing a label and tape to indicate maximum cargo height). These documents are distinct since they apply to different airplane models.

The FAA also reviewed Sabena Technics Weight & Balance Manual Supplement 0110–09–A–2305–R06, Revision 06, dated September 15, 2023; and Sabena Technics Weight & Balance Manual Supplement 0110–11–A–2305–R07, Revision 07, dated September 15, 2023. The maximum cargo height in the cargo compartment is described in Section 2.9., ''Cargo Compartment—Loading Limitation,'' of Sabena Technics Weight & Balance Manual Supplement 0110–09–A–2305–R06, Revision 06, dated September 15, 2023; and section 2.11., ''Cargo Compartment-Loading Limitation,'' of Sabena Technics Weight & Balance Manual Supplement 0110–11–A–2305–R07, Revision 07, dated September 15, 2023. These documents are distinct since they apply to different airplane models.

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

Costs of Compliance

The FAA estimates that this AD affects 2 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
8 work-hours × $85 per hour = $680	$100	$780	$1,560

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–23–10 ATR—GIE Avions de Transport Régional: Amendment 39–22889; Docket No. FAA–2024–2129; Project Identifier MCAI–2024–00066–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to ATR—GIE Avions de Transport Régional airplanes identified in paragraphs (c)(1) and (2) of this AD, certificated in any category, modified in accordance with FAA Supplemental Type Certificate (STC) ST116–004NM or STC ST04602NY.

(1) Model ATR42–200, –300, –320, and –500 airplanes.

(2) Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 11, Placards and Marking.

(e) Unsafe Condition

This AD was prompted by a report that for airplanes converted from passenger to cargo configuration using certain supplemental type certificates, no height limitation for the cargo, when loaded in the cargo compartment, is defined, and that as a consequence, cargo may be loaded up to the ceiling of the cargo compartment. The FAA is issuing this AD to address cargo being loaded up to the ceiling of the cargo compartment, which could affect the proper functioning of the smoke detectors. This condition, if not corrected, could lead to smoke not being detected in time, possibly resulting in an uncontrolled fire.

(f) Compliance

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

(g) Modification of Cargo Compartment

Within 6 months after the effective date of this AD, modify the cargo compartment in accordance with the Accomplishment Instructions of Sabena Technics Airworthiness Technical Instructions 0110–09–A–ATI–F01–R00, dated September 19, 2023 (for Model ATR42 airplanes); or Sabena Technics Airworthiness Technical Instructions 0110–11–A–ATI–F01–R00, dated September 19, 2023 (for Model ATR72 airplanes).

(h) Revision of Weight and Balance Manual

Prior to or concurrently with accomplishing the actions required by paragraph (g) of this AD, implement the cargo loading procedures specified in Section 2.9., ''Cargo Compartment—Loading Limitation,'' of Sabena Technics Weight & Balance Manual Supplement 0110–09–A–2305–R06, Revision 06, dated September 15, 2023 (for Model ATR42 airplanes); or Section 2.11., ''Cargo Compartment-Loading Limitation,'' of Sabena Technics Weight & Balance Manual Supplement 0110–11–A–2305–R07, Revision 07, dated September 15, 2023 (for Model ATR72 airplanes).

(i) No Reporting Requirement

Although Sabena Technics Airworthiness Technical Instructions 0110–09–A–ATI–F01–R00, and 0110–11–A–ATI–F01–R00, both dated September 19, 2023, specify to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD. Information may be emailed to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or the European Union Aviation Safety Agency (EASA); or Sabena Technic BGC's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Sabena Technics Airworthiness Technical Instructions 0110–09–A–ATI–F01–R00, dated September 19, 2023.

(ii) Sabena Technics Airworthiness Technical Instructions 0110–11–A–ATI–F01–R00, dated September 19, 2023.

(iii) Sabena Technics Weight & Balance Manual Supplement 0110–09–A–2305–R06, Revision 06, dated September 15, 2023. This document has the revision level and date on page 2; no other page of the document has this information.

(iv) Sabena Technics Weight & Balance Manual Supplement 0110–11–A–2305–R07, Revision 07, dated September 15, 2023. This document has the revision level and date on page 2; no other page of the document has this information.

(3) For Sabena Technics material identified in this AD, contact Sabena Technics BGC, Le Galilée, 9 Bd Henri Ziegler, 31700 Blagnac France; telephone 33 (0)1 56 54 42 30; email *airworthiness.office@sabenatechnics.com.*

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

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

Issued on November 21, 2024.

Victor Wicklund,

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

[FR Doc. 2024–28789 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2025; Project Identifier MCAI–2024–00120–T; Amendment 39–22888; AD 2024–23–09]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A321–251NX, –252NX, –253NX, –271NX, and –272NX airplanes. This AD was prompted by the discovery during a quality review performed during manufacturing, that a torque strip indicator (material ''Dykem'') had been applied on the orifice fitting on certain slides' inflation reservoirs' venting holes. This AD requires an inspection for discrepancies of affected parts (certain reservoirs having certain orifices) and replacement of discrepant affected parts, and prohibits installing affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2025; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu*; website *easa.europa.eu*. You may find this material on the EASA website at *ad.easa.europa.eu*.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2025.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *timothy.p.dowling@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A321–251NX, –252NX, –253NX, –271NX, and –272NX airplanes. The NPRM published in the **Federal Register** on August 21, 2024 (89 FR 67575). The NPRM was prompted by AD 2024–0057, dated February 28, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0057) (also referred to as the MCAI). The MCAI states that during a quality review performed during manufacturing, a quality escape was identified on the Model A321NX door 3 slide and offwing slide inflation reservoirs' venting holes, where a torque strip indicator (material ''Dykem'') had been applied on the orifice fitting (clogging the vent hole). This condition, in combination with a slide reservoir pressure loss, if not detected and corrected, could lead to deployment in flight of a non-inflated slide, possibly resulting in damage to, and reduced control of, the airplane.

In the NPRM, the FAA proposed to require an inspection for discrepancies of affected parts (certain reservoirs having certain orifices) and replacement of discrepant affected parts, and prohibit installing affected parts, as specified in EASA AD 2024–0057. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2025.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0057 specifies a general visual inspection of affected parts (certain reservoirs having certain orifices) for discrepancies (the presence of ''Dykem'' material on the orifice fitting) and replacement of discrepant affected parts, and prohibits installing affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 227 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$19,295

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	Negligible	$85

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–23–09 Airbus SAS: Amendment 39–22888; Docket No. FAA–2024–2025; Project Identifier MCAI–2024–00120–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A321–251NX, –252NX, –253NX, –271NX, and –272NX airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by the discovery during a quality review performed during manufacturing, that a torque strip indicator (material ''Dykem'') had been applied on the orifice fitting on certain slides' inflation reservoirs' venting holes. The FAA is issuing this AD to address blocked venting holes on the orifice fitting on an escape slide's inflation reservoir. The unsafe condition, if not addressed, could, in combination with a slide reservoir pressure loss, result in deployment in flight of a non-inflated slide, possibly resulting in damage to, and reduced control of, the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0057, dated February 28, 2024 (EASA AD 2024–0057).

(h) Exceptions to EASA AD 2024–0057

(1) Where EASA AD 2024–0057 refers to March 13, 2024, or its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0057.

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's

EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information referenced in EASA AD 2024–0057 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *timothy.p.dowling@faa.gov*.

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0057, dated February 28, 2024.

(ii) [Reserved]

(3) For EASA AD 2024–0057 identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu*. You may find this EASA AD on the EASA website at *ad.easa.europa.eu*.

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

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

Issued on November 18, 2024.

Peter A. White,

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

[FR Doc. 2024–28779 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1698; Project Identifier AD–2024–00005–T; Amendment 39–22895; AD 2024–24–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 767–300F series airplanes. This AD was prompted by a determination that certain cargo compartment insulation blankets do not adequately fit some locations and allow smoke to migrate past the cargo compartment sidewall liners and upward into the main cabin. This AD requires replacing cargo compartment insulation blankets. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1698; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1698.

FOR FURTHER INFORMATION CONTACT: Julie Linn, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3684; email: *julie.linn@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767–300F series airplanes. The NPRM published in the **Federal Register** on June 26, 2024 (89 FR 53370). The NPRM was prompted by a determination that certain cargo compartment insulation blankets do not adequately fit some locations and allow smoke to migrate past the cargo compartment sidewall liners and upward into the main cabin. In the NPRM, the FAA proposed to require replacing the cargo compartment insulation blankets. The FAA is issuing this AD to address inadequately fitting cargo compartment insulation blankets. The unsafe condition, if not addressed, could result in a fire in the bilge area of the cargo compartment, which if not contained could lead to a smoke and fire event in the passenger compartment.

Discussion of Final Airworthiness Directive

Comments

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

The FAA also received comments from Boeing, Aviation Partners Boeing, and All Nippon Airways. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Add a Boeing Alternative Method of Compliance (AMOC) Notice to the Proposed AD

All Nippon Airways and Boeing requested that the FAA add Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, to the proposed AD. All Nippon Airways requested that Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, be added to paragraph (g) of the proposed AD to specify that the actions should be done in accordance with both Boeing Special Attention Service Bulletin 767–25–0550 Revision 2, dated December 18, 2023, and Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024. All Nippon Airways stated that Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, provides changes regarding Boeing

Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023.

Boeing requested that the FAA revise paragraph (h) of the proposed AD, (the ''Alternative Methods of Compliance (AMOCs)'' paragraph), to include language approving Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, as an AMOC to the proposed AD. Boeing stated that Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, applies to Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023, and was approved and published as an alternative to accomplishing the requirements specified by paragraph (g) of AD 2021–12–11 Amendment 39–21598 (86 FR 33112, June 24, 2021) (AD 2021–12–11).

The FAA notes that the approved FAA AMOC letter 522–24–00097, dated March 12, 2024, allows Boeing AMOC Notice 767–25–0550 AMOC 01, dated March 13, 2024, as an alternative to certain steps in Boeing Special Attention Service Bulletin 767–25–0550 Revision 2, dated December 18, 2023. FAA AMOC letter 522–24–00097, dated March 12, 2024, was previously approved for use in AD–2021–12–11. The FAA has revised paragraph (h)(4) of this AD to include FAA AMOC letter 522–24–00097, dated March 12, 2024, as an approved AMOC for the corresponding actions specified in paragraph (g) of this AD.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate (STC) ST01920SE does not affect compliance with the proposed actions.

The FAA agrees with the commenter that STC ST01920SE does not affect the accomplishment of the manufacturer's service instructions. Therefore, the installation of STC ST01920SE does not affect the ability to accomplish the actions required by this AD. The FAA has not changed this AD in this regard.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023. This material specifies procedures for replacing insulation blankets in the cargo compartment with insulation blankets with integrated fire stops.

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

Costs of Compliance

The FAA estimates that this AD affects 32 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	270 work-hours × $85 per hour = $22,950	$35,900	$58,850	$1,883,200

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–24–05 The Boeing Company: Amendment 39–22895; Docket No. FAA–2024–1698; Project Identifier AD–2024–00005–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 767–300F series airplanes, certificated in any category, identified as Group 7, 11 through 15, and 18 in Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a determination that certain cargo compartment insulation blankets do not adequately fit some locations and allow smoke to migrate past the cargo compartment. The FAA is issuing this AD to require replacing these cargo compartment insulation blankets. The unsafe condition, if not addressed, could result in a fire in the bilge area of the cargo compartment, which if not contained could lead to a smoke and fire event in the passenger compartment.

(f) Compliance

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

(g) Required Actions

Within 36 months after the effective date of this AD, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023.

(h) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(4) FAA AMOC letter 522–24–00097, dated March 12, 2024, approved for AD 2021–12–11, Amendment 39–21598 (86 FR 33112, June 24, 2021) is approved as an AMOC for the corresponding provisions of Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023, that are required by paragraph (g) of this AD.

(5) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(5)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(i) Related Information

For more information about this AD, contact Julie Linn, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3684; email: *julie.linn@faa.gov.*

(j) Material Incorporated by Reference

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

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

(i) Boeing Special Attention Service Bulletin 767–25–0550, Revision 2, dated December 18, 2023.

(ii) [Reserved]

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

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

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

Issued on November 20, 2024.

Peter A. White,

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

[FR Doc. 2024–28781 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2403; Project Identifier AD–2023–00888–T; Amendment 39–22893; AD 2024–24–03]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model MD–11 and MD–11F airplanes. This AD was prompted by a report of a Model MD–11F airplane experiencing an uncommanded deployment of a thrust reverser in flight at low altitude. This AD requires initial and repetitive detailed inspections and repetitive wire integrity tests of the engine pylon thrust reverser control system wire harnesses, junction box assembly and junction box cover, left-side and right-side thrust reverser electrical harnesses, core (engine compartment) miscellaneous wire harness assembly, and 30-degree bulkhead wire harness assembly; and applicable on-condition actions. This AD also requires reporting inspection results. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2403; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

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

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–2403.

FOR FURTHER INFORMATION CONTACT: Tak Kobayashi, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3553; email *takahisa.kobayashi@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model MD–11 and MD–11F airplanes equipped with General Electric (GE) CF6–80C2D1F high-bypass turbofan engines. The NPRM published in the **Federal Register** on December 29, 2023 (88 FR 90134). The NPRM was prompted by a report of a Model MD–11F airplane equipped with three GE CF6–80C2D1F high-bypass turbofan engines experiencing an uncommanded deployment of a thrust reverser in flight at low altitude. In the NPRM, the FAA proposed to require a one-time detailed inspection of the engine pylon thrust reverser control system wire harnesses; repetitive detailed inspections and wire integrity tests of the engine pylon thrust reverser control system wire harnesses, junction box assembly and junction box cover, left-side and right-side thrust reverser electrical harnesses, core (engine compartment) miscellaneous wire harness assembly, and 30-degree bulkhead wire harness assembly; and applicable on-condition actions. The FAA also proposed to require reporting inspection results. The FAA is issuing this AD to address uncommanded deployment of a thrust reverser in flight at low altitude, which could result in loss of flight control of the airplane and loss of continued safe flight and landing.

Discussion of Final Airworthiness Directive

Comments

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

The FAA received additional comments from five commenters, including Boeing, FedEx Express (FedEx), United Parcel Service (UPS), and two individuals. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Delete an Incorrect Location

Boeing requested that the FAA delete the text ''(in the pylon)'' in the Summary and Material Incorporated by Reference under 1 CFR part 51 section of the NPRM. Boeing explained that the text ''(in the pylon)'' implies that the wire integrity tests shall be applied only to the pylon wiring as part of the repetitive wire integrity tests. Boeing stated that these tests also apply to the engine pylon thrust reverser control system wiring from the nose of the airplane.

The FAA agrees with the request. While a detailed inspection is performed on the wire harnesses in the pylon, the location for performing the wire integrity tests of the engine pylon thrust reverser control system wire harnesses is not limited to the pylon. The FAA has deleted the text ''(in the pylon)'' in this final rule accordingly.

Concern for the Workability of the Service Bulletin

FedEx expressed their concern regarding the workability of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023. FedEx stated that a prime example of complexity in Work Package 2 of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, is Part 19, which requires actions to be concurrently performed on the left and right thrust reverser halves, instead of having two separate PARTs to perform required actions on each thrust reverser half independently from the other thrust reverser half. This results in the need to evaluate four possible conditions of the wire harnesses on the left and right thrust reverser halves. The commenter stated that due to complexity of the service bulletin as well as the sheer scope of the work being performed, a significant risk exists for introducing human errors during the accomplishment of the required work.

The FAA recognizes that the work instructions provided in this service bulletin are extensive and complex. Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, was revised to Revision 1, dated June 4, 2024, to correct errors and improve clarity. The FAA reviewed Revision 1 of the service bulletin and determined it provides adequate information. Although the work instructions provided in the original and revised service bulletins are extensive and complex, the actions specified in the service bulletin that is required by this AD are necessary to address the unsafe condition. This AD mandates Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, and provides credit for actions accomplished before the effective date of this AD using Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023. In addition, the exception in paragraph (h)(2) of the proposed AD was addressed and corrected in Revision 1 of the service bulletin; therefore, paragraph (h)(2) of the proposed AD was removed from this AD. The current instructions in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, and Revision 1, dated June 4, 2024, can be followed without any major issue that would prevent accomplishment of the required actions. Further, additional actions in the revised service bulletin are intended for best maintenance practice and not necessary to address the unsafe condition. Those additional actions include the detailed inspection of the junction box assembly for any loose electrical connection in Step 1, Part 10, and application of torque to any loose electrical connection in Step 2, Part 11 of the revised service bulletin. Therefore, those parts in either the original or Revision 1 of the service bulletin are acceptable for compliance with the AD. For clarity, the FAA added a new exception to paragraph (h) of this AD specifying the added steps in Revision 1 of the service bulletin are not required for compliance with the AD.

Request To Remove Work Package 2

FedEx stated that Work Package 2 in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, is too broad in scope, and not supported or warranted by the results of the investigation. FedEx stated that a third protection feature to prevent in-flight thrust reverser deployment is not required for Model MD–11 airplanes since it was predicted that the airplane will be controllable with the thrust reverser deployed in air. FedEx stated that the outcome of the service event has served to validate this prediction. FedEx further stated that damaged wire bundles and grounds in the pylon discovered on the event airplane could have allowed energization of the pressure regulator shutoff valve (PRSOV) and directional pilot valve (DPV), which could result in in-flight thrust reverser deployment. No other element that could have contributed to the event was found by the investigation. Finally, FedEx stated that the actions in Work Package 2 will disturb the areas that are not routinely disturbed and therefore could introduce unintended consequences. FedEx added

that to properly accomplish Work Package 2, it is necessary to expend significant resources to deal with the complexity and extent of the requirements, including training of personnel.

The FAA does not agree with the request. The FAA infers that FedEx is requesting that Work Package 2 be removed from the requirements of the AD. Although the event airplane was safely brought back to the ground after in-flight uncommanded thrust reverser deployment, this does not suggest that Model MD–11 airplanes will be controllable under any anticipated operating condition with the thrust reverser deployed in air. Model MD–11 airplanes have not been demonstrated for their controllability when the deployment of single or dual thrust reverser halves is encountered on any single engine at low altitudes under anticipated operating conditions. The wiring damage discovered in the pylon of the event airplane was for the PRSOV and DPV circuits, and the manufacturer concluded that this damage was a contributing factor to the event. However, it is unclear what conditions resulted in power-to-power short—instead of power-to-ground [1] (shield), which would not result in uncommanded thrust reverser deployment. Based on available data, it is likely that a combination of conditions needs to be encountered to result in uncommanded thrust reverser deployment. Considering the age of the affected fleet, undetected degradation in wiring installation could have contributed to the event. Such a latent wiring anomaly could make an airplane vulnerable to a single failure that would impose a significant risk. Work Package 1 requires inspections of wiring in the pylon to detect any damage, and this action is intended to eliminate any similar condition discovered on the event airplane in a quick and practical manner. Work Package 2 requires wire integrity tests in addition to inspections of various wiring harnesses, and those actions are necessary to prevent and detect a potential latent anomalous condition of wiring installation. The FAA agrees that those actions are extensive, and the areas affected by the required actions are not routinely disturbed. However, in the FAA's assessment, Work Package 2 (which specifies the same substantive requirements in both the original issue and Revision 1 of Boeing Alert Service Bulletin MD11–78A017) is appropriate and necessary to understand and eliminate the root cause of the event, and the cost of any additional ''significant resources'' necessary to accomplish those actions would be outweighed by the safety benefits of the AD. This AD has not been changed regarding this request.

Request To Remove the Inspection Requirement for the Junction Box Assembly in Work Package 2

FedEx requested that the FAA remove the inspection requirement for the junction box assembly included in Work Package 2 in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023. FedEx stated that no chafed or burnt wires were found inside the junction box assembly of the event airplane or on numerous units examined as part of investigations. FedEx stated that removal of the junction box assembly for inspection will increase the risk of damage to the junction box assembly and surrounding wire harnesses.

The FAA does not agree with the request. Although the event airplane did not reveal any evidence directly linked to the PRSOV and DPV system wiring inside the junction box assembly, damage to those wires inside the junction box assembly could result in the same outcome encountered on the event airplane. The junction box assembly is a high-density area of wire routing, where wires with power are routed with the thrust reverser control wires. The inspection of the junction box assembly is intended to detect and eliminate any riding condition of wires since such condition could damage the thrust reverser control wires. The FAA does not have any data regarding the other units investigated. These units are subject to the same unsafe condition because of their similar design and installation. This AD has not been changed regarding this request.

Request To Remove the Required Actions on Engine 2

FedEx requested that the required actions on engine 2 (tail-mounted engine) be removed from the proposed AD. The commenter stated that in-flight deployment of a thrust reverser of engine 2 will have considerably less impact on controllability of the airplane than the wing-mounted engine 1 and engine 3. The commenter stated that wiring running through the wings and attaching structures are far more exposed to vibration and variable loading than those in the more stable tail structure. Because of the less harsh operating environment for engine 2, combined with the historical reliability and a lack of wire damage findings in the tail thrust reverser, FedEx concluded that the required actions on the engine are not justified.

The FAA does not agree with the request. As discussed earlier, Model MD–11 airplanes have not been demonstrated for their controllability when the deployment of single or dual thrust reverser halves is encountered on any single engine at low altitudes under anticipated operating conditions. Therefore, prevention of in-flight thrust reverser deployment is as critical for the tail-mounted engines as the wing-mounted engines. Also, routing of wire harnesses is not the same for the tail-mounted engines and wing-mounted engines as the wire routing is restricted by available space. Vibration is a factor that could contribute to wire chafing damage, but that is not the only factor. Available gaps between wire harnesses and surrounding structure as well as the types of wire support could also contribute to wire chafing damage. Therefore, an inspection of all engines, including engine 2, is critical and necessary. This AD has not been changed regarding this request.

Concern for Economic Impact

FedEx stated that the FAA considerably underestimated the economic impact to operators. FedEx claimed that the estimated costs in the NPRM completely ignored the expense of acquiring contingency material. Even if the inspections do not identify any out-of-limit conditions, operators must still be prepared for the eventuality of findings to prevent the possibility of extended grounding of airplanes. Preliminary attempts to acquire necessary spare materials have revealed little or no global supply. Boeing has not provided firm timelines for making spare materials available and pricing for this commitment. FedEx concluded that, because pricing has not been provided, it has not been correctly incorporated in the cost estimate of the NPRM.

The FAA acknowledges FedEx's concern but does not agree with the request. As explained in the NPRM, the FAA did not receive definitive data that would enable the FAA to provide a labor and parts cost estimate for the on-condition repairs or replacements. With regards to necessary parts, the manufacturer has been addressing this issue, and the FAA has concluded that the necessary spare materials would be available. To the extent spare parts may not exist to replace parts that fail the inspection requirements of this AD, the FAA cannot base its AD action on whether spare parts are available or can be produced. While every effort is made

[1] The words ''ground'' and ''shield'' may be used interchangeably in Boeing's documents.

to avoid grounding aircraft, the FAA must address the unsafe condition. However, if parts availability becomes a problem during compliance with the AD requirements, operators may request approval of an extension of the compliance time as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (k) of this AD, if the operator submits sufficient data to substantiate that an acceptable level of safety would be provided with such an extension. This AD has not been changed regarding this request.

Request for More Economical Solution

One individual requested that the FAA consider alternatives that could reduce the operational/economic burden on operators.

The commenter did not propose any alternative approach to addressing the unsafe condition. In developing the most appropriate solution, the FAA considered the recommendations of the manufacturer, the urgency associated with the unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required actions within a period of time that corresponds to the normal scheduled maintenance for most affected operators. The FAA has determined that the cost to operators to comply with this AD, as proposed, is outweighed by the safety benefits.

Requests To Change Parts Necessary for Each Airplane Section in Service Bulletin

FedEx requested revision of the parts necessary for each airplane section in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, to make it workable. The commenter stated that the information provided in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, regarding parts necessary for each airplane is incomplete and insufficient for operators to effectively plan for the execution of the service bulletin requirements. The commenter stated that determining part numbers necessary for accomplishing the required action by researching Boeing documents should not fall under the operator's responsibility. The service bulletin provides an option of repair, but it will still require identification and availability of specific wire and related electrical components. The commenter stated that all part numbers of potentially affected assemblies and components would need to be identified in the service bulletin, or the materials necessary for repair would need to be available for procurement.

Similarly, UPS requested a comprehensive parts list in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, as well as a source of suitable available spares, prior to the implementation of the AD. UPS added that the components such as wiring and connectors are out of production, and available parts are limited. UPS requested that the AD be delayed until a suitable parts list and spare source are determined.

The FAA does not agree with the requests. Regarding the parts information provided in the service bulletin, the manufacturer anticipated that new replacement parts for full wire harnesses or junction box assemblies would not be available from suppliers. Therefore, a repair would be the only available option to address damaged or failed parts, unless serviceable parts removed from an airplane are installed as replacement parts for an affected airplane. As stated previously, if parts availability becomes a problem during compliance with the AD requirements, an operator may request approval of an extension of the compliance time as an AMOC in accordance with the procedures specified in paragraph (k) of this AD, if the operator submits sufficient data to substantiate that an acceptable level of safety would be provided with such an extension. The intent of the service bulletin was to provide sufficient information necessary to accomplish required actions instead of providing full details of all parts since providing such information for all wiring configurations would require a substantial amount of time for this urgent issue and may further complicate the service bulletin. Based on the information provided in the service bulletin and available documents, such as wiring diagrams, the illustrated parts catalog, and drawings, the operators should be able to determine the necessary parts for repairs. The manufacturer confirmed that they would support operators to confirm the necessary parts for accomplishing the required actions. This AD has not been changed regarding this request.

Request To Add an Instruction for a Condition With Multiple Options

FedEx requested that an instruction be added in the AD regarding how a required condition should be handled when the condition provides multiple options. The commenter stated that instructions identified as required for compliance (RC) are also identified as an option that is contingent on certain conditions being met and a choice being made by the operator. The commenter expressed a concern that if this is not directly addressed in the language of the AD, it is anticipated that these RC options will be difficult to deal with when maintenance work cards are generated, putting the technicians in the position of making a choice to sign off an AD-required step as not applicable for the option not taken.

The FAA does not agree with the comment. In addition to Section 1.E., Compliance, of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, or Revision 1, dated June 4, 2024, Note 13 in Section 3.A. of the service bulletin provides the instruction on how to handle a required condition when multiple options are provided under that condition. This instruction provided by a general note has been used in numerous service bulletins and is not unique to this specific service bulletin. Therefore, it is unnecessary to repeat this instruction in the AD. No further changes have been made to this AD regarding this request.

Request To Provide Instructions for Insulation Resistance Test

FedEx stated that Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, does not provide sufficient detail to ensure that wire harness insulation resistance checks in Parts 6 through 8 in the service bulletin are performed properly. The commenter recommended including a statement that each of the checks should be measured against ground. The commenter also stated that unless precautionary or explanatory statements are included to indicate application of 500V between the pins and each of the other contacts on the same connector may damage other components on the circuit, uncertainty around validating the test may result.

The FAA does not agree with the request. The insulation resistance check is a standard practice. The operators are expected to follow applicable instructions in the standard wiring practice manual to perform the test for the connectors specified in the service bulletin. The test requirement is to measure between every pin and ground (shielding) and between all two adjacent pins. This AD has not been changed regarding this request.

Request for Additional Details in Part 19 in the Service Bulletin

FedEx stated that the instructions for Part 19 in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, are too vague since the specific connectors and pins are not identified. FedEx added that Boeing does not have adequate data to specify the detail since the harnesses to be tested are not

controlled by Boeing. This lack of detail places the burden onto the operators to ensure that the tests are performed as intended. The commenter does not believe the instructions in the service bulletin are adequate to ensure successful compliance.

The FAA does not agree with the request. As the commenter stated, the manufacturer does not have the details of the pins or connectors, as the data for the wire harnesses is not controlled by Boeing. Further, due to the urgency of the unsafe condition, the FAA cannot delay issuance of this final rule further for Boeing to identify the connectors or pins. This will place the burden on the operators, but the operators should utilize available data and ensure that the tests are performed adequately based on input provided by the manufacturer. This AD has not been changed regarding this request.

Request To Revise the Work Instructions for Part 13 in the Service Bulletin

FedEx requested revision of the work instructions in Part 13 of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, which requires an inspection of the internal surface of the junction box cover per Figure 13 for burn marks, signs of arcing, and fretting. The commenter stated that many inspected junction boxes' covers exhibited smudges and discoloration that can be misinterpreted as soot and burn residual, rather than the dust from the harness lacings rubbing against the cover. The instructions as currently written may result in many false findings. The commenter requested that a note be added to the service bulletin to call attention to the possibility of the benign discoloration and allow for the presence of such residue.

The FAA partially agrees with the request. The FAA agrees that the work instructions in Part 13 of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, may result in false findings. However, this AD will require Revision 1 of the service bulletin. The work instructions in Part 13 of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, have been updated to eliminate the potential misinterpretation of the conditions found on the junction box cover during the inspection. No change to this AD has been made as a result of this comment.

Request To Revise Figures 14 and 15 in the Service Bulletin

FedEx requested that Figures 14 and 15 of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, be revised to remove the minimum clearance requirement between the wire harnesses and the junction box cover or to add a clarification stating that contact between the junction box cover and lacing material is acceptable. In the alternative, FedEx asked that the language of the proposed AD be revised to add an exemption to the minimum clearance requirement in paragraph (h) of the proposed AD. The commenter noted that Parts 14 and 15 of the service bulletin require a minimum clearance of 0.20 inch between the junction box cover and the wire bundles inside the junction box assembly. However, there is no instruction to confirm that this minimum clearance is maintained when the junction box cover is closed. The commenter stated that the wire harnesses inside the junction box assembly are very stiff and rigid and generally cannot be appreciably compacted. Although this condition may result in minor interference of the lacings with the cover, the commenter has not found any evidence of wire damage resulting from this contact.

The FAA partially agrees with the request. The FAA agrees that the instructions to achieve the required minimum clearance were unclear in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023. The work instructions have been revised in Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, for clarification. However, Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, or Revision 1, dated June 4, 2024, does not allow contact between the junction box cover and lacing material since such a condition may eventually result in wire damage. No change has been made to this AD as a result of this comment.

Request To Correct Typographical Errors

FedEx noted multiple errors and typographical errors in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, and requested revision of the service bulletin to correct these errors and typographical errors.

The errors and typographical errors identified by the commenter have been corrected in Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, which is the primary source of service information in this AD. No change has been made to this AD as a result of this comment.

Request To Revise the Compliance Time of the Reporting Requirement

FedEx requested revision of the compliance time of the reporting requirement in paragraph (i) of the proposed AD. The commenter stated that the proposed compliance time of 30 days is inadequate to prepare the data package and submit the reports. The commenter stated they do not understand the urgency of the reporting requirement considering the overall compliance span of the AD.

The FAA agrees that the proposed compliance time of 30 days for the reporting requirement is unnecessarily short considering the burden on the operators and the intent that those reports will be used for root cause assessment while managing the potential risk by the inspections. The FAA has revised the compliance time of paragraph (i) of this AD to 90 days accordingly.

Request To Change Reporting Requirements

FedEx requested that the FAA eliminate the reporting requirement of paragraph (i) of the proposed AD or revise the requirements to clarify what must be reported to meet the compliance criteria. The commenter was concerned that the reporting criteria in the service bulletin are open-ended and could be misinterpreted as to what qualifies as reportable and what level of detail is required. The commenter stated that because of the breadth of the reporting criteria involved, it would be extremely hard to definitively comply with the reporting requirement. Also, the commenter stated that the relationship between Boeing and the operators should be sufficient to ensure that findings will be provided to Boeing without a mandatory reporting requirement.

The FAA partially agrees with the request.

The FAA agrees to revise the reporting criteria for clarification so that the results of the inspections or tests are reported in a consistent manner. The reporting form in Appendix C of the original service bulletin was updated in Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024. The updated reporting forms in Appendixes C through E of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, provide clear instructions to address the concern expressed by the commenter.

The FAA disagrees, however, with the request to remove the reporting requirement in paragraph (i) of this AD. The findings provided by the reports will be used for the root cause assessment and the development of a final corrective action. Therefore, the reporting requirement is a critical piece of this interim action AD.

Request To Use Boeing Service Bulletin as an Optional Inspection

UPS requested that the actions specified in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, remain as an optional inspection until the root cause can be determined.

The FAA does not agree with the request. As discussed in the preamble of the NPRM, wiring damage was found in the engine pylon of the event airplane. The root cause of uncommanded thrust reverser deployment has not been determined yet, but the manufacturer concluded that wiring damage was a contributing factor of the event based on the assessment of on-wing data and laboratory inspection. The FAA considers this AD to be an interim action. The FAA issues an interim action AD when, for example, an unsafe condition that requires a mitigating action relatively quickly is identified on airplanes, but the root cause leading to the unsafe condition is still undetermined due to limited available data. In this case, the interim mitigating action is needed to address the overall risk of the unsafe condition. Based on the FAA's assessment, the actions required by this AD would mitigate the unsafe condition in the interim period while additional inspection data would allow the manufacturer to determine the root cause and develop an adequate corrective action. This AD has not been changed regarding this request.

Request To Delay Issuance of Final Rule

UPS requested that the effective date of the AD be extended until Boeing Alert Service Bulletin MD11–78A017 is revised. UPS stated that Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, identified in the NPRM is unworkable due to discrepancies and disagreements between the configurations specified in the instructions and the actual installation.

Because this AD has been changed to mandate Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, which clarifies these instructions, no further change is necessary to this AD as a result of this comment. The manufacturer also worked with the operators to ensure that the work instructions in Revision 1 can be accomplished. This AD has not been changed regarding this request.

Request To Extend the Compliance Time for Work Package 1 and Increase Labor Hours

UPS requested that the FAA revise paragraph (h) of the proposed AD to extend the compliance time of Work Package 1 of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, to 27 months from the current proposal of 12 months. UPS stated that the labor estimate provided in the service bulletin underestimates the tasks involved in Work Package 1. UPS estimated that about 700 work-hours would be involved, while Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, estimated 134.25 hours. Considering extensive work-hours and limited parts availability, UPS stated that the proposed compliance time of 12 months does not provide sufficient time to accomplish the required actions for the affected fleet.

The FAA does not agree with the request. The FAA infers that the labor estimates provided by UPS include the labor necessary for repairs. The labor estimates provided in the service bulletin do not include the labor necessary for repairs since a repair is an on-condition action that would be affected by the extent of the damage discovered on the affected parts. The FAA recognizes that a gap would exist between the estimates provided in the service bulletin and the actual labor needed for each airplane because of those on-condition actions. The FAA established the compliance time so that operators can accomplish this interim mitigation action in a quick and practical manner, considering the potential effect of the unsafe condition. The FAA also assessed parts availability and necessary labor and determined that the compliance time of 12 months would be appropriate for Work Package 1. Operators can request approval of an extension of the compliance time in accordance with paragraph (k) of this AD if operators can provide the evidence that would make the required compliance time impractical and justification for maintaining an acceptable level safety with such an extension. This AD has not been changed regarding these requests.

Request To Include Spare Engines and Thrust Reversers in Applicability

UPS requested that paragraph (c) of the proposed AD be revised to include spare engines and thrust reversers in the AD applicability. Although Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, requires inspections and repair of the components for the engines and thrust reversers, an engine or thrust reverser on which the actions of Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, were accomplished may be replaced with an engine or thrust reverser on which the actions specified in Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, have not been accomplished.

The FAA disagrees with the request. The FAA understands the concern of an AD-compliant engine or thrust reverser being inadvertently replaced with a non-AD-compliant engine or thrust reverser. However, the AD is issued to address the unsafe condition identified at the airplane level. The affected airplanes must be maintained in the AD-compliant configuration once each airplane is demonstrated to be compliant with the AD. Installing an engine or thrust reverser that has not been inspected or tested as required by this AD on an airplane that was demonstrated to be compliant with the AD is not allowed since such an action will bring the airplane back to a non-AD-compliant configuration, unless the engine or thrust reverser is inspected or tested as required by the AD prior to returning the airplane back to service. It is the operator's responsibility to maintain each airplane in the AD-compliant configuration. This AD has not been changed regarding this request.

Request for a Specific Interval Inspection

An individual commenter recommended that the FAA analyze the frequency of the occurrence of uncommanded thrust reverser deployment in air and determine a specific interval for this inspection.

Although the FAA agrees with the intent behind this request, it is not necessary to change the AD based on this request. The FAA already assessed the aspect the commenter raised. The FAA has assessed the risk of in-flight thrust reverser deployment, considering the frequency of occurrence based on available data, and determined that the compliance times for the initial and repetitive inspections are adequate. As discussed in the preamble of the NPRM, the actions required by this AD are considered an interim action. Additional data to be provided by the operators through the reporting requirement of this AD will enable the manufacturer to obtain better insight into the potential conditions that led to the event. Based on the information provided by those reports, the FAA may consider further rulemaking.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these

products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024. This material specifies Work Package 1 inspection procedures to do an initial detailed inspection of the engine 1, engine 2, and engine 3 pylon thrust reverser control system wire harnesses. The material also specifies Work Package 2 procedures to do repetitive detailed inspections and wire integrity tests at the following locations: engine 1, engine 2, and engine 3 thrust reverser control system wire harnesses; junction box assembly and junction box cover (only detailed inspection); left side and right side thrust reverser electrical harnesses; core (engine compartment) miscellaneous wire harness assembly; and 30-degree bulkhead wire harness assembly. The material also specifies applicable on-condition actions (including repairs, replacements, installations, post-replacement inspections and tests, and return to service tests). The material also specifies that accomplishing the initial inspections and tests by doing Action 1 through Action 3 in Work Package 2 terminates the need to do the inspection in accordance with Part 2 as required in Work Package 1. However, this substitution of actions does not change the compliance time of Work Package 1 as specified in Table 1 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024.

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

Interim Action

The FAA considers this AD to be an interim action. The reports that are required by this AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the unsafe condition, and eventually to develop final action to address the unsafe condition. If final action is later identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD affects 79 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections and Tests	Up to 78 work-hours × $85 per hour = Up to $6,630 per inspection/test cycle.	$0	Up to $6,630 per inspection/test cycle.	Up to $523,770 per inspection/test cycle.
Reporting	1 work-hour × $85 per hour = $85 per inspection/test cycle.	0	$85 per inspection/test cycle.	$6,715 per inspection/test cycle.

The FAA estimates the following costs to do any on-condition actions that would be required based on the results of the inspections and tests. The agency has no way of determining the number of aircraft that might need these repairs/replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repairs/Replacements/Tests	Up to 120 work-hours × $85 per hour = Up to $10,200	* $0	Up to $10,200.

* The FAA has received no definitive data that would enable the FAA to provide a parts cost estimate for the on-condition repairs/replacements specified in this AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to take approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a

substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–24–03 The Boeing Company: Amendment 39–22893; Docket No. FAA–2023–2403; Project Identifier AD–2023–00888–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model MD–11 and MD–11F airplanes, certificated in any category, equipped with General Electric (GE) CF6–80C2D1F high-bypass turbofan engines.

(d) Subject

Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by a report of a Model MD–11F airplane experiencing an uncommanded deployment of a thrust reverser at approximately 500 feet above ground level. The FAA is issuing this AD to address uncommanded deployment of a thrust reverser in-flight at low altitude, which could result in loss of flight control of the airplane and loss of continued safe flight and landing.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024.

(h) Exceptions to Service Bulletin Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, use the phrase ''the original issue date of this service bulletin,'' this AD requires using the effective date of this AD.

(2) Where Step 1, Part 10 of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, specifies doing a detailed inspection of the junction box assembly for any loose electrical connection and Step 2, Part 11 of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024, specifies applying applicable torque to any loose electrical connection, those actions are not required for compliance with this AD.

(i) Reporting

At the applicable time specified in paragraph (i)(1) or (2) of this AD, submit a report to The Boeing Company via the Boeing Communication System (BCS) and include the information specified in Appendixes C, D, and E of Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024.

(1) If the inspection or test was done on or after the effective date of this AD: Submit the report within 90 days after the inspection or test.

(2) If the inspection or test was done before the effective date of this AD: Submit the report within 90 days after the effective date of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (g) and (i) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin MD11–78A017, dated December 4, 2023, except where step 6.c.(2)(a), ''CONDITON 14 OPTION 1 (ACTION 1),'' and step 6.c.(2)(b)4)d), ''CONDITION 14.4 OPTION 2 (ACTION 1),'' of the Accomplishment Instructions of Boeing Service Bulletin MD11–78017, dated December 4, 2023, specify to replace the junction box, that replacement must be accomplished in accordance with ''PART 12: JUNCTION BOX REPLACEMENT'' of the Accomplishment Instructions of Boeing Service Bulletin MD11–78017, dated December 4, 2023.

(k) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(4) Except as specified by paragraph (h)(2) of this AD: For Boeing service bulletin that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(l) Related Information

(1) For more information about this AD, contact Tak Kobayashi, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3553; email *takahisa.kobayashi@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (m)(3) of this AD.

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin MD11–78A017, Revision 1, dated June 4, 2024.

(ii) [Reserved]

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

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

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

Issued on November 19, 2024.

Peter A. White,

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

[FR Doc. 2024–28780 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2134; Project Identifier MCAI–2024–00125–T; Amendment 39–22894; AD 2024–24–04]

RIN 2120–AA64

Airworthiness Directives; Airbus Defense and Space S.A. (Formerly Known as Construcciones Aeronauticas, S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2018–18–09, which applied to all Airbus Defense and Space S.A. Model CN–235, CN–235–100, CN–235–200, and CN–235–300 airplanes; and certain Model C–295 airplanes. AD 2018–18–09 required a detailed inspection of the upper and lower lugs of each horizontal stabilizer-to-fuselage rear attachment fitting, repair if necessary, and a report of findings. This AD was prompted by reports of new occurrences of cracking. This AD requires repetitive inspections, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also revises the applicability. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2134; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2134.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2018–18–09, Amendment 39–19388 (83 FR 45041, September 5, 2018) (AD 2018–18–09). AD 2018–18–09 applied to all Airbus Defense and Space S.A. Model CN–235, CN–235–100, CN–235–200, and CN–235–300 airplanes; and certain Model C–295 airplanes. AD 2018–18–09 required a detailed inspection of the upper and lower lugs of each horizontal stabilizer-to-fuselage rear attachment fitting, repair if necessary, and a report of findings. The FAA issued AD 2018–18–09 to address cracking, which could lead to reduced structural integrity of the lugs on the horizontal stabilizer-to-fuselage rear attachment fittings. The unsafe condition, if not addressed, could result in lug or fitting failure, and could result in reduced controllability of the airplane.

The NPRM published in the **Federal Register** on August 30, 2024 (89 FR 70582). The NPRM was prompted by AD 2024–0049, dated February 20, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0049) (also referred to as the MCAI). The MCAI states that since EASA AD 2017–0218, dated November 8, 2017, was issued, new occurrences of cracking were reported and the manufacturer issued new material to provide instructions for repetitive high-frequency eddy current (HFEC) inspections for cracking of the affected part for all airplanes.

In the NPRM, the FAA proposed to require repetitive inspections, as specified in EASA AD 2024–0049. The NPRM also proposed to revise the applicability. The FAA is issuing this AD to address cracking, which could lead to reduced structural integrity of the lugs on the horizontal stabilizer-to-fuselage rear attachment fittings and consequent lug or fitting failure, and could result in reduced controllability of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2134.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from a commenter who supported the NPRM without change.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0049 specifies procedures for repetitive HFEC inspections for discrepancies (including cracking, rework, and sharp corner radii) of the upper and lower lugs of

each horizontal stabilizer-to-fuselage rear attachment fitting and contacting the manufacturer for corrective actions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 14 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
New actions	Up to 15 work-hours × $85 per hour = $1,275	None	Up to $1,275	Up to $17,850.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:
■ a. Removing Airworthiness Directive (AD) 2018–18–09, Amendment 39–19388 (83 FR 45041, September 5, 2018); and
■ b. Adding the following new AD:

2024–24–04 Airbus Defense and Space S.A. (Formerly known as Construcciones Aeronauticas, S.A.): Amendment 39–22894; Docket No. FAA–2024–2134; Project Identifier MCAI–2024–00125–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

This AD replaces AD 2018–18–09, Amendment 39–19388 (83 FR 45041, September 5, 2018) (AD 2018–18–09).

(c) Applicability

This AD applies to all Airbus Defense and Space S.A. (formerly known as Construcciones Aeronauticas, S.A.) Model CN–235, CN–235–200, CN–235–300, and C–295 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by a report that cracks were found on the horizontal stabilizer-to-fuselage rear attachment fitting. The FAA is issuing this AD to address cracking, which could lead to reduced structural integrity of the lugs on the horizontal stabilizer-to-fuselage rear attachment fittings. The unsafe condition, if not addressed, could result in lug or fitting failure, and could result in reduced controllability of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0049, dated February 20, 2024 (EASA AD 2024–0049).

(h) Exceptions to EASA AD 2024–0049

(1) Where paragraph (1) of EASA AD 2024–0049 specifies to do the initial inspection within certain compliance times, for this AD, accomplish the initial inspection at the time specified in paragraph (h)(1)(i) or (ii) of this AD, whichever occurs later.

(i) At the applicable compliance time specified in paragraph (1) of EASA AD 2024–0049.

(ii) Within 50 flight cycles or 50 flight hours, whichever occurs first, after the effective date of this AD.

(2) Where paragraph (1) of EASA AD 2024–0049 specifies ''thereafter, at intervals as defined in paragraph 3.1.1 of the AOT,'' this AD requires replacing that text with ''thereafter, at intervals not to exceed the intervals defined in paragraph 3.1.1 of the AOT.''

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0049.

(4) Where paragraph (2) of EASA AD 2024–0049 specifies ''If, during any inspection as required by paragraph (1) of this AD, discrepancies are detected, as defined in the AOT, before next flight, contact Airbus DS for approved corrective action instructions and accomplish those instructions accordingly,'' this AD requires replacing that text with ''If, during any inspection as required by paragraph (1) of this AD, any discrepancy is detected, the discrepancy must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus Defense and Space S.A.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0049 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD. Information may be emailed to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus Defense and Space S.A.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email *shahram.daneshmandi@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0049, dated February 20, 2024.

(ii) [Reserved]

(3) For EASA AD 2024–0049, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on November 21, 2024.

Victor Wicklund,

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

[FR Doc. 2024–28787 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1053; Project Identifier AD–2023–00164–T; Amendment 39–22891; AD 2024–24–01]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 757–200, –200CB, and –200PF series airplanes. This AD was prompted by a crack growth analysis, which indicated that current inspections are not adequate to detect cracks in certain sections of the upper frame at the frame splice between certain stringers before a single frame fails. This AD requires an inspection or records review for existing repairs, repetitive inspections for cracks of the upper frame at the frame splices between certain stringers in certain sections, and applicable on-condition actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1053, or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–1053.

FOR FURTHER INFORMATION CONTACT: Wayne Ha, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: 562–627–5238; email: *wayne.ha@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 757–200, –200CB, and –200PF series airplanes. The NPRM published in the **Federal Register** on July 24, 2023 (88 FR 47402). The NPRM was prompted by a crack growth analysis, which indicated that current inspections are not adequate to detect cracks in certain sections of the upper frame at the frame splice between certain stringers before a single frame fails. In the NPRM, the FAA proposed to require an inspection or records review for existing repairs, repetitive inspections for cracks of the upper frame at the frame splices between certain stringers in certain sections, and applicable on-condition actions.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 757–200, –200CB, and –200PF series airplanes. The SNPRM published in the **Federal Register** on April 22, 2024 (89 FR 29274). The SNPRM was prompted by a determination that the repetitive inspection intervals for airplanes that were modified by Aviation Partners Boeing (APB) supplemental type certificate (STC) ST01518SE needed to be revised. The SNPRM proposed to require the actions specified in the NPRM, with certain revised compliance times.

The FAA is issuing this AD to address cracking at the upper frames common to the splice at stringers S–13 to S–14, which could interact with fuselage skin cracking at the stringer S–14 lap splice. This unsafe condition, if not addressed, could result in the inability of a principal structural element to sustain

limit loads, and could adversely affect the structural integrity of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Boeing who supported the SNPRM without change.

The FAA received additional comments from FedEx Express, United Airlines (United), and European Air Transport Leipzig GmbH (EATL). The following presents the comments received on the SNPRM and the FAA's response to each comment.

Request To Use Different Figures

FedEx Express noted that its 757 fleet has been modified by VT MAE STC ST03562AT, passenger-to-freighter modification for Model 757–200 series airplanes, which adds a main deck cargo door to the airplane. After consultation with the STC holder, FedEx Express requested modifications for Groups 1, 2, and 3 of Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022, for airplanes modified by VT MAE STC ST03562AT. FedEx Express requested using the different figures from the requirements bulletin for the factory freighter airplanes along with shorter repeat intervals associated with those figures. FedEx Express stated that all other figures along with the method of inspections called out in the requirements bulletin will be complied with according to their respective effectivity.

The FAA finds no justification for airplanes modified by VT MAE STC ST03562AT to utilize the inspections, methods, and intervals in Groups 1, 2, and 3 of Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022. FedEx did not provide sufficient justification and data for airplanes modified by VT MAE STC ST03562AT to support a revision to this AD. Operators must request approval of an alternative method of compliance (AMOC) for airplanes modified by VT MAE STC ST03562AT to address the unsafe condition of this AD and comply with its requirements. For those airplanes, the FAA has added paragraph (h)(4) of this AD to provide an exception to the actions specified in Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022.

Comment Regarding Compliance Time

United stated that the proposed requirement to divide the applicable compliance times and repeat intervals specified in Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022, by a factor of two is excessive and could create an undue burden on the operators. United added that the FAA did not provide details regarding how it determined requiring a reduction in compliance by a factor of two. United understood that a reduction is necessary because APB does not yet have an approved service bulletin to provide its compliance requirements. However, United believed the reduction required by APB will likely show a factor of two is not an accurate determination.

EATL stated the proposed exception in paragraph (h)(3) of the proposed AD includes strong penalties for airplanes equipped with winglets, as modified by APB STC ST01518SE. EATL noted Boeing and APB usually work closely together to align impacts generated by installation of winglets, which is then included in the compliance tables of the requirements bulletin. EATL added that Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022, does not include such penalties or any indication that installation of winglets affects the compliance times.

EATL stated the proposed exception in paragraph (h)(3) of the proposed AD would prevent airplanes equipped with winglets, as modified by APB STC ST01518SE, from scheduling the inspections required by this AD during base maintenance events. EATL requested that the FAA re-evaluate halving the applicable compliance times and repeat intervals specified in Boeing Alert Requirements Bulletin 757–53A0115, dated January 25, 2022.

The FAA stated the reduction in compliance by a factor of two is to allow for APB to complete its evaluation of airplanes with APB STC ST01518SE installed. The FAA determined this is a conservative and appropriate compliance time for this AD. No changes have been made to this AD in this regard.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022. This material specifies procedures for a general visual inspection (GVI) or records review between stringers S–13 and S–14 in Sections 43 and 46 for existing repairs. This material also describes procedures, depending on the configuration, for repetitive high frequency eddy current (HFEC) and low frequency eddy current (LFEC) inspections for cracking of the upper frames and splice doublers at the frame splices between stringers S–13 and S–14, left- and right-hand sides, in Sections 43 and 46; and applicable on-condition actions. On-condition actions include repair.

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

Costs of Compliance

The FAA estimates that this AD affects 456 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
GVI	2 work-hours × $85 per hour = $170 per inspection cycle.	$0	$170 per inspection cycle	$77,520 per inspection cycle.
Repetitive Inspections	Up to 267 work-hours × $85 per hour = Up to $22,695 per inspection cycle.	0	Up to $22,695 per inspection cycle.	Up to $10,348,920 per inspection cycle.

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–24–01 The Boeing Company: Amendment 39–22891; Docket No. FAA–2023–1053; Project Identifier AD–2023–00164–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 757–200, –200CB, and –200PF series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a crack growth analysis, which indicated that current inspections are not adequate to detect cracks in the Sections 43 and 46 upper frame at the frame splice between stringers S–13 and S–14 before a single frame fails. The FAA is issuing this AD to address cracking at the upper frames common to the splice at stringers S–13 to S–14, which could interact with fuselage skin cracking at the stringer S–14 lap splice. The unsafe condition, if not addressed, could result in the inability of a principal structural element to sustain limit loads, and could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 757–53A0115, dated January 25, 2022, which is referred to in Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022, use the phrase ''the original issue date of Requirements Bulletin 757–53A0115 RB,'' this AD requires using the effective date of this AD.

(2) Where Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022, specifies contacting Boeing for repair instructions or for alternative inspections: This AD requires doing the repair and doing the alternative inspections and applicable on-condition actions using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(3) For airplanes on which winglet structural provisions (original equipment manufacturer (OEM) wingtips) or Aviation Partners Boeing (APB) winglets have been installed in accordance with APB Supplemental Type Certificate (STC) ST01518SE: This AD requires dividing the applicable compliance times and repeat intervals specified in the ''Compliance'' paragraph of Boeing Requirements Bulletin 757–53A0115 RB, dated January 25, 2022, by a factor of two.

(4) For airplanes modified by VT MAE STC ST03562AT: Where paragraph (g) of this AD requires doing ''all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022,'' this AD requires obtaining inspection instructions and applicable repair instructions in accordance with the procedures specified in paragraph (i) of this AD at the later of the compliance times specified in paragraphs (h)(4)(i) and (ii) of this AD. Comply with all applicable instructions at the time specified in the instructions.

(i) Before 50,000 total flight cycles.

(ii) Within 2,500 flight cycles after the effective date of this AD.

(i) Alternative Methods of Compliance (AMOCs)

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

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Related Information

(1) For more information about this AD, contact Wayne Ha, Aviation Safety Engineer,

Continued Operational Safety Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: 562–627–5238; email: *wayne.ha@faa.gov*.

(2) Service information identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) of this AD.

(k) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 757–53A0115 RB, dated January 25, 2022.

(ii) [Reserved]

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

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

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

Issued on November 19, 2024.

Peter A. White,

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

[FR Doc. 2024–28782 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0468; Project Identifier MCAI–2023–00762–T; Amendment 39–22898; AD 2024–24–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This AD was prompted by multiple occurrences of pilot and co-pilot seats locking in a fore-aft position due to the seat fore-aft adjustment mechanism disconnecting, caused by a broken cotter pin in the seat base egress linkage. This AD requires modifying the pilot and co-pilot seats by replacing the hardware of the seat base egress linkage, as specified in a Transport Canada AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0468; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca*. You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–0468.

FOR FURTHER INFORMATION CONTACT: Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 516–228–7300; email *fatin.r.saumik@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The NPRM published in the **Federal Register** on March 21, 2024 (89 FR 20144). The NPRM was prompted by AD CF–2023–40, dated June 13, 2023, issued by Transport Canada, which is the aviation authority for Canada (Transport Canada AD CF–2023–40) (also referred to as the MCAI). The MCAI states that there have been in-service occurrences of pilot and co-pilot seats becoming locked in a fore-aft position due to disconnection of the seat fore-aft adjustment mechanism caused by a broken cotter pin in the seat base egress linkage.

In the NPRM, the FAA proposed to require modifying the pilot and co-pilot seats by replacing the hardware of the seat base egress, as specified in Transport Canada AD CF–2023–40. The FAA is issuing this AD to address the disconnection of the seat fore-aft adjustment mechanism caused by a broken cotter pin in the seat base egress linkage. The unsafe condition, if not addressed, could result in a significant increase in crew workload for continued safe flight and landing.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0468.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters, including Collins Aerospace and Delta Airlines (Delta). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Later-Approved Service Information

Collins Aerospace and Delta requested that the FAA edit paragraph (h)(3) of the proposed AD so that it would allow the use of later service information. Paragraph (h)(3) of the proposed AD would mandate Goodrich Interiors Service Bulletin 1430–25–003, Revision C, dated November 22, 2022.

The FAA disagrees with the request. Transport Canada AD CF–2023–40, dated June 13, 2023, refers to ''Airbus Canada Service Bulletin (SB) BD500–251006, Issue 001, dated 05 April 2023, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada,'' but does not specifically allow later-approved revisions of any service information cited in that Airbus Canada service bulletin. The FAA has not changed this AD as a result of this comment.

Request for Clarification of Paragraph (h)(3) of Proposed AD

Delta requested clarification of the wording in (h)(3) of the proposed AD

where it is specified to ''Do Goodrich Interiors Service Bulletin 1430–25–003'' and to update paragraph (h)(3) of the proposed AD to include either ''refer to'' or ''in accordance with.'' The commenter would like clarification whether the verb ''do'' implies ''refer to'' or ''in accordance with.'' Conditional on the FAA's concurrence with this request, Delta also requested an additional similar exception be included in paragraph (h) of the proposed AD to allow accomplishment of the operational test specified in Goodrich Interiors Service Bulletin 1430–25–003 instructions for the Function Check under Section 3.F. using the A220 AMP Task BD500–A–J25–11–00–01AAA–320A–A in lieu of CMM 25–11–20.

The FAA disagrees with changing paragraph (h)(3) of this AD to include ''refer to'' or ''in accordance with.'' To clarify, this AD and the service information use the word ''do'' to communicate what operators need to accomplish, and therefore indicates a required action.

Request for Additional Exception

Delta requested the addition of the following paragraph: ''(h)(4) As the Goodrich Interiors Service Bulletin 1430–25–003 have instructions of removal and installation of the affected seats from the seat tracks, this AD allows the seat removal and installation procedures using the AMP procedures as listed in the procedure of Service Bulletin BD500–251006 Issue No. 001, dated 05 April 2023, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada.'' Airbus SB BD500–251006 Issue 001 Procedures section and Goodrich Interiors SB 1430–25–003 Accomplishment Instructions section both state that the pilot seats need to be removed, so the commenter is concerned with confusion due to both service bulletins giving instructions to perform the same tasks.

The FAA agrees that the repetition of steps in the Airbus and Goodrich Interiors SB could lead to confusion if operators are trying to follow SB steps. The AD should clarify what procedures the operators should follow because operators may not know whether they are in compliance with this AD if there are steps that cannot be accomplished. The FAA has added paragraph (h)(4) to this AD to allow the use of only Airbus SB BD500–251006, Issue 001, dated April 5, 2023, for seat removal and installation procedures.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

Transport Canada AD CF–2023–40 specifies procedures for modifying the pilot and co-pilot seats by replacing the hardware of the seat base egress linkage. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 23 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 2 work-hours × $85 per hour = $170	Up to $200	Up to $370	Up to $8,510.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–24–08 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–22898; Docket No. FAA–2024–0468; Project Identifier MCAI–2023–00762–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–40, dated June 13, 2023 (Transport Canada AD CF–2023–40).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by multiple occurrences of pilot and co-pilot seats locking in a fore-aft position due to the seat fore-aft adjustment mechanism disconnecting. The FAA is issuing this AD to address the disconnection of the seat fore-aft adjustment mechanism caused by a broken cotter pin in the seat base egress linkage. The unsafe condition, if not addressed, could result in a significant increase in crew workload for continued safe flight and landing.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–40.

(h) Exceptions to Transport Canada AD CF–2023–40

(1) Where Transport Canada AD CF–2023–40 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2023–40 refers to ''hours air time,'' this AD requires using flight hours.

(3) Where the service information referenced in Transport Canada AD CF–2023–40 specifies to ''Do Goodrich Interiors Service Bulletin 1430–25–003,'' this AD requires replacing that text with ''Do Goodrich Interiors Service Bulletin 1430–25–003, Revision C, dated November 22, 2022.''

(4) Where the service information specified in Transport Canada AD CF–2023–40 specifies removal and installation steps in accordance with both Airbus Canada Limited Partnership Service Bulletin BD500–251006 and Goodrich Interiors Service Bulletin 1430–25–003, this AD does not require the removal/installation steps in Goodrich Interiors Service Bulletin 1430–25–003.

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 516–228–7300; email *fatin.r.saumik@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2023–40, dated June 13, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–40 identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this Transport Canada AD on the Transport Canada website at *tc.canada.ca/en/aviation.*

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

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

Issued on November 22, 2024.

Peter A. White,

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

[FR Doc. 2024–28785 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1890; Project Identifier MCAI–2024–00087–T; Amendment 39–22899; AD 2024–24–09]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2022–24–05, which applied to all Airbus SAS Model A318, A319, A320, and A321 series airplanes. AD 2022–24–05 required repetitive inspections of certain galleys for corrosion of trolley retainer aluminum blocks and delamination of the upper panel of the trolley compartment, and applicable corrective action. This AD was prompted by the list of affected galleys being revised, and a new modification that was developed to restore the design integrity of the affected galleys. This AD continues to require the actions in AD 2022–24–05, provides optional terminating action for the repetitive inspections, revises the list of affected parts, and prohibits the installation of affected parts under certain conditions; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1890; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1890.

FOR FURTHER INFORMATION CONTACT:

Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 817–222–5102; email: *Timothy.P.Dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2022–24–05, Amendment 39–22245 (87 FR 74291, December 5, 2022) (AD 2022–24–05). AD 2022–24–05 applied to all Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes; Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes. AD 2022–24–05 required repetitive inspections of certain galleys for corrosion of trolley retainer aluminum blocks and delamination of the upper panel of the trolley compartment, and applicable corrective actions. The FAA issued AD 2022–24–05 to address damage that could affect the galley's capability to hold the trolley under emergency landing loads, which could lead to trolley detachment, possibly resulting in blocking of an escape path during an emergency exit.

The NPRM published in the **Federal Register** on July 17, 2024 (89 FR 58086). The NPRM was prompted by AD 2024–0038, dated February 5, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0038) (also referred to as the MCAI). The MCAI states that the list of affected galleys has been revised, and Airbus and the galley manufacturer have developed a modification to restore the design integrity of the affected galleys.

In the NPRM, the FAA proposed to continue to require the actions in AD 2022–24–05, provide optional terminating action for the repetitive inspections, revise the list of affected parts, and prohibit the installation of affected parts under certain conditions, as specified in EASA AD 2024–0038. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1890.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Airbus. The following presents the comment received on the NPRM and the FAA's response.

Request To Include a Missing Part Number

Airbus requested [1] that the FAA revise the NPRM to include a missing forward-facing galley part number. Airbus stated that the missing part number is 601891–006801, which is derived from the delivered part number 601891–001501 by the optional vendor service bulletin 601891–25–001501–002, as specified in Airbus Service Bulletin 25–1BK4.

The FAA agrees to include forward-facing galley, part number 601891–006801, in this AD. Part number 601891–006801 is derived from the unsafe part number 601891–001501; therefore, part number 601891–006801 has the same unsafe condition. The FAA confirmed with EASA that part number 601891–006801 is an affected part. The FAA has added paragraph (h)(5) of this AD to include part number 601891–006801 as an affected part.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0038 includes the following provisions:

- Procedures for repetitive general visual inspections of certain galleys for discrepancies including corrosion of trolley retainer aluminum blocks and delamination of upper panel of trolley compartment;
- Corrective actions including repeating the inspection at an earlier interval, repairing the trolley compartment upper panel, and limiting the trolley weight;
- Procedures for modifying the affected galleys as optional terminating action for the repetitive inspections;
- A revised the list of affected galleys; and
- Prohibition of the installation of affected parts unless the parts are inspected and corrected.

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

Costs of Compliance

The FAA estimates that this AD affects 1,425 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

[1] Airbus' comment on this AD was submitted directly to the FAA but has been placed into the rulemaking docket.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2022–24–05	2 work-hours × $85 per hour = $170	$0	$170	$242,250

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
Up to 40 work-hours × $85 per hour = $3,400	(*)	Up to $3,400.*

*The FAA has received no definitive data on which to base the cost estimates for the parts associated with the modification specified in this AD.

The FAA estimates the following costs to do any necessary on-condition action that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION COSTS

Labor cost	Parts cost	Cost per product
1 work-hours × $85 per hour = $85	$0	$85

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–24–05, Amendment 39–22245 (87 FR 74291, December 5, 2022); and

■ b. Adding the following new AD:

2024–24–09 Airbus SAS: Amendment 39–22899; Docket No. FAA–2024–1890; Project Identifier MCAI–2024–00087–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

This AD replaces AD 2022–24–05, Amendment 39–22245 (87 FR 74291, December 5, 2022) (AD 2022–24–05).

(c) Applicability

This AD applies to all Airbus SAS Model airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report that damage (including delamination of work deck and corroded and cracked retainer blocks) was found during inspection of certain galleys. The FAA is issuing this AD to address damage that could affect the galley's capability to hold the trolley under emergency landing loads, which could lead to trolley detachment, possibly resulting in blocking of an escape path during an emergency exit.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0038, dated February 5, 2024 (EASA AD 2024–0038).

(h) Exceptions to EASA AD 2024–0038

(1) Where EASA AD 2024–0038 refers to ''18 August 2021 [the effective date of the EASA AD 2021–0183 at original issue],'' this AD requires using January 9, 2023 (the effective date of AD 2022–24–05).

(2) Where EASA AD 2024–0038 refers to its effective date, this AD requires using the effective date of this AD.

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0038.

(4) Where EASA AD 2024–0038 does not specify corrective action after a post-repair inspection that has findings of damage, this AD requires obtaining repair instructions before further flight from the FAA, EASA, or Airbus SAS's EASA Design Organization Approval (DOA), and accomplishing those actions accordingly. Any approval by the DOA must include the DOA-authorized signature.

(5) Where EASA AD 2024–0038 defines an affected part as ''Forward-facing galleys, having a Part Number (P/N) as listed in Appendix 1 of this AD,'' for this AD, replace that text with ''Forward-facing galleys, having a Part Number (P/N) as listed in Appendix 1 of this AD, or having P/N 601891–006801.''

(i) No Reporting Requirement

Although material referenced in EASA AD 2024–0038 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD. Information may be emailed to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any material contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 817–222–5102; email: *Timothy.P.Dowling@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0038, dated February 5, 2024.

(ii) [Reserved]

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

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

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

Issued on November 25, 2024.

Peter A. White,

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

[FR Doc. 2024–28791 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2128; Project Identifier MCAI–2024–00136–T; Amendment 39–22896; AD 2024–24–06]

RIN 2120–AA64

Airworthiness Directives; ATR–GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–03–09, which applied to certain ATR–GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes. AD 2023–03–09 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require the actions in AD 2023–03–09 and requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 3, 2023 (88 FR 12139, February 27, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2128; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

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

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2128.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–03–09, Amendment 39–22334 (88 FR 12139, February 27, 2023) (AD 2023–03–09). AD 2023–03–09 applied to certain ATR–GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes. AD 2023–03–09 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–03–09 to address fatigue cracking and damage in principal structural elements, which could result in reduced structural integrity of the airplane.

The NPRM published in the **Federal Register** on August 20, 2024 (89 FR 67329). The NPRM was prompted by AD 2024–0053, dated February 23, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0053) (also referred to as the MCAI). The MCAI states that new or more restrictive airworthiness limitations have been developed.

In the NPRM, the FAA proposed to continue to require the actions in AD 2023–03–09 and to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in EASA AD 2024–0053. The FAA is issuing this AD to address fatigue cracking and damage in principal structural elements, which could result in reduced structural integrity of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2128.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0053, dated February 23, 2024, specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits. EASA AD 2024–0053 states that the new limitations include repetitive operational tests as required by EASA AD 2020–0249R1, dated November 30, 2021 (EASA AD 2020–0249R1).

This AD also requires EASA AD 2022–0201, dated September 26, 2022, which the Director of the Federal Register approved for incorporation by reference as of April 3, 2023 (88 FR 12139, February 27, 2023).

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

Related AD

EASA AD 2020–0249, dated November 11, 2020, corresponds to FAA AD 2020–26–17, Amendment 39–21372 (85 FR 81795, December 17, 2020) (AD 2020–26–17), which applies to Model ATR42 and ATR72 airplanes. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of AD 2020–26–17 for Model ATR72 airplanes.

Costs of Compliance

The FAA estimates that this AD affects 41 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2023–03–09, Amendment 39–22334 (88 FR 12139, February 27, 2023); and

■ b. Adding the following new AD:

2024–24–06 ATR–GIE Avions de Transport Régional: Amendment 39–22896; Docket No. FAA–2024–2128; Project Identifier MCAI–2024–00136–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

(1) This AD replaces AD 2023–03–09, Amendment 39–22334 (88 FR 12139, February 27, 2023) (AD 2023–03–09).

(2) This AD affects AD 2020–26–17, Amendment 39–21372 (85 FR 81795, December 17, 2020) (AD 2020–26–17).

(c) Applicability

This AD applies to ATR–GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 16, 2023.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking and damage in principal structural elements. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (j) of AD 2023–03–09, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before September 21, 2022: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0201, dated September 26, 2022 (EASA AD 2022–0201). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2022–0201, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2023–03–09, with no changes.

(1) Where EASA AD 2022–0201 refers to its effective date, this AD requires using April 3, 2023 (the effective date of AD 2023–03–09).

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0201 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2022–0201 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after April 3, 2023 (the effective date of AD 2023–03–09).

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0201 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0201, or within 90 days after April 3, 2023 (the effective date of AD 2023–03–09), whichever occurs later.

(5) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0201 do not apply to this AD.

(6) The ''Remarks'' section of EASA AD 2022–0201 does not apply to this AD.

(i) Retained Provisions for Alternative Actions, With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2023–03–09, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0201.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0053, dated February 23, 2024 (EASA AD 2024–0053). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2024–0053

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0053.

(2) Paragraph (3) of EASA AD 2024–0053 specifies revising ''the approved AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0053 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0053, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2024–0053 do not apply to this AD.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0053.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections)and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0053.

(m) Terminating Action for AD 2020–26–17

Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of AD 2020–26–17, for Model ATR72 airplanes only.

(n) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (o) of this AD. Information may be emailed to: *AMOC@faa.gov.*

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or ATR–GIE Avions de Transport Régional's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on January 13, 2025.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0053, dated February 23, 2024.

(ii) [Reserved]

(4) The following material was approved for IBR on April 3, 2023 (88 FR 12139, February 27, 2023).

(i) EASA AD 2022–0201, dated September 26, 2022.

(ii) [Reserved]

(5) For EASA AD 2022–0201 and EASA AD 2024–0053, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on November 21, 2024.

Victor Wicklund,

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

[FR Doc. 2024–28788 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2139; Project Identifier MCAI–2024–00123–T; Amendment 39–22900; AD 2024–24–10]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–05–02, which applied to certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. AD 2023–05–02 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 18, 2023 (88 FR 15600, March 14, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2139; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2139.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3667; email: *Timothy.P.Dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–05–02, Amendment 39–22371 (88 FR 15600, March 14, 2023) (AD 2023–05–02). AD 2023–05–02 applied to certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. AD 2023–05–02 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–05–02 to address the risks associated with the effects of aging on airplane systems.

The NPRM published in the **Federal Register** on September 11, 2024 (89 FR 73608). The NPRM was prompted by AD 2024–0046, dated February 19, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0046) (also referred to as the MCAI). The MCAI states that new or more restrictive airworthiness limitations have been developed.

In the NPRM, the FAA proposed to retain all of the requirements of EASA AD 2023–05–02. The FAA also proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, as specified in EASA AD 2024–0046. The FAA is issuing this AD to address the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics. The unsafe condition, if not addressed, could result in an increased potential for failure of certain life-limited parts, and reduced structural integrity of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2139.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters, including Air Line Pilots Association, International (ALPA) and two individuals, who supported the NPRM without change.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined

that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0046 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires EASA AD 2022–0102, dated June 8, 2022, which the Director of the Federal Register approved for incorporation by reference as of April 18, 2023 (88 FR 15600, March 14, 2023).

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

Costs of Compliance

The FAA estimates that this AD affects 1,920 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2023–05–02 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2023–05–02, Amendment 39–22371 (88 FR 15600, March 14, 2023); and

■ b. Adding the following new AD:

2024–24–10 Airbus SAS: Amendment 39–22900; Docket No. FAA–2024–2139; Project Identifier MCAI–2024–00123–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

(1) This AD replaces AD 2023–05–02, Amendment 39–22371 (88 FR 15600, March 14, 2023) (AD 2023–05–02).

(2) This AD affects AD 2018–23–02, Amendment 39–19488 (83 FR 59278, November 23, 2018) (AD 2018–23–02).

(c) Applicability

This AD applies to Airbus SAS airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 6, 2023.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address the risks associated with the effects of aging on airplane systems. Such effects could change system characteristics. The unsafe condition, if not addressed, could result in an increased potential for failure of certain life-limited parts, and reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (n) of AD 2023–05–02, with no changes. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before February 18, 2022, comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0102, dated June 8, 2022 (EASA AD 2022–0102). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2022–0102, With No Changes

This paragraph restates the exceptions specified in paragraph (o) of AD 2023–05–02, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2022–0102.

(2) Paragraph (3) of EASA AD 2022–0102 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after April 18, 2023 (the effective date of AD 2023–05–02).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0102 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0102, or within 90 days after April 18, 2023 (the effective date of AD 2023–05–02), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2022–0102.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0102.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (p) of AD 2023–05–02, with a new exception. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0102.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0046, dated February 19, 2024 (EASA AD 2024–0046). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2024–0046

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0046.

(2) Paragraph (3) of EASA AD 2024–0046 specifies revising ''the AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0046 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0046, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0046.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0046.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0046.

(m) Terminating Action for Certain Requirements of AD 2018–23–02

Accomplishing the revision of the existing maintenance or inspection program required by paragraph (g) or (j) of this AD terminates the requirements of paragraphs (g) through (k) of AD 2018–23–02.

(n) Additional AD Provisions

The following provisions also apply to this AD:

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

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(ii) AMOCs approved for AD 2023–05–02 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

(iii) AMOCs approved previously for AD 2023–05–02 are approved as AMOCs for the corresponding provisions of EASA AD 2024–0046 that are required by paragraph (j) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3667; email: *Timothy.P.Dowling@faa.gov.*

(p) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on January 13, 2025.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0046, dated February 19, 2024.

(ii) [Reserved]

(4) The following material was approved for IBR on April 18, 2023 (88 FR 15600, March 14, 2023).

(i) EASA AD 2022–0102, dated June 8, 2022.

(ii) [Reserved]

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

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

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

Issued on November 25, 2024.

Peter A. White,

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

[FR Doc. 2024–28790 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0995; Project Identifier MCAI–2023–01075–T; Amendment 39–22897; AD 2024–24–07]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. This AD was prompted by a determination that the overhead bin attachment could fail under certain conditions. This AD requires replacing existing overhead bin hook assemblies and support tubes with a different type, as specified in a Transport Canada AD, which is incorporated by reference (IBR). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 13, 2025.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 13, 2025.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket

No. FAA–2024–0995; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website at *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–0995.

FOR FURTHER INFORMATION CONTACT: Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The NPRM published in the **Federal Register** on April 9, 2024 (89 FR 24745). The NPRM was prompted by AD CF–2023–71, dated October 16, 2023 (Transport Canada AD CF–2023–71) (also referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. The MCAI states that during a review of the certification test of the overhead bin configuration (also referred to as overhead storage compartment), it was discovered that the aft serrated hook attachment could fail when the overhead bin is subjected to the 9G forward emergency landing condition certification requirements. A design review revealed that a tolerance buildup could lead to a lack of engagement between the serrated hooks and the supporting serrated tube. This condition leads to a lack of forward load reaction capability, which is essential during an emergency landing, and could result in displacement of the overhead bins. As a result, the overhead bins could fall on the occupants and/or prevent access to emergency exits.

In the NPRM, the FAA proposed to require replacing existing overhead bin hook assemblies and support tubes with a different type, as specified in Transport Canada AD CF–2023–71. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0995.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from Air Wisconsin Airlines. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request for Revising the Applicability

Air Wisconsin Airlines requested that the FAA list the serial numbers the proposed AD is applicable to, instead of stating the proposed AD applies to MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes as identified in Transport Canada AD CF–2023–71. The commentator stated Transport Canada AD CF–2023–71 lists the applicable serial numbers.

The FAA disagrees with the request. As noted by the commenter, paragraph (c) of this AD states that this AD applies to Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes as identified in Transport Canada AD CF–2023–71, which lists the affected serial numbers. This AD was developed using the ''incorporate by reference (IBR) the MCAI'' method, which simplifies FAA ADs and facilitates a simpler AD process. The applicability of FAA ADs developed using the IBR the MCAI process identifies the airplane models that are on the U.S. type certificate data sheet and refers to the MCAI AD for the specific affected airplanes. The FAA has not changed this AD in this regard.

Request for Revising Estimated Costs

Air Wisconsin Airlines requested the FAA amend the ''Costs of Compliance'' paragraph in the NPRM to include an additional 120 hours if actions are not completed during a ''heavy check.'' The commenter stated that the estimate of 21 labor hours does not account for the removal and installation of interior products (*e.g.,* seats, sidewall, panels, ceiling panels, etc.) as specified in one of the aircraft maintenance manual (AMM) tasks.

The FAA agrees with the request. The FAA has revised the ''Costs of Compliance'' paragraph of this final rule accordingly.

Request To Refer to an Additional Document

Air Wisconsin Airlines requested the addition of MHI RJ Reference Instruction Letter (RIL) 10059, Revision A, dated June 6, 2024, to the proposed AD because AMM Task 25–23–01–400–805 was not yet published in the AMM. The commenter stated that MHI RJ Service Bulletin 601R–25–206, dated June 29, 2023, instructs installation of overhead bins and references AMM Task 25–23–01–400–805.

The FAA agrees with this request. MHI RJ Reference Instruction Letter (RIL) 10059, Revision A, dated June 6, 2024, may also be referred to for the installation of overhead bins. The FAA has added paragraph (h)(3) to this AD accordingly.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

Transport Canada AD CF–2023–71 specifies procedures for the replacement of the existing serrated hook assemblies and serrated support tubes with hook assemblies using a shear pin and non-serrated support tubes on the overhead bins.

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

Costs of Compliance

The FAA estimates this AD affects 230 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
141 * work-hours × $85 per hour = $11,985	$1,764	$13,749	$3,162,270

* This figure does not include the time (up to 24 hours) for curing the sealant applied around the new hook assembly.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–24–07 MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Amendment 39–22897; Docket No. FAA–2024–0995; Project Identifier MCAI–2023–01075–T.

(a) Effective Date

This airworthiness directive (AD) is effective January 13, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (Type Certificate previously held by Bombardier, Inc.) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–71, dated October 16, 2023 (Transport Canada AD CF–2023–71).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a determination that the overhead bin attachment could fail under certain conditions. The FAA is issuing this AD to address a lack of forward load reaction capability during a high forward G emergency landing condition that could result in displacement of the overhead bins. The unsafe condition, if not addressed, could result in the overhead bins falling on the occupants and/or preventing access to emergency exits.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–71.

(h) Exception to Transport Canada AD CF–2023–71

(1) Where Transport Canada AD CF–2023–71 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2023–71 refers to hours air time, this AD requires using flight hours.

(3) Where the service information specified in Transport Canada AD CF–2023–71, specifies to ''refer to AMM 25–23–01–400–805,'' for this AD, replace that text with '' refer to AMM 25–23–01–400–805 or MHI RJ Reference Instruction Letter (RIL) 10059, Revision A, dated June 6, 2024.''

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2023–71, dated October 16, 2023.

(ii) [Reserved]

(3) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this Transport Canada AD on the Transport Canada website at *tc.canada.ca/en/aviation.*

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

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

Issued on November 21, 2024.

Victor Wicklund,

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

[FR Doc. 2024–28786 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–1707; Airspace Docket No. 24–ASW–4]

RIN 2120–AA66

Amendment of VOR Federal Airways V–68, V–76, V–212, V–222, and V–558, and United States Area Navigation Route T–220 in the Vicinity of Industry, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Very High Frequency Omnidirectional Range (VOR) Federal Airways V–68, V–212, and V–222, and United States Area Navigation (RNAV) Route T–220; and revokes VOR Federal Airway V–558. The proposed V–76 airway amendment is removed from this action due to the amendment already being accomplished by a separate airspace docket action. The FAA is taking this action due to the planned decommissioning of the VOR portion of the Industry, TX (IDU), VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Industry VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) Program.

DATES: Effective date 0901 UTC, February 20, 2025. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the Notice of Proposed Rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

History

The FAA published a NPRM for Docket No. FAA–2024–1707 in the **Federal Register** (89 FR 50537; June 14, 2024), proposing to amend VOR Federal Airways V–68, V–76, V–212, V–222, and V–558, and United States RNAV Route T–220 due to the planned decommissioning of the VOR portion of the Industry, TX, VORTAC NAVAID. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Differences From the NPRM

Subsequent the NPRM, the FAA published a final rule for Docket No. FAA–2024–0485 in the **Federal Register** (89 FR 67853, August 22, 2024; corrected September 30, 2024 (89 FR 79429)), amending VOR Federal Airway V–76 by removing the airway segment between the San Angelo, TX, VORTAC and the Industry, TX, VORTAC. As amended, V–76 was changed to extend between the Lubbock, TX, VORTAC and the San Angelo, TX, VORTAC, effective October 31, 2024. As a result of that final rule, the proposed V–76 amendment in this airspace docket is removed.

Additionally, the final rule for Docket No. FAA–2024–0485 (89 FR 67853, August 22, 2024; corrected September 30, 2024 (89 FR 79429)) amended V–558 by removing the airway segment between the Llano, TX, VORTAC and the Centex, TX, VORTAC. As amended, V–558 was changed to extend between the Centex, TX, VORTAC and the Industry, TX, VORTAC, effective October 31, 2024. That amendment is included in this action.

Incorporation by Reference

VOR Federal Airways are published in paragraph 6010(a) and United States Area Navigation Routes (T-routes) are published in paragraph 6011 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. These amendments will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending VOR Federal Airways V–68, V–212, and V–222, and RNAV Route T–220; and revoking VOR Federal Airway V–558. The FAA is taking this action due to the planned decommissioning of the VOR portion of the Industry, TX, VORTAC NAVAID. The Air Traffic Service route actions are described below.

V–68: Prior to this final rule, V–68 extended between the Montrose, CO, VOR/Distance Measuring Equipment (VOR/DME) and the Industry, TX, VORTAC. The airway segment between

the San Antonio, TX, VORTAC and the Industry VORTAC is removed. Additionally, the designated Federal airway floor information in the airway description between the Corona, NM, VORTAC and the Chisum, NM, VORTAC is removed also. As amended, the airway is changed to now extend between the Montrose VOR/DME and the San Antonio VORTAC.

V–212: Prior to this final rule, V–212 extended between the Industry, TX, VORTAC and the Mc Comb, MS, VORTAC. The airway segment between the Industry VORTAC and the Navasota, TX, VOR/DME is removed. As amended, the airway is changed to now extend between the Navasota VOR/DME and the Mc Comb VORTAC.

V–222: Prior to this final rule, V–222 extended between the El Paso, TX, VORTAC and the Humble, TX, VORTAC; and between the Lake Charles, LA, VORTAC and the intersection of the LaGrange, GA, VORTAC 048° and Rome, GA, VORTAC 166° radials (TIROE Fix). The airway segment between the Stonewall, TX, VORTAC and the Humble, TX, VORTAC is removed. Additionally, the designated Federal airway floor information in the airway description between the Fort Stockton, TX, VORTAC and the Junction, TX, VORTAC is removed. As amended, the airway is changed to now extend between the El Paso VORTAC and the Stonewall VORTAC, and between the Lake Charles VORTAC and the TIROE Fix.

V–558: Prior to this final rule, V–558 extended between the Centex, TX, VORTAC and the Industry, TX, VORTAC. The airway segment between the Centex VORTAC and the Industry VORTAC is removed; therefore, the airway is removed in its entirety.

T–220: Prior to this final rule, T–220 extended between the Industry, TX, VORTAC and the Sabine Pass, TX, VOR/DME. The Industry VORTAC route point is replaced with the MNURE, TX, WP located approximately 2 nautical miles north of the Industry VORTAC and the route is extended westward from the MNURE WP to the MARCS, TX, Fix. As amended, the route is changed to now extend between the MARCS Fix and the Sabine Pass VORTAC. The full T–220 route description is listed in the regulatory text of this final rule.

The NAVAID radials listed in the VOR Federal airway descriptions in the regulatory text of this final rule are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action amending VOR Federal Airways V–68, V–212, and V–222, and United States RNAV Route T–220; and revoking VOR Federal Airway V–558, due to the planned decommissioning of the VOR portion of the Industry, TX, VORTAC NAVAID, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5i, which categorically excludes from further environmental impact review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–68 [Amended]

From Montrose, CO; Cones, CO; Dove Creek, CO; Cortez, CO; Rattlesnake, NM; INT Rattlesnake 128° and Albuquerque, NM, 345° radials; Albuquerque; INT Albuquerque 120° and Corona, NM, 311° radials; Corona; Chisum, NM; Hobbs, NM; Midland, TX; San Angelo, TX; Junction, TX; Center Point, TX; to San Antonio, TX.

* * * * *

V–212 [Amended]

From Navasota, TX; INT Navasota 019° and Lufkin, TX, 250° radials; Lufkin; Alexandria, LA; to Mc Comb, MS.

* * * * *

V–222 [Amended]

From El Paso, TX; Salt Flat, TX; Fort Stockton, TX; Junction, TX; to Stonewall, TX. From Lake Charles, LA; Mc Comb, MS; Eaton, MS; Monroeville, AL; Montgomery, AL; LaGrange, GA; to INT LaGrange 048° and Rome, GA, 166° radials.

* * * * *

V–558 [Removed]

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–220 MARCS, TX to Sabine Pass, TX (SBI) [Amended]

MARCS, TX	FIX	(Lat. 29°53′52.04″ N, long. 097°51′40.70″ W)
CRAYS, TX	FIX	(Lat. 29°55′06.43″ N, long. 097°25′59.46″ W)
MNURE, TX	WP	(Lat. 29°59′34.88″ N, long. 096°33′57.84″ W)
SEALY, TX	FIX	(Lat. 29°51′15.54″ N, long. 095°56′36.33″ W)
MOLLR, TX	WP	(Lat. 29°39′20.23″ N, long. 095°16′35.83″ W)
Sabine Pass, TX (SBI)	VOR/DME	(Lat. 29°41′12.19″ N, long. 094°02′16.72″ W)

* * * * *

Issued in Washington, DC, on December 3, 2024.

Richard Lee Parks,

Manager (A), Rules and Regulations Group.

[FR Doc. 2024–28750 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31579; Amdt. No. 582]

IFR Altitudes; Miscellaneous Amendments

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

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective date:* 0901 UTC, 26 December 2024.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., STB Annex, Bldg. 26, Room 217, Oklahoma City, OK 73169–6918. Telephone: (405) 954–1139.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, DC, on November 22, 2024.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, 26 December 2024.

PART 95—IFR ALTITUDES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, and 14 CFR 11.49(b)(2).

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 582 effective date December 26, 2024]

From	To	MEA
Color Routes		
§ 95.5 Green Federal Airway G16 Is Amended To Delete		
POINT LAY, AK NDB	WAINWRIGHT VILLAGE, AK NDB	*1700
*1200—MOCA		MAA—17500
WAINWRIGHT VILLAGE, AK NDB	BROWERVILLE, AK NDB	2000
		MAA—17500
BROWERVILLE, AK NDB	NUIQSUT VILLAGE, AK NDB	1600
	COP 050UQS	MAA—17500
NUIQSUT VILLAGE, AK NDB	PUT RIVER, AK NDB	1700
		MAA—17500
§ 95.11 Amber Federal Airway A17 Is Amended To Delete		
CHENA, AK NDB	*CHANDALAR LAKE, AK NDB	7000
*10000—MCA CHANDALAR LAKE, AK NDB, NW BND		MAA—17500
CHANDALAR LAKE, AK NDB	PUT RIVER, AK NDB	10000
		MAA—17500
§ 95.10 Amber Federal Airway A3 Is Amended To Delete		
EVANSVILLE, AK NDB	PUT RIVER, AK NDB	10000
		MAA—17500

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3487 RNAV Route T487 Is Added To Read			
SEATTLE, WA VORTAC	LOFAL, WA FIX	4000	17500
LOFAL, WA FIX	U.S. CANADIAN BORDER	5400	17500
§ 95.4000 High Altitude RNAV Routes			
§ 95.4001 RNAV Route Q1 Is Amended by Adding			
ELMAA, WA FIX	U.S. CANADIAN BORDER	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
Is Amended To Read in Part			
ERAVE, WA WP	ELMAA, WA FIX	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
§ 95.4010 RNAV Route Q10 Is Amended by Adding			
EMMONAK, AK VOR/DME	ANIAK, AK FIX	*18000	45000
*GNSS REQUIRED			
ANIAK, AK FIX	SPARREVOHN, AK VOR/DME	*18000	45000
*GNSS REQUIRED			
SPARREVOHN, AK VOR/DME	AKGAS, AK FIX	*18000	45000
*GNSS REQUIRED			
AKGAS, AK FIX	KENAI, AK VOR/DME	*18000	45000
*GNSS REQUIRED			
KENAI, AK VOR/DME	MIDDLETON ISLAND, AK VOR/DME	*18000	45000
*GNSS REQUIRED			
§ 95.4083 RNAV Route Q83 Is Amended To Delete			
EFFAY, SC WP	SLOJO, SC WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
Is Amended by Adding			
EFFAY, SC WP	WHTTL, NC WP	*18000	45000
*18000—GNSS MEA			
*DME/DME/IRU MEA			
WHTTL, NC WP	GREENSBORO, NC VORTAC	*18000	45000
*18000—GNSS MEA			

From	To	MEA	MAA
*DME/DME/IRU MEA			
Is Amended To Read in Part			
ROYCO, GA WP *18000—GNSS MEA *DME/DME/IRU MEA	WURFL, SC WP	*18000	45000
WURFL, SC WP *18000—GNSS MEA *DME/DME/IRU MEA	EFFAY, SC WP	*18000	45000
§ 95.4902 RNAV Route Q902 Is Amended To Delete			
SEATTLE, WA VORTAC *GNSS REQUIRED	ORCUS, WA WP	*18000	45000
ORCUS, WA WP *GNSS REQUIRED	U.S. CANADIAN BORDER	*18000	45000
U.S. CANADIAN BORDER *GNSS REQUIRED	ANNETTE ISLAND, AK VOR/DME	*18000	45000
ANNETTE ISLAND, AK VOR/DME *GNSS REQUIRED	GESTI, AK FIX	*18000	45000
GESTI, AK FIX *GNSS REQUIRED	DOOZI, AK FIX	*18000	45000
DOOZI, AK FIX *GNSS REQUIRED	LEVEL ISLAND, AK VOR/DME	*18000	45000
LEVEL ISLAND, AK VOR/DME *GNSS REQUIRED	HOODS, AK FIX	*18000	45000
HOODS, AK FIX *GNSS REQUIRED	SISTERS ISLAND, AK VORTAC	*18000	45000
SISTERS ISLAND, AK VORTAC *GNSS REQUIRED	U.S. CANADIAN BORDER	*18000	45000
U.S. CANADIAN BORDER *GNSS REQUIRED	NORTHWAY, AK VORTAC	*18000	45000
NORTHWAY, AK VORTAC *GNSS REQUIRED	RDFLG, AK FIX	*18000	45000
RDFLG, AK FIX *GNSS REQUIRED	HRDNG, AK FIX	*18000	45000
HRDNG, AK FIX *GNSS REQUIRED	FAIRBANKS, AK VORTAC	*18000	45000
FAIRBANKS, AK VORTAC *GNSS REQUIRED	KOTZEBUE, AK VOR/DME	*18000	45000
Is Added To Read			
KOTZEBUE, AK VOR/DME *GNSS REQUIRED	FAIRBANKS, AK VORTAC	*18000	45000
FAIRBANKS, AK VORTAC *GNSS REQUIRED	NORTHWAY, AK VORTAC	*18000	45000
NORTHWAY, AK VORTAC *GNSS REQUIRED	U.S. CANADIAN BORDER	*18000	45000
U.S. CANADIAN BORDER *GNSS REQUIRED	SISTERS ISLAND, AK VORTAC	*18000	45000
SISTERS ISLAND, AK VORTAC *GNSS REQUIRED	LEVEL ISLAND, AK VOR/DME	*18000	45000
LEVEL ISLAND, AK VOR/DME *GNSS REQUIRED	ANNETTE ISLAND, AK VOR/DME	*18000	45000
ANNETTE ISLAND, AK VOR/DME *GNSS REQUIRED	U.S. CANADIAN BORDER	*18000	45000
U.S. CANADIAN BORDER *GNSS REQUIRED	SEATTLE, WA VORTAC	*18000	45000

From	To	MEA
§ 95.6001 Victor Routes—U.S **§ 95.6009 VOR Federal Airway V9 Is Amended To Delete**		
SPINNER, IL VORTAC *2300—MOCA	PONTIAC, IL VOR/DME	*3000 MAA—17500
Is Amended To Read in Part		
ST LOUIS, MO VORTAC *2200—MOCA	SPINNER, IL VORTAC	*2700 MAA—17500

From	To	MEA
§ 95.6041 VOR Federal Airway V41 Is Amended To Delete		
CUTTA, OH FIX	YOUNGSTOWN, OH VORTAC	*5000
*3600—GNSS MEA		MAA—17500
§ 95.6048 VOR Federal Airway V48 Is Amended To Delete		
PEORIA, IL VORTAC	MAROC, IL FIX	*3000
*2400—MOCA		MAA—17500
MAROC, IL FIX	PONTIAC, IL VOR/DME	2500
		MAA—17500
§ 95.6069 VOR FEDERAL AIRWAY V69 Is Amended To Delete		
SPINNER, IL VORTAC	PONTIAC, IL VOR/DME	*3000
*2300—MOCA		MAA—17500
PONTIAC, IL VOR/DME	JOLIET, IL VOR/DME	*3000
*2300—MOCA		MAA—17500
§ 95.6147 VOR Federal Airway V147 Is Amended To Read in Part		
SLATT, PA FIX	WILKES–BARRE, PA VORTAC	4000
		MAA—17500
§ 95.6173 VOR Federal Airway V173 Is Amended To Read in Part		
SPINNER, IL VORTAC	JILLY, IL FIX	*4500
*2400—MOCA		MAA—17500
§ 95.6227 VOR Federal Airway V227 Is Amended To Delete		
ROBERTS, IL VOR/DME	PONTIAC, IL VOR/DME	3000
		MAA—17500
PONTIAC, IL VOR/DME	PLANO, IL FIX	3000
		MAA—17500
§ 95.6233 VOR Federal Airway V233 Is Amended To Delete		
MOUNT PLEASANT, MI VOR/DME	CARGA, MI FIX	5500
		MAA—17500
CARGA, MI FIX	GAYLORD, MI VOR/DME	4000
		MAA—17500
GAYLORD, MI VOR/DME	PELLSTON, MI VORTAC	3200
		MAA—17500
§ 95.6262 VOR Federal Airway V262 Is Amended To Read in Part		
PEORIA, IL VORTAC	BRADFORD, IL VORTAC	2700
		MAA—17500
§ 95.6313 VOR Federal Airway V313 Is Amended To Delete		
ADDERS, IL VORTAC	PONTIAC, IL VOR/DME	3000
		MAA—17500
§ 95.6321 VOR Federal Airway V321 Is Amended To Read in Part		
PECAN, GA VOR/DME	KUTVE, GA FIX	2600
		MAA—17500
KUTVE, GA FIX	*PREST, GA FIX	2600
*7000—MCA PREST, GA FIX, NW BND		MAA—17500
PREST, GA FIX	*RSVLT, GA FIX	**7000
*7000—MCA RSVLT, GA FIX, SE BND		
**3300—MOCA		MAA—17500
RSVLT, GA FIX	LAGRANGE, GA VORTAC	2700
		MAA—17500
§ 95.6420 VOR Federal Airway V420 Is Amended To Delete		
TRAVERSE CITY, MI VOR/DME	GAYLORD, MI VOR/DME	*3000
*TRAVERSE CITY R–062 UNUSABLE USE GAYLORD R–247.		MAA—17500
GAYLORD, MI VOR/DME	ALPENA, MI VORTAC	3200
		MAA—17500

From	To	MEA
§ 95.6495 VOR Federal Airway V495 Is Amended To Delete		
U.S. CANADIAN BORDER	WHATCOM, WA VORTAC	*3000
*1900—MOCA		MAA—17500
WHATCOM, WA VORTAC	U.S. CANADIAN BORDER	3000
		MAA—17500
U.S. CANADIAN BORDER	*JAWBN, WA FIX	**5400
*MTA V495 SE TO V4 W 8000		
**4300—MOCA		MAA—17500
JAWBN, WA FIX	LOFAL, WA FIX	*5400
*4300—MOCA		MAA—17500
LOFAL, WA FIX	*SEATTLE, WA VORTAC	**4000
*4700—MCA SEATTLE, WA VORTAC, S BND		
**2800—MOCA		MAA—17500
SEATTLE, WA VORTAC	CIDUG, WA FIX	
	S BND	*9000
	N BND	*5000
*3000—GNSS MEA		MAA—17500
CIDUG, WA FIX	*ALDER, WA FIX	
	S BND	**9000
	N BND	**5000
*9000—MCA ALDER, WA FIX, S BND		
**4200—GNSS MEA		MAA—17500
ALDER, WA FIX	*TOUTL, WA FIX	**9000
*9000—MCA TOUTL, WA FIX, N BND		
**7000—GNSS MEA		MAA—17500
TOUTL, WA FIX	BATTLE GROUND, WA VORTAC	
	N BND	*9000
	S BND	*5300
*5300—GNSS MEA		MAA—17500
BATTLE GROUND, WA VORTAC	NEWBERG, OR VOR/DME	4000
		MAA—17500
NEWBERG, OR VOR/DME	CORVALLIS, OR VOR/DME	*4000
*3400—MOCA		MAA—17500
CORVALLIS, OR VOR/DME	HORTE, OR FIX	4000
		MAA—17500
HORTE, OR FIX	*VAUGN, OR FIX	
	S BND	7000
	N BND	4000
*7000—MRA		MAA—17500
VAUGN, OR FIX	ROSEBURG, OR VOR/DME	*7000
*4400—MOCA		MAA—17500
ROSEBURG, OR VOR/DME	MERLI, OR FIX	*8000
*7500—MOCA		MAA—17500
MERLI, OR FIX	*PAPLE, OR FIX	**9000
*10100—MRA		
**6500—MOCA		MAA—17500
PAPLE, OR FIX	*BAYTS, OR FIX	**10100
*10000—MRA		
**7300—MOCA		MAA—17500
BAYTS, OR FIX	FORT JONES, CA VOR/DME	*10000
*9400—MOCA		MAA—17500
Is Added To Read		
FORT JONES, CA VOR/DME	*BAYTS, OR FIX	**10000
*10000—MRA		
**9400—MOCA		MAA—17500
BAYTS, OR FIX	*PAPLE, OR FIX	**10100
*10100—MRA		
**7300—MOCA		MAA—17500
PAPLE, OR FIX	MERLI, OR FIX	*9000
*6500—MOCA		MAA—17500
MERLI, OR FIX	ROSEBURG, OR VOR/DME	*8000
*7500—MOCA		MAA—17500
ROSEBURG, OR VOR/DME	*VAUGN, OR FIX	**7000
*7000—MRA		
**4400—MOCA		MAA—17500
VAUGN, OR FIX	HORTE, OR FIX	
	S BND	7000
	N BND	4000
		MAA—17500
HORTE, OR FIX	CORVALLIS, OR VOR/DME	4000
		MAA—17500

From	To	MEA
CORVALLIS, OR VOR/DME	NEWBERG, OR VOR/DME	*4000
*3400—MOCA		MAA—17500
NEWBERG, OR VOR/DME	BATTLE GROUND, WA VORTAC	4000
		MAA—17500
BATTLE GROUND, WA VORTAC	*TOUTL, WA FIX	
	N BND	**9000
	S BND	**5300
*9000—MCA TOUTL, WA FIX, N BND		
**5300—GNSS MEA		MAA—17500
TOUTL, WA FIX	*ALDER, WA FIX	**9000
*9000—MCA ALDER, WA FIX, S BND		
**7000—GNSS MEA		MAA—17500
ALDER, WA FIX	CIDUG, WA FIX	
	S BND	*9000
	N BND	*5000
*4200—GNSS MEA		MAA—17500
CIDUG, WA FIX	SEATTLE, WA VORTAC	
	S BND	*9000
	N BND	*5000
*3000—GNSS MEA		MAA—17500

§ 95.6586 VOR Federal Airway V586 Is Amended To Delete

PEORIA, IL VORTAC	MAROC, IL FIX	*3000
*2400—MOCA		MAA—17500
MAROC, IL FIX	PONTIAC, IL VOR/DME	2500
		MAA—17500
PONTIAC, IL VOR/DME	JOLIET, IL VOR/DME	*3000
*2300—MOCA		MAA—17500

From	To	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7035 Jet Route J35 Is Amended To Delete			
FARMINGTON, MO VORTAC	ST LOUIS, MO VORTAC	18000	45000
ST LOUIS, MO VORTAC	SPINNER, IL VORTAC	18000	45000
SPINNER, IL VORTAC	PONTIAC, IL VOR/DME	18000	31000
PONTIAC, IL VOR/DME	JOLIET, IL VOR/DME	18000	35000
JOLIET, IL VOR/DME	NORTHBROOK, IL VOR/DME	18000	45000
§ 95.7101 Jet Route J101 Is Amended To Delete			
SPINNER, IL VORTAC	PONTIAC, IL VOR/DME	18000	31000
PONTIAC, IL VOR/DME	JOLIET, IL VOR/DME	18000	35000
JOLIET, IL VOR/DME	NORTHBROOK, IL VOR/DME	18000	45000
§ 95.7179 Jet Route J179 Is Amended To Delete			
MIDDLETON ISLAND, AK VOR/DME	KENAI, AK VOR/DME	18000	45000
KENAI, AK VOR/DME	SPARREVOHN, AK VOR/DME	18000	45000
SPARREVOHN, AK VOR/DME	ANIAK, AK NDB	18000	45000
ANIAK, AK NDB	ST MARYS, AK NDB	18000	45000
ST MARYS, AK NDB	EMMONAK, AK VOR/DME	18000	45000
§ 95.7211 Jet Route J211 Is Amended To Delete			
JOHNSTOWN, PA VOR/DME	YOUNGSTOWN, OH VORTAC	18000	45000
§ 95.7502 Jet Route J502 Is Amended To Delete			
SEATTLE, WA VORTAC	U.S. CANADIAN BORDER	18000	45000
U.S. CANADIAN BORDER	ANNETTE ISLAND, AK VOR/DME	22000	45000
ANNETTE ISLAND, AK VOR/DME	LEVEL ISLAND, AK VOR/DME	18000	45000
LEVEL ISLAND, AK VOR/DME	SISTERS ISLAND, AK VORTAC	18000	45000
NORTHWAY, AK VORTAC	FAIRBANKS, AK VORTAC	18000	45000
FAIRBANKS, AK VORTAC	KOTZEBUE, AK VOR/DME	*27000	45000
*MEA IS ESTABLISHED WITH A GAP IN NAVIGATION SIGNAL COVERAGE.			
Is Added To Read			
KOTZEBUE, AK VOR/DME	FAIRBANKS, AK VORTAC	*27000	45000

From	To	MEA	MAA
*MEA IS ESTABLISHED WITH A GAP IN NAVIGATION SIGNAL COVERAGE.			
FAIRBANKS, AK VORTAC	NORTHWAY, AK VORTAC	18000	45000
§ 95.7589 Jet Route J589 Is Amended To Delete			
ROSEBURG, OR VOR/DME	CORVALLIS, OR VOR/DME	18000	45000
CORVALLIS, OR VOR/DME	U.S. CANADIAN BORDER	28000	45000

Airway segment		Changeover points	
From	To	Distance	From
§ 95.8003 VOR Federal Airways Changeover Points V495 Is Amended To Delete Changeover Point			
WHATCOM, WA VORTAC	VICTORIA, CA VOR/DME	10	WHATCOM
SEATTLE, WA VORTAC	VICTORIA, CA VOR/DME	50	SEATTLE
§ 95.8005 Jet Routes Changeover Points J502 Is Amended To Delete Changeover Point			
SEATTLE, WA VORTAC	VICTORIA, CA VOR/DME	50	SEATTLE
J589 Is Amended To Delete Changeover Point			
CORVALLIS, OR VOR/DME	VICTORIA, CA VOR/DME	100	CORVALLIS

[FR Doc. 2024–28429 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM96–1–043; Order No. 587–AA]

Standards for Business Practices of Interstate Natural Gas Pipelines

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission amends its regulations to incorporate by reference, with certain enumerated exceptions, the latest version (Version 4.0) of Standards for Business Practices of Interstate Natural Gas Pipelines adopted by the Wholesale Gas Quadrant (WGQ) of the North American Energy Standards Board (NAESB). NAESB's revisions in this version of the standards are designed to promote greater efficiency and reliability of the natural gas industry's operations and strengthen the cybersecurity protections provided within the standards.

DATES:

Effective date: This rule is effective February 7, 2025.

Compliance date: Compliance filings required by this final rule are due on February 3, 2025. Compliance with the standards incorporated by reference in this rule is required by August 1, 2025.

Incorporation by reference: The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of February 7, 2025.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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I. Overview

1. In this final rule, the Federal Energy Regulatory Commission (Commission) amends its regulations at 18 CFR 284.12 to incorporate by reference, with certain enumerated exceptions,[1] the latest version (WGQ Version 4.0) of business practice standards applicable to natural gas pipelines. On October 2, 2023, NAESB reported to the Commission that it had approved WGQ Version 4.0 to replace the currently incorporated version (Version 3.2) of those business practice standards. On May 21, 2024, NAESB reported a minor correction to WGQ Version 4.0. This final rule requires interstate natural gas pipelines to file compliance filings with the Commission by February 3, 2025, with an effective date of the tariff records of August 1, 2025.

2. The implementation of these standards will promote greater efficiency and reliability of the natural gas industry's operations and strengthen the cybersecurity protections provided within the standards.[2]

II. Background

3. Since 1996, the Commission has adopted regulations to standardize the business practices and communication methodologies of interstate natural gas pipelines to create a more integrated and efficient pipeline system. These regulations have been promulgated in the Order No. 587 series of orders,[3] wherein the Commission has incorporated by reference standards for interstate natural gas pipeline business practices and electronic communications that were developed and adopted by NAESB's WGQ. Upon incorporation by reference, this version of the standards will replace the currently incorporated version (Version 3.2) of those business practice standards.

4. On October 2, 2023, NAESB filed a report (Informational Report) informing the Commission that it had adopted and ratified WGQ Version 4.0 of its business practice standards applicable to interstate natural gas pipelines. WGQ Version 4.0 includes business practice standards developed and modified in response to industry requests and directives from the NAESB Board of Directors. This version also includes the standards developed in response to the recommendations of Sandia National Laboratories (Sandia),[4] which in 2019 issued a DOE-sponsored cybersecurity surety assessment of the NAESB standards.[5]

5. NAESB's Informational Report identifies all the changes made to the WGQ Version 3.2 standards and summarizes the deliberations that led to the changes being made. It also identifies changes to the existing standards that were considered but not adopted due to a lack of consensus or other reasons.

6. On March 21, 2024, the Commission issued a Notice of Proposed Rulemaking proposing to amend its regulations to incorporate by reference, with certain enumerated exceptions, the WGQ Version 4.0 business practice standards applicable to interstate natural gas pipelines.[6]

7. On May 21, 2024, NAESB submitted, and the Commission noticed for comment, an errata filing to update the Informational Report, noting a minor correction to an existing WGQ standard.[7] The standard supports the communication of invoices between trading partners, including transactions for natural gas transportation and sales and related charges and/or allowances. NAESB states that it adopted and ratified the changes for that standard on March 23, 2020, which became effective on November 3, 2020, but were inadvertently omitted from WGQ Version 3.2 and WGQ Version 4.0. The minor correction revised the Electronic Delivery Mechanism (EDI) X12 Mapping Guidelines for existing WGQ standard 3.4.1—Transportation/Sales Invoice to add code values for five data elements.[8]

8. In response to the WGQ Version 4.0 NOPR, the American Gas Association (AGA) and the Interstate Natural Gas Association (INGAA) filed comments. AGA expresses support of the Commission's proposed rulemaking as well as the minor correction submitted by NAESB on May 21, 2024.[9] INGAA also supports the Commission's proposed rulemaking but urges that the Commission not implement the final rule during the winter heating season, and thus, requests that the implementation date of the final rule should not be earlier than April 1, 2025.[10]

III. Discussion

9. In the WGQ Version 4.0 NOPR, the Commission proposed to incorporate by reference in its regulations the NAESB WGQ Version 4.0 business practice standards, with the exception of NAESB's standards specifying the terms of optional model contracts and the eTariff-related standards. No commenters opposed the Commission's proposal.

[1] As explained below, we are not incorporating by reference in this final rule the optional model contracts and the eTariff-related standards included in the North American Energy Standards Board (NAESB) Wholesale Gas Quadrant (WGQ) Version 4.0 package of business practice standards.

[2] As explained below, NAESB has developed and adopted, in conjunction with Sandia National Laboratories, a series of business practice standards to strengthen the cybersecurity protections provided within the standards.

[3] This series of orders began with the Commission's issuance of Order No. 587, *Standards for Business Practices of Interstate Natural. Gas Pipelines.* 61 FR 39053 (July 26, 1996), FERC Stats. & Regs. ¶ 31,038 (1996) (cross-referenced at 76 FERC ¶ 61,042).

[4] Sandia is a multidisciplinary national laboratory and federally funded research and development center for the U.S. Department of Energy's (DOE) National Nuclear Security Administration that supports numerous federal, state, and local government agencies, companies, and organizations.

[5] In April 2017, NAESB announced that Sandia, through funding provided by DOE, would be performing a surety assessment of the NAESB standards. As determined by Sandia and DOE, the purpose of the surety assessment was to analyze cybersecurity elements within the standards, focusing on four areas: (1) the NAESB Certification Program for Accredited Certification Authorities, including the Wholesale Electric Quadrant (WEQ)-012 Public Key Infrastructure Business Practice Standards, the NAESB Accreditation Requirements for Authorized Certificate Authorities, and the Authorized Certification Authority Process; (2) the WEQ Open Access Same-Time Information Systems suite of standards; (3) the WGQ and Retail Markets Quadrant internet Electronic Transport (IET) and Quadrant Electronic Delivery Mechanism (EDM) Related Standards Manual; and (4) a high-level dependency analysis between the gas and electric markets to evaluate the different security paradigms the markets employ.

[6] *Standards for Bus. Pracs. of Interstate Nat. Gas Pipelines,* Notice of Proposed Rulemaking, 89 FR 23954 (Apr. 4, 2024), 186 FERC ¶ 61,196 (2024) (WGQ Version 4.0 NOPR).

[7] NAESB WGQ implemented the minor correction, Minor Correction MC24002, on May 17, 2024, which modifies NAESB WGQ Standard No. 3.4.1—Transportation/Sales Invoice included in the WGQ Invoicing Related Standards.

[8] NAESB states that the standard changes are to ensure the hierarchal structure of the dataset complied with the Accredited Standards Institute X12 Transaction Set 811 Consolidated Service Invoice/Statement.

[9] AGA Comments at 1. AGA also expresses its disappointment that Standards Request No. 23001 was not part of the proposed revisions. AGA Comments at 1–2. These comments do not pertain to this final rule, and thus, will not be addressed.

[10] INGAA Comments at 2.

10. In this final rule, we adopt the proposal to incorporate by reference, in our regulations, the NAESB WGQ Version 4.0 business practice standards, with certain exceptions. As an initial matter, we note that the WGQ Version 4.0 business practice standards include modifications, reservations, deletions, and additions to the following set of Version 3.2 WGQ Standards. (Each set of Business Practice Standards is referred to as a manual.)

Manual	Business practice standards
0	Additional Standards.
2	Flowing Gas Related Standards.
3	Invoicing Related Standards.
4	Quadrant Electronic Delivery Mechanism Standards.
5	Capacity Release Related Standards.
10	WGQ/REQ/RGQ Internet Electronic Transport.

Additionally, the WGQ Version 4.0 business practice standards include one new manual of standards:

Manual	Business practice standards
12	Cybersecurity Related Standards.

11. We require compliance filings be made by February 3, 2025, with an effective date of August 1, 2025. as more fully described below.

12. We discuss below some specific aspects of NAESB's Informational Report.

A. The NAESB WGQ Version 4.0 Business Practice Standards

13. NAESB used its consensus procedures to develop and approve the WGQ Version 4.0 business practice standards. As the Commission found in Order No. 587, the adoption of consensus standards is appropriate, because the consensus process helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of industry participants representing all segments of the industry. Moreover, since the industry itself must conduct business under these standards, the Commission's regulations should reflect those standards that have the widest possible support. In section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTT&AA),[11] Congress affirmatively requires federal agencies to use technical standards developed by voluntary consensus standards organizations, like NAESB, as means to carry out policy objectives or activities.

14. We incorporate by reference into the Commission's regulations the WGQ Version 4.0 business practice standards, with the exception of NAESB's standards specifying the terms of optional model contracts and the eTariff-related standards, as discussed below.

1. WGQ Cybersecurity Related Standards

15. The new WGQ Cybersecurity Related Standards Manual consolidates existing NAESB cybersecurity-related standards from various NAESB standards manuals into a single manual. This consolidation should make the NAESB and Commission processes for revising NAESB cybersecurity standards easier and faster to help match the fast pace of changes in cybersecurity practices. These standards focus on strengthening the cybersecurity practices used by the industry through the mitigation of potential vulnerabilities and the use of secure communication and encryption methodologies.

2. Other Standards Modifications

16. In response to industry request, WGQ Version 4.0 adds new data elements to the WGQ Additional Standards and the WGQ Capacity Release Related Standards and modifies existing data elements in the WGQ Flowing Gas Related Standards and the WGQ Invoicing Related Standards to improve efficiencies of business processes for transportation service providers and parties interacting with these entities.[12]

17. The revised WGQ Additional Standards add a new data element, ''Cycle Indicator,'' to the data set for the Storage Information standard to address technical details for reporting natural gas storage balances and the activities that affect storage balances. The new sender's option data element ''Cycle Indicator'' will support the reporting of storage information data for each cycle while also allowing parties receiving such information to distinguish between the data more easily for individual transactions.[13]

18. Revisions to the WGQ Flowing Gas Related Business Practice Standards include a change to the ''Service Requester Contract'' data element from ''not used'' to ''mutually agreed,'' for allocation of natural gas between parties under two pre-determined allocation transaction types, found within the allocation matrix included as part of WGQ Standard 2.4.3.[14]

19. NAESB revised the WGQ Invoicing Related Standards by modifying the ''Charge Type Rate'' data element contained in the data set for the Transportation/Sales Invoice standard to allow for the identification of multiple rates that may be applicable for a single transaction or service. The modification to the data element allows transportation service providers to use a ''null'' value in circumstances where information describing the applicable charge type rate is included as part of miscellaneous notes. This change will allow transportation service providers to make available a summary of the amount due for each line item of an invoice with detailed, breakout information regarding the applicable rate and make it easier for a customer to ascertain the final charge amount.[15]

20. The revised WGQ Capacity Release Related Standards add a new sender's option data element, ''Location Indicator Data,'' to the Transactional Reporting—Capacity Release standard to provide a mechanism for a transportation service provider to communicate the locations at which a discounted rate is offered as well as if the rate is associated with a single location, multiple locations, or all locations.

21. Also included in WGQ Version 4.0 is a previous revision to an existing WGQ Invoicing Related Standard that modifies the ''Electronic Delivery Mechanism (EDI) X12 Mapping Guidelines'' by adding code values for five data elements to WGQ Standard 3.4.1—Transportation/Sales Invoice to ensure the hierarchal structure of the dataset complied with the Accredited Standards Institute X12 Transaction Set 811 Consolidated Service Invoice/ Statement.

3. Standards Not Incorporated by Reference

22. We continue our past practice [16] of not incorporating by reference into our regulations the WGQ standard contracts relating to the sale of natural gas because we do not require the use of these contracts.[17] Thus, we also do not incorporate by reference the WGQ 4.0

[11] Public Law 104–113, 12(d), 110 Stat. 775 (1996).

[12] Natural gas transportation service is provided by interstate pipelines, intrastate pipelines, natural gas gathering pipelines, and local distribution companies; all are referred to as ''transportation service providers.''

[13] Informational Report at 4.

[14] The matrix identifies the data elements needed to communicate the results of the allocation process.

[15] Informational Report at 5.

[16] *See, e.g., Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Notice of Proposed Rulemaking, 86 FR 12879 (March 5, 2021), 174 FERC ¶ 61,103, at P 19 (2021) (*Version 3.2 NOPR*).

[17] *Id.; Standards for Bus. Practices of Interstate Nat. Gas Pipelines,* Order No. 587–V, 77 FR 43711 (Jul. 26, 2012), 140 FERC ¶ 61,036, at P 11 n.11 (2012).

Contracts Related Standards Manual. In addition, consistent with our findings in past proceedings, we do not incorporate by reference the WGQ eTariff Related Standards because the Commission has previously adopted and posted its standards and protocols for electronic tariff filings based on NAESB standards.[18]

B. Required Compliance Filings

23. As suggested by INGAA, we will delay implementation of this final rule until after the 2024–2025 winter heating period. To implement the standards that we are incorporating by reference in this final rule, we will require each interstate natural gas pipeline to file a separate tariff record reflecting the changed standards by February 3, 2025.[19] In response to INGAA's concern that the Commission could require implementation of this final rule during the winter heating season, we will require the compliance filings to be made with an effective date of August 1, 2025. We are adopting this implementation schedule to give the interstate natural gas pipelines subject to these standards adequate time to implement these changes.

C. Implementation Procedures

24. We will continue the compliance filing requirements as revised and prescribed in Order No. 587–V to increase the transparency of the interstate natural gas pipelines' incorporation by reference of the NAESB WGQ Standards so that shippers and the Commission will know which tariff provision(s) implements each standard as well as the status of each standard.[20] We require each interstate natural gas pipeline to submit its compliance filing no later than February 3, 2025.

25. Consistent with the Commission's practice since Order No. 587–V, each interstate natural gas pipeline must designate a single tariff section under which every NAESB WGQ Standard incorporated by reference by the Commission is listed.[21] In that tariff section, the pipeline must list for each standard:

(a) whether the standard is incorporated by reference;

(b) for those standards not incorporated by reference, the tariff provision that complies with the standard; or

(c) for those standards with which the pipeline does not comply, an explanatory statement, including an indication of whether the pipeline has been granted a waiver, extension of time, or other variance with respect to compliance with the standard.[22]

26. Likewise, consistent with past practice, we will post on our eLibrary website (under Docket No. RM96–1–043) a sample tariff format, to provide filers with an illustrative example to aid them in preparing their compliance filings.

27. Consistent with our policy since Order No. 587–V,[23] entities may request waivers under the requirements set forth in Order No. 587–V and the Commission will then evaluate those requests at that time.[24]

28. If the pipeline is requesting a continuation of an existing waiver or extension of time, it must include a table in its transmittal letter that identifies the standard for which the Commission granted a waiver or extension of time, and the docket number or order citation to the proceeding in which the Commission granted the waiver or extension of time. The pipeline also must present an explanation for why such waiver or extension of time should remain in force with regard to the WGQ Version 4.0 Standards.

29. This implementation approach continues the Commission's practice of having pipelines include in their tariffs a common location that identifies the way in which the pipeline is incorporating all the NAESB WGQ Standards and the standards with which it is required to comply.

IV. Notice of Use of Voluntary Consensus Standards

30. Office of Management and Budget (OMB) Circular A–119 (section 11) (Feb. 10, 1998) provides that when a federal agency issues or revises a regulation containing a standard, the agency should publish a statement in the final rule stating whether the adopted standard is a voluntary consensus standard or a government-unique standard. In this final rule, we are incorporating by reference voluntary consensus standards developed by NAESB's WGQ. In section 12(d) of NTT&AA, Congress affirmatively requires federal agencies to use technical standards developed by voluntary consensus standards organizations to carry out policy objectives or activities determined by the agencies unless use of such standards would be inconsistent with applicable law or otherwise impractical.[25]

V. Incorporation by Reference

31. The Office of the Federal Register requires agencies incorporating material by reference in final rules to discuss the ways that the materials it incorporates by reference are reasonably available to interested parties and how interested parties can obtain the materials.[26] The regulations also require agencies to summarize, in the preamble of the final rule, the material it incorporates by reference. The standards that we are incorporating by reference in this final rule consist of seven suites of NAESB WGQ Business Practice Standards, which include a minor correction to the invoicing related standards, that address a variety of topics and are designed to streamline the transactional processes for the wholesale natural gas industry by promoting a more competitive and efficient market. These include the: WGQ Additional Business Practice Standards; WGQ Nominations Related Business Practice Standards; WGQ Flowing Gas Related Business Practice Standards; WGQ Invoicing Related Business Practice Standards, with WGQ Invoicing Related Standards Minor Correction MC24002; WGQ Quadrant Electronic Delivery Mechanism Related Business Practice Standards; WGQ Capacity Release Related Business Practice Standards; and WGQ Cybersecurity Related Standards.

32. As noted above, included in the standards incorporated by reference is the WGQ Invoicing Related Standards Minor Correction (MC 24002), which is an errata to update the Informational Report to the existing standard which supports the communication of invoices between trading partners.

33. We summarize these standards below. The WGQ Additional Business Practice Standards address six areas: Creditworthiness; Storage Information;

[18] *Version 3.2 NOPR,* 174 FERC ¶ 61,103 at P 19; *Elec. Tariff Filings,* Order No. 714, 73 FR 57515 (Oct. 3, 2008), 124 FERC ¶ 61,270 (2008).

[19] To aid in compliance, promptly after issuance of this final rule, we will post a sample tariff record on the Commission's website that may be accessed at *www.ferc.gov/ferc-online/elibrary.* All interstate natural gas pipelines are to file their tariff records in conformance with this sample tariff record.

[20] Order No. 587–V, 140 FERC ¶ 61,036 at PP 36–39.

[21] *Trans-Union Interstate Pipeline L.P.,* 141 FERC ¶ 61,167, at P 36 (2012) (Order No. 587–V Compliance Order); *Version 3.2 NOPR,* 174 FERC ¶ 61,103 at P 21.

[22] Shippers can use the Commission's electronic tariff system to locate the tariff record containing the NAESB standards, which will indicate the docket in which any waiver or extension of time was granted.

[23] Order No. 587–V, 140 FERC ¶ 61,036.

[24] Order No. 587–V Compliance Order, 141 FERC ¶ 61,167 at PP 4, 38 (a pipeline does not need to seek a waiver for standards that address business practices that the pipeline does not offer).

[25] Public Law 104–113, 12(d), 110 Stat. 775 (1996), 15 U.S.C. 272 note (1997).

[26] 1 CFR 51.5 (2023). *See* Incorporation by Reference, 79 FR 66267 (Nov. 7, 2014).

Gas/Electric Operational Communications; Operational Capacity; Unsubscribed Capacity; and Location Data Download.

- The Creditworthiness related standards describe requirements for the exchange of information, notification, and communication between parties during the creditworthiness evaluation process.
- The Storage Information related standards define the information to be provided to natural gas service requesters related to storage activities and/or balances.
- The Gas/Electric Operational Communications related standards define communication protocols intended to improve coordination between the natural gas and electric industries in daily operational communications between gas transportation service providers and gas-fired power plants. These standards include requirements for communicating anticipated power generation fuel needs for the upcoming day as well as any operating problems that might hinder gas-fired power plants from receiving contractual gas quantities.
- The Operational Capacity related standards define requirements for the transportation service provider's reporting of its operational capacity, total scheduled quantity, and operationally available capacity.
- The Unsubscribed Capacity related standards define requirements for the transportation service provider's reporting of its available unsubscribed capacity.
- The Location Data Download related standards define requirements for the use of codes assigned by the transportation service provider for locations and common codes for parties communicating electronically.

34. The WGQ Nominations Related Business Practice Standards define the process by which a natural gas service requester with a natural gas transportation contract nominates (or requests) service from a pipeline or a transportation service provider for the delivery of natural gas.

35. The WGQ Flowing Gas Related Business Practice Standards define the business processes related to the communication of entitlement rights of flowing gas at a location, of the entitlement rights on a contractual basis, of the management of imbalances, and of the measurement and gas quality information of the actual flow of gas.

36. The WGQ Invoicing Related Business Practice Standards define the process for the communication of charges for services rendered (Invoice), communication of details about funds rendered in payment for services rendered (Payment Remittance), and communication of the financial status of a customer's account (Statement of Account).

37. The WGQ Quadrant Electronic Delivery Mechanism Related Business Practice Standards define the framework for the electronic dissemination and communication of information between parties in the North American wholesale gas marketplace for Electronic Data Interchange/EDM transfers, batch flat file/EDM transfers, informational postings websites, Electronic Bulletin Boards/EDM, and interactive flat file/EDM.

38. The WGQ Capacity Release Related Business Practice Standards define the business processes for communication of information related to the selling of all or any portion of a transmission service requester's contract rights.

39. The WGQ Cybersecurity Related Standards consolidate existing NAESB cybersecurity-related standards from various standards manuals into a single manual. These standards define the requirements for ensuring the security of electronic communications and transactions among parties.

40. Commission regulations provide that copies of the standards incorporated by reference may be obtained through purchase or otherwise from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002; phone: (713) 356–0060; website: *www.naesb.org/.* The standards can also be reviewed without purchasing them.

41. The procedures used by NAESB make its standards reasonably available to those affected by Commission regulations, which generally is comprised of entities that have the means to acquire the information they need to effectively participate in Commission proceedings. Participants can join NAESB, for an annual membership cost of $8,000, which entitles them to full participation in NAESB and enables them to obtain these standards at no additional cost. Non-members may obtain any of the ten individual standards manuals for $250 per manual, which in the case of these standards would total $2,500 for all ten manuals. Non-members also may obtain the complete set of Standards Manuals for $2,000.

42. NAESB provides ample opportunities for non-members, including agents, subsidiaries, and affiliates of NAESB members, to obtain access to the copyrighted standards through a no-cost limited copyright waiver. The limited copyright waivers are issued by the NAESB office and are granted to non-members on a case-by-case basis for the purpose of evaluating standards prior to purchase and/or reviewing the standards to prepare comments to a regulatory agency. Following the granting of a limited copyright waiver, the non-member is provided with read-only access to the standards through the end of the comment period or some other set period of time via Locklizard Safeguard Secure Viewer.[27] NAESB will grant one limited copyright wavier per company for each set of standards or final actions. Any entity seeking a limited copyright waiver should contact the NAESB office.

VI. Information Collection Statement

43. The OMB regulations require that OMB approve certain reporting, record keeping, and public disclosure requirements (information collection) imposed by an agency.[28] Therefore, we are submitting our proposed information collection to OMB for review in accordance with section 3507(d) of the Paperwork Reduction Act of 1995. Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to these collections of information unless the collection of information displays a valid OMB control number.

44. The Commission solicited comments on our need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

45. *Public Reporting Burden:* The burden estimates for this final rule are for one-time implementation of the information collection requirements of this final rule (including tariff filing, documentation of the process and procedures, and information technology work).

46. The collections of information related to this final rule fall under FERC–545 (Gas Pipeline Rates: Rate Change (Non-Formal)) [29] and FERC–549C (Standards for Business Practices

[27] For more information on Locklizard, please refer to the company's website: *www.locklizard.com.*

[28] 5 CFR 1320.11 (2023).

[29] FERC–545 covers rate change filings made by natural gas pipelines, including tariff changes.

of Interstate Natural Gas Pipelines).[30] The following estimates of reporting burden are related only to this Final Rule and include the costs to pipelines for compliance with the Commission's directives in this final rule. The burden estimates are primarily related to implementing these standards and regulations and will not result in ongoing costs.

RM96–1–043 NOPR (STANDARDS FOR BUSINESS PRACTICES OF INTERSTATE NATURAL GAS PIPELINES)

	Number of respondents[31] (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden hr. per response (4)	Total annual burden hours & total annual cost[32] (3) * (4) = (5)	Annual costs per respondent ($) (5)/(1) = (6)
FERC–545 (one-time)	193	1	193	10 hrs.; $1,110	1,930 hrs.; $214,230	$1,110
FERC–549C (one-time)	193	1	193	100 hrs.; $11,100	19,300 hrs.; $2,142,300	$11,100
Total			386		21,230 hrs.; $2,356,530.	

The one-time burden (for both the FERC–545 and FERC–549C) would take place in Year 1 and will be averaged over 3 years as follows:

FERC–545: 1,930 ÷ 3 = 643.33 hours/year over 3 years

FERC–549C: 19,300 ÷ 3 = 6,433.33 hours/year over 3 years

The responses and burden for Years 1–3 would total respectively as follows:

Year 1: 64.33 responses; 643.33 hours (FERC–545); 6,433.33 hours (FERC–549C)

Year 2: 64.33 responses; 643.33 hours (FERC–545); 6,433.33 hours (FERC–549C)

Title: FERC–545, Gas Pipeline Rates: Rates Change (Non-Formal); FERC–549C, Standards for Business Practices of Interstate Natural Gas Pipelines.

Action: Proposed information collections

OMB Control Nos.: 1902–0154 (FERC–545), 1902–0174 (FERC–549C).

Respondents: Business or other for profit (*e.g.,* Natural Gas Pipelines, applicable to only a few small businesses).

Frequency of Responses: One-time implementation (related to business procedures, capital/start-up).

Necessity of Information: In response to NAESB's standard development activities, the Commission has determined that the revisions the Commission makes in this final rule to its regulations would make minor adjustments to the standards previously adopted by the Commission. The standards consolidate the cybersecurity standards in one standards manual for ease of reference and revision, deleting one element in the Data Dictionary for internet ET included in the WGQ Cybersecurity Related Standards and makes numerous minor changes throughout the corresponding manual and the WGQ EDM Related Standards to correct typographical and capitalization errors.

47. Further, in response to industry requests or through the normal course of WGQ activities, the Commission has determined that the revisions the Commission makes in this final rule to its regulations would upgrade current business practices and communication standards by specifically: (1) adding a new data element, ''Cycle Indicator,'' to the data set for the Storage Information standard to address technical details for the reporting of storage balances and the activities that affect storage balances; (2) revising the data element ''Service Requester Contract'' contained in the data set for the Flowing Gas Related Allocation standard to identify the applicable contract and to support the communication of the results of processes used to allocate the actual flow of gas quantities to parties involved in a transaction; (3) modifying the ''Charge Type Rate'' data element contained in the data set for the Transportation/Sales Invoice standard that allows for the identification of multiple rates that may be applicable for a single transaction or service; (4) adding a new sender's option data element, ''Location Indicator Data,'' to the Transactional Reporting—Capacity Release standard to improve efficiencies by providing a mechanism for a transportation service provider to communicate the locations at which a discounted rate is offered as well as if the rate is associated with a single location, multiple locations, or all locations; (5) adding code values for five data elements to the EDI X12 Mapping Guidelines in the Transportation/Sales Invoice standard to ensure the hierarchal structure of the dataset complied with the Accredited Standards Institute X12 Transaction Set 811 Consolidated Service Invoice/Statement. In addition, the Commission's Office of Enforcement will use the data for general industry oversight.

Internal Review: The Commission has reviewed the requirements pertaining to business practices of interstate natural gas pipelines adopted by NAESB and has determined that the revisions the Commission makes in this final rule to its regulations are necessary to promote greater efficiency and reliability of the natural gas industry's operations and strengthen cybersecurity protections. These requirements conform to our plan for efficient information collection, communication, and management within the natural gas pipeline industry. The Commission has determined through its internal review that there is specific, objective support for the burden estimates associated with the information requirements.

48. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426; email: *DataClearance@ferc.gov.*

49. Comments concerning the collection of information(s) and the associated burden estimate(s), should be

[30] FERC–549C covers Standards for Business Practices of Interstate Natural Gas Pipelines.

[31] The number of respondents is the number of entities in which a change in burden from the current standards to the proposed exists, not the total number of entities from the current or proposed standards that are applicable.

[32] The estimated hourly cost (salary plus benefits) provided in this section is based on the salary figures for March 2024 posted on June 18, 2024 by the Bureau of Labor Statistics for the Utilities sector (available at *www.bls.gov/oes/current/naics3221000.htm*) and scaled to reflect benefits using the relative importance of employer costs for employee compensation (available at *https://www.bls.gov/news.release/ecec.nr0.htm*). The hourly estimates for salary plus benefits are:

Computer and Information Systems Manager (Occupation Code: 11–3021), $115.47.

Computer and Information Analysts (Occupation Code: 15–1221, $87.19.

Electrical Engineer (Occupation Code: 17–2071), $79.31.

Legal (Occupation Code: 23–0000), $162.66.

The average hourly cost (salary plus benefits), weighting these skill sets evenly, is $111.16. We round it to $111/hour.

sent to the Office of Information and Regulatory Affairs, the Office of Management and Budget, Washington, DC 20503; attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–0710; fax: (202) 395–4718. A copy of the comments on information collection should also be sent to the Commission, in Docket No. RM96–1–043 by any of the following methods:

- eFiling at Commission's website: *www.ferc.gov/docs-filing/efiling.asp;*
- U.S. Postal Service Mail: Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426; or
- Delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

VII. Environmental Analysis

50. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[33] The actions that we take here fall within categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, for information gathering, analysis, and dissemination, and for rules regarding sales, exchange, and transportation of natural gas that require no construction facilities.[34] Therefore, an environmental review is unnecessary and has not been prepared as part of this final rule.

VIII. Regulatory Flexibility Act

51. The Regulatory Flexibility Act of 1980 (RFA) [35] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect.

52. As we stated in the WGQ Version 4.0 NOPR, approximately 193 interstate natural gas pipelines, both large and small, are potential respondents subject to the requirements adopted by this rule. Most of the natural gas pipelines regulated by the Commission do not fall within the RFA's definition of a small entity,[36] which is currently defined for natural gas pipelines as a company that, in combination with its affiliates, has total annual receipts of $41.5 million or less.[37] For the year 2022, only 14 potential respondents not affiliated with larger companies had annual revenues in combination with their affiliates of $41.5 million or less and therefore could be considered a small entity under the RFA. This represents about eight percent of the total universe of potential respondents that may have a significant burden imposed on them. We estimate that the one-time implementation cost of the proposals in this final rule is $2,356,530 (or $12,210 per entity, regardless of entity size).[38] We do not consider the estimated $12,210 impact per entity to be significant. Moreover, these requirements are designed to benefit all customers, including small businesses that must comply with them. Further, as noted above, adoption of consensus standards helps ensure the reasonableness of the standards by requiring that the standards draw support from a broad spectrum of industry participants representing all segments of the industry. Because of that representation and the fact that industry conducts business under these standards, the Commission's regulations should reflect those standards that have the widest possible support.

53. Accordingly, pursuant to section 605(b) of the RFA,[39] the regulations proposed herein should not have a significant economic impact on a substantial number of small entities.

IX. Document Availability

54. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*www.ferc.gov/*).

55. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

56. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room; phone: (202) 502–8371, TTY (202) 502–8659; email: *public.referenceroom@ferc.gov.*

X. Effective Date and Congressional Notification

57. These regulations are effective February 7, 2025. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule is being submitted to the Senate, House, and Government Accountability Office.

List of Subjects in 18 CFR Part 284

Continental shelf, Incorporation by reference, Natural gas, Reporting and recordkeeping requirements.

By direction of the Commission.

Issued: November 22, 2024.

Debbie-Anne A. Reese,

Secretary.

In consideration of the foregoing, the Commission amends 18 CFR part 284 as follows.

PART 284—CERTAIN SALES AND TRANSPORTATION OF NATURAL GAS UNDER THE NATURAL GAS POLICY ACT OF 1978 AND RELATED AUTHORITIES

■ 1. The authority citation for part 284 continues to read as follows:

Authority: 15 U.S.C. 717–717z, 3301–3432; 42 U.S.C. 7101–7352; 43 U.S.C. 1331–1356.

■ 2. Amend § 284.12 by:
■ A. Revising paragraphs (a)(1)(i) through (vii);
■ B. Adding paragraph (a)(1)(viii); and
■ C. Revising paragraph (a)(2).

The revisions and additions read as follows:

§ 284.12 Standards for pipeline business operations and communications.

(a) * * *

(1) * * *

(i) WGQ Additional Standards (Version 4.0, September 29, 2023);

(ii) WGQ Nominations Related Standards (Version 4.0, September 29, 2023);

[33] *Regulations Implementing the National Environmental Policy Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986–1990 ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[34] *See* 18 CFR 380.4(a)(2)(ii), 380.4(a)(5), and 380.4(a)(27) (2023).

[35] 5 U.S.C. 601–612.

[36] *See* 5 U.S.C. 601(3) citing section 3 of the Small Business Act (SBA), 15 U.S.C. 623. Section 3 of the SBA defines a ''small business concern'' as a business that is independently owned and operated, and that is not dominant in its field of operation.

[37] 13 CFR 121.201 (Subsector 486-Pipeline Transportation; North American Industry Classification System code 486210; Pipeline Transportation of Natural Gas) (2023). ''Annual Receipts'' are total income plus cost of goods sold.

[38] This number is derived by dividing the total cost figure by the number of respondents. $2,356,530/193 = $12,210.

[39] 5 U.S.C. 605(b).

(iii) WGQ Flowing Gas Related Standards (Version 4.0, September 29, 2023);

(iv) WGQ Invoicing Related Standards (Version 4.0, September 29, 2023);

(v) WGQ Invoicing Related Standards Minor Correction/Clarification MC24002, approved by the WGQ on May 2, 2024 (Minor Correction/Clarification MC24002 was implemented on May 17, 2024).

(vi) WGQ Quadrant Electronic Delivery Mechanism Related Standards (Version 4.0, September 29, 2023);

(vii) WGQ Capacity Release Related Standards (Version 4.0, September 29, 2023); and

(viii) WGQ Cybersecurity Related Standards (Version 4.0, September 29, 2023)

(2) The material listed paragraph (a)(1) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Federal Energy Regulatory Commission and at the National Archives and Records Administration (NARA). For assistance in viewing the material, contact the Federal Energy Regulatory Commission at: 888 First Street NE, Washington, DC 20426 phone: 202–502–8371; email: *public.referenceroom@ferc.gov;* website: *https://www.ferc.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material also may be obtained from the North American Energy Standards Board, 801 Travis Street, Suite 1675, Houston, TX 77002; phone: (713) 356–0060; website: *https://www.naesb.org/.*

* * * * *

[FR Doc. 2024–28090 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 50

[Docket No. OAG 177; AG Order No. 6101–2024]

RIN 1105–AB62

Guidelines and Limitations for Settlement Agreements Involving Payments to Non-Governmental Third Parties

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without change the interim final rule issued by the Department of Justice (''Department'' or ''DOJ'') on May 10, 2022, that revoked a prohibition on the inclusion of provisions in settlement agreements directing or providing for a payment or loan to a non-governmental person or entity not a party to the dispute, subject to limited exceptions.

DATES: This rule is effective December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department has established a docket for this action on the *www.regulations.gov* site under Docket DOJ–OAG–2022–0001. All documents in the docket are listed on the *http://www.regulations.gov* website.

I. Summary of This Rulemaking

A. Overview of This Rule

On December 16, 2020, the Department issued a regulation prohibiting, subject to limited exceptions, the inclusion of provisions in settlement agreements directing or providing for a payment or loan, in cash or in kind, to any non-governmental person or entity not a party to a dispute. *Prohibition on Settlement Payments to Non-Governmental Third Parties,* 85 FR 81409 (''the December 2020 Rule'') (adding 28 CFR 50.28). On May 10, 2022, DOJ published for public comment an interim final rule (''IFR'') that revoked the December 2020 Rule, *Guidelines and Limitations for Settlement Agreements Involving Payments to Non-Governmental Third Parties,* 87 FR 27936.

The IFR also solicited public comment on an Attorney General memorandum posted on the DOJ website in conjunction with the IFR, the Memorandum for the Heads of Department Components and United States Attorneys from the Attorney General, *Re: Guidelines and Limitations for Settlement Agreements Involving Payments to Non-Governmental Third Parties* (May 5, 2022) (the ''May 2022 Memorandum''), *https://www.justice.gov/d9/pages/attachments/2022/05/05/02._ag_guidlines_and_limitations_memorandum_0.pdf* (last visited Oct. 31, 2024).

This preamble responds to comments received on the IFR. As reflected in this preamble, the Department is not making any changes to the rule or to the May 2022 Memorandum.

That said, DOJ is using the opportunity of this final rule to publicly announce that it will add two provisions to the section of the *Justice Manual* (*https://www.justice.gov/jm/justice-manual*) addressing third-party payments, section 1–17.000, *Settlement Agreements Involving Payments to Non-Governmental Third Parties,* as discussed later in this preamble.

B. Background Explanation for This Rule

The Department, as explained in this preamble, has concluded that its action in May 2022 to revoke 28 CFR 50.28 and establish the current policy continues to be appropriate. The Department has authority to settle litigation incident to the Attorney General's power to supervise litigation for the United States. *Authority of the United States to Enter Settlements Limiting the Future Exercise of Executive Branch Discretion,* 23 Op. O.L.C. 126, 135 (1999) (''*Authority of the United States to Enter Settlements*''). The Department regularly settles civil and criminal matters to compensate victims, redress harms, and punish and deter unlawful conduct without the costs and delay that can accompany trials. For decades and across Administrations, Department components entered into settlement agreements that involved payments to certain third parties as a means of addressing harms arising from violations of Federal law.

It has been the consistent view of the Office of Legal Counsel (''OLC''), acknowledged when the December 2020 Rule was promulgated, that settlements involving payments to non-governmental third parties can comport with the Miscellaneous Receipts Act (''MRA''), 31 U.S.C. 3302(b). *See* Memorandum for William P. Barr, Attorney General, from Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, *Re: Final Rule Prohibiting Settlement Payments to Non-Governmental Third Parties* at 2 (Dec. 4, 2020) (''December 2020 OLC Memo'') (citing *Application of the Government Corporation Control Act and the Miscellaneous Receipts Act to the Canadian Softwood Lumber Settlement Agreement,* 30 Op. O.L.C. 111, 119 (2006) (''*Softwood Lumber*'')), *https://www.justice.gov/oip/foia-library/foia-processed/general_topics/settlement_guidelines_third_parties_2_14_23/download* (last visited Oct. 31, 2024).

In 2017, the Attorney General issued a memorandum prohibiting Department attorneys from entering into case resolutions in civil and criminal matters providing for certain third-party payments. *See* Memorandum for All Component Heads and United States Attorneys from the Attorney General,

Re: Prohibition on Settlement Payments to Third Parties (June 6, 2017). In 2020, through the December 2020 Rule, the Department amended its regulations to add 28 CFR 50.28, memorializing prohibitions set forth in the 2017 memorandum and additionally expressly prohibiting expenditure of funds ''to provide goods or services to third parties for Supplemental Environmental Projects.'' 85 FR 81410.

In 2022, after considering the views of the Department's components and their experience with 28 CFR 50.28, the Attorney General concluded that the regulations at 28 CFR 50.28 were too restrictive and should be revoked, *see* 87 FR 27937, and issued an IFR revoking 28 CFR 50.28, *see* 87 FR 27936–38. The Attorney General determined that, when properly tailored, agreements providing for payments to third parties are lawful and allow the United States to more fully accomplish the goals of civil and criminal enforcement. *Id.* at 27937. For example, the Department usually seeks a penalty and injunctive relief to resolve violations of Federal environmental statutes. However, the harms caused by these violations, including harms to the communities most directly impacted by them, can be difficult to redress in particular cases. *Id.* For instance, in environmental enforcement cases, the Department may seek a defendant's agreement to make third-party payments in the form of a Supplemental Environmental Project (''SEP'') to counteract some of the downstream effects of a violation, and often as well to prevent future harm. *Id.* A SEP is a type of project or activity that a defendant undertakes as part of the settlement of an environmental enforcement action. As an illustration, a defendant refinery that violated its Clean Air Act permit by emitting excess volatile organic compounds (''VOCs'') agreed to perform a SEP to abate lead-based paint hazards in child-occupied facilities and lower-income residences located within a 50-mile radius of the refinery, in addition to an appropriate penalty and other relief. VOCs can accelerate the weathering and deterioration of lead-based paint, increasing potential lead exposure. The project, therefore, was designed to reduce a downstream harm to local residents, exacerbated by the defendant's conduct.

The May 2022 Memorandum contains important safeguards to ensure that case resolutions containing third-party payments are appropriately tailored. Permissible settlements with third-party payments must satisfy conditions that define with particularity the nature and scope of any third-party project; require a strong connection between the underlying violation(s) and the project; prevent the Federal Government from proposing the selection of a particular third party to receive payments; restrict the Federal Government's role after a settlement is entered; require that such settlements occur before an admission or finding of liability in favor of the United States; prohibit use of such settlements to satisfy existing statutory obligations or to provide additional resources to perform any activity for which a Federal agency receives a specific appropriation; and prohibit certain practices such as unrestricted cash donations. May 2022 Memorandum at 3. Such settlements are also subject to approval by the Deputy Attorney General or the Associate Attorney General. *Id.* at 3–4.

The May 2022 Memorandum also exempts four types of payments from these requirements, including payments providing restitution to non-party victims to directly remedy the harm the lawsuit seeks to redress, as well as payments for legal or professional services undertaken in connection with the case being settled, consistent with pre-2017 practice. *Id.* at 4. (The exception for legal or professional services includes payments to contractors implementing injunctive relief; payments to monitors, arbitrators, mediators, or other neutral third parties; and payments for other categories of legal and professional services.) In developing the new policy, the Department sought to address specific concerns that had been raised over such payments, while preserving the availability of these payments as a potential remedy when appropriate. In 2022, DOJ incorporated the terms of the May 2022 Memorandum in *Justice Manual* section 1–17.000.

C. Justice Manual Revisions

As part of the process of reviewing comments on the IFR and May 2022 Memorandum, the Department has determined that it will add two provisions to the *Justice Manual* section 1–17.000.[1] In particular, the Department is sensitive to the perception that it will ''strong-arm'' defendants to agree to third-party payments by declining to agree to a settlement unless the defendant agrees to make one or more third-party payments. It also recognizes the concern that the lack of public input into the development of third-party payments, and the difficulty of obtaining information on settlements that include such provisions, could lead to a lack of accountability and could give rise to claims of ''cronyism'' or favoritism. As discussed in greater detail below, *see infra* Part II.B.5.1, these concerns do not suggest that third-party payments writ large are unlawful, or that a rule prohibiting third-party payments is the only way to guard against them. Instead (and as also discussed in greater detail throughout this preamble), the Department has concluded that it can respond to these concerns through the more flexible approach of making changes to the *Justice Manual,* a course that preserves the benefits of third-party payments while responding in a more surgical manner to the concerns raised.

Specifically, with respect to concerns that the Department will ''strong-arm'' defendants into agreeing to third-party payments, the forthcoming revisions to the *Justice Manual* will specify that the Department may decline to agree to settle a civil claim in the absence of a particular remedy where the remedy in question would be available relief were the case litigated to judgment; but that if the third-party payment is not within the scope of the remedies the court could order, the Department will negotiate such a payment as part of a settlement only if the defendant expresses interest in doing so. For example, to resolve an antitrust investigation or filed case, the Antitrust Division may condition a settlement on the entity's agreement to divest itself of certain assets, because that is relief the Antitrust Division could receive if it litigated the case to judgment. *See, e.g., United States* v. *E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 331 (1961); *see generally California* v. *Am. Stores Co.,* 495 U.S. 271, 280–81 (1990) (''[I]n Government actions divestiture is the preferred remedy for an illegal merger or acquisition.''). (Because these benefits would go to another unrelated entity, such a condition could potentially have the appearance of a third-party payment.) The Department believes that this division—between relief available if the case were litigated to judgment and relief that would not be—is an appropriate way to guard against concerns that the Department would strong-arm defendants into agreeing to third-party payments. In cases in which a court could order a particular remedy but a defendant is not

[1] The Department will limit these new provisions to civil settlements covered by the May 2022 Memorandum but not exempted under the four circumstances described therein. Plea agreements are always subject to court review and approval, ensuring the protection of the public's interest and the rights of the defendant. The timing and other process requirements of a criminal proceeding also make it less feasible to apply these new requirements in criminal cases.

willing to include it in a settlement, the Department has the option of litigating the case to judgment in order to secure the relief in question without the defendant's consent. In those cases in which a settlement term is not backed by a possible judicial remedy in this way, the Department is sensitive to the concern raised by commenters and views it as preferable (although not legally required) to include this additional safeguard to ensure that the defendant is amenable to the relief in the form of a third-party payment.

As to claims that information about settlements that include third-party payments is not readily available and that such settlements are concluded without adequate participation from the public, the Department will add a provision to the existing *Justice Manual* requirements that would provide additional opportunities for the public to participate in certain civil settlements.[2]

II. Public Comments on the IFR and May 2022 Memorandum

A. Summary of Public Comments

The comment period for the IFR and the May 2022 Memorandum closed on July 11, 2022, and the Department received 16 public comments.[3] The comments express both support for and opposition to the IFR and May 2022 Memorandum. DOJ is exercising its discretion to respond to public comments here.

B. Response to Comments

1. Applicability of the MRA

Comments: According to some commenters, under the 1980 OLC opinion *Effect of 31 U.S.C. § 484 on the Settlement Authority of the Attorney General,* 4B Op. O.L.C. 684 (1980) (''*Effect of 31 U.S.C. § 484*''), money available to the United States is constructively received and must be directed to the U.S. Treasury to comply with the MRA. Those commenters argue that any deviation from this result, such as an agency directing settlement money to a non-governmental third party, is a violation of that requirement. In particular, some commenters claim that SEPs are a violation of the MRA because the money used for them is public and the value of the SEP is exchanged, without congressional authorization, for a proportional reduction in the ultimate civil penalty that could have been payable to the U.S. Treasury. And still others contend that private defendants violate 31 U.S.C. 3302(c) by making third-party payments pursuant to settlements.

One commenter states that DOJ fails to explain why it applies the doctrine of constructive receipt from tax law cases (requiring the Government to exercise substantive control over the funds without significant limitation) to this context and argues that the Department has ''cherry-picked a version of constructive receipt in an attempt to thwart equity.''

Several commenters claim that SEPs are illegally diverted penalties except for the two instances in which SEPs are expressly authorized by statute: 42 U.S.C. 16138, which grants the Executive Branch permission to seek SEPs related to diesel emissions reductions; and 42 U.S.C. 7604(g)(2), which gives courts discretion to order that penalties received under the citizens suit provision of the Clean Air Act be used to fund beneficial mitigation projects that are consistent with that Act and enhance the public health or the environment, up to $100,000. Commenters assert that Congress's enactment of these provisions indicates that Congress views these types of payments as otherwise impermissible.

One commenter argues that the 2006 *Softwood Lumber* OLC opinion is not persuasive and, even if it were, the commenter claims that it would not authorize SEPs, which the commenter claims are designed entirely to exchange monetary penalties destined for the Treasury for a particular project. This commenter also suggests that caselaw supporting the legality of these payments cannot be reconciled with subsequent Supreme Court decisions and statutory provisions related to diesel emissions projects and citizens suits under the Clean Air Act, and cites Comptroller General/U.S. Government Accountability Office (''GAO'') opinions as supportive. Commenters further invoke a memorandum authored by then-Assistant Attorney General for ENRD Jeffrey Bossert Clark, *Supplemental Environmental Projects (''SEPs'') in Civil Settlements with Private Defendants* (Mar. 12, 2020) (''Clark Memorandum''), in support of their view that third-party settlements (and SEPs in particular) violate the MRA.

Other commenters cite with approval the OLC view (reflected in the May 2022 Memorandum) that settlement-funded projects do not violate the MRA if they are executed prior to a finding of the defendant's liability and if the United States does not retain control over the projects following settlement except for purposes of oversight of the settlement. Citing *U.S. Environmental Protection Agency Supplemental Environmental Projects Policy 2015 Update* (Mar. 10, 2015) (''*2015 SEP Policy*''), commenters make the point that SEPs are not substitutes for monetary penalties because settlements that include a SEP must always include a settlement penalty that recoups the economic benefit a violator gained from noncompliance with the law, as well as appropriate penalties that reflect the environmental and regulatory harm caused by the violations. These commenters state that SEPs are a factor to consider in making the decision to settle and on what terms to settle. By confusing SEPs with penalties or diversions of Treasury funds, these commenters argue, the previous Administration misconstrued decades of Federal practice.

Response: The Department appreciates commenters' statements that settlement-funded projects do not violate the MRA if they comply with the criteria set forth in *Softwood Lumber;* and that agreeing to SEPs as part of settlement agreements is consistent with those criteria.

The Department disagrees with commenters' contention that any settlement that includes a payment to a non-government third party violates the MRA and continues to conclude that the MRA permits such settlements in certain circumstances. The MRA requires that ''an official or agent of the Government receiving money for the Government from any source shall deposit the money in the Treasury as soon as practicable without deduction for any charge or claim.'' 31 U.S.C. 3302(b). The funds paid under these types of settlements, however, are not ''drawn from the Treasury'' and have not been ''receiv[ed] . . . for the Government'' by the United States.

Consistent with authoritative OLC opinions and advice, the Department

[2] Existing laws require public disclosure of settlement terms in certain circumstances. The Antitrust Procedures and Penalties Act, codified at 15 U.S.C. 16(b)–(h), provides for a notice-and-comment process before a consent decree can be finalized in civil antitrust cases. The Clean Air Act includes a similar requirement, 42 U.S.C. 7413(g), as do laws relating to cleanup and control of hazardous materials. *See* 42 U.S.C. 9622(d)(2) and (i); 42 U.S.C. 6973(d); *see also* 28 CFR 50.7 (providing for a notice-and-comment process in civil ''actions to enjoin [the] discharges of pollutants.''). Where legal requirements such as these do not apply, and to minimize disrupting or delaying the resolution of a wide range of routine matters, the Department will limit the *Justice Manual* requirement to cases involving a third-party payment that a court could not order in law or in equity. Where a court could order such relief, the public is already on notice that it might do so.

[3] *Regulations.gov* contains seventeen comments, one of which is a superseded version of a comment omitted from review at the request of the commenter. *FDMS.gov* contains one additional document, which is not a comment on the IFR and May 2022 Memorandum.

has long understood that the MRA applies when an official or agent of the Government either actually or ''constructively'' receives money for the Government. *See Effect of 31 U.S.C. § 484,* 4B Op. O.L.C. at 688. ''The doctrine of constructive receipt will ignore the form of a transaction in order to get to its substance,'' and the Department has accordingly concluded that a Federal agency will be considered to be in ''constructive receipt'' of money ''if a federal agency could have accepted possession and retains discretion to direct the use of the money.'' *Id.*

To ensure that a settlement including payment to a third party does not violate the MRA through constructive receipt, OLC has ''consistently advised that (1) the settlement be executed before an admission or finding of liability in favor of the United States; and (2) the United States not retain post-settlement control over the disposition or management of the funds or any projects carried out under the settlement, except for ensuring that the parties comply with the settlement.'' *Softwood Lumber,* 30 Op. O.L.C. at 119; *see also id.* at 119–20 (citing past precedent, including *Effect of 31 U.S.C. § 384*). ''If these two criteria are met, then the governmental control over settlement funds is so attenuated that the government cannot be said to be 'receiving money for the Government' '' under the MRA. *Id.*

The May 2022 Memorandum also does not implicate anti-augmentation concerns, which the Comptroller General decisions cited by commenters invoke in addition to the MRA. *See also Applicability of the Miscellaneous Receipts Act to an Arbitral Award of Legal Costs,* 42 Op. OLC 1, 3 (2018) (''[A]n agency may not augment its appropriations from outside sources without statutory authority''). The May 2022 Memorandum specifies that settlements may not ''be used to satisfy the statutory obligation of the Justice Department or any other federal agency to perform a particular activity. Nor shall any such settlement provide the Justice Department or any other federal agency with additional resources to perform a particular activity for which the Justice Department or any other federal agency, respectively, receives a specific appropriation.'' May 2022 Memorandum at 3.

Thus, as stated in the May 2022 Memorandum, ''[i]t has been the consistent view of the Office of Legal Counsel, including in 2020 when the Justice Department's current regulation [now-revoked 28 CFR 50.28] was promulgated, that settlements involving payments to non-governmental third parties, if properly structured, do not violate the Miscellaneous Receipts Act.'' *Id.* at 1. In support of this statement, the May 2022 Memorandum cites the OLC memorandum approving the now-revoked December 2020 Rule for form and legality, which recognized the longstanding position of the Department that properly structured settlement agreements do not violate the MRA. December 2020 OLC Memo at 2. This memorandum stated that the rule was ''consistent with the policy underlying the MRA—that Congress, and not the agency, should determine when government resources may be spent on behalf of third parties.'' *Id.* But it elaborated that the rule ''does not reflect an interpretation of the statute itself and thus prohibits certain payments to third parties that this Office has concluded that the MRA otherwise allows,'' *id.,* as detailed in the cited *Softwood Lumber* OLC opinion. And the May 2022 Memorandum explicitly incorporates the two criteria that *Softwood Lumber* identifies—the ''settlement must be executed before an admission or finding of liability in favor of the United States, and the Justice Department and its client agencies must not retain post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement, except for ensuring that the parties comply with the settlement.'' May 2022 Memorandum at 3.

To the extent that commenters disagree with the *Softwood Lumber* opinion or believe it inapplicable, they do not offer authoritative judicial precedents or similar authoritative sources meaningfully undercutting its reasoning or its support for the current Department policy as set forth in the May 2022 Memorandum. *Softwood Lumber* remains applicable to this context, for several reasons.

First, Comptroller General opinions cited by commenters were addressed in the *Softwood Lumber* opinion itself, which noted that concerns in those matters were ''inapposite'' because the MRA is inapplicable where there has been no constructive receipt of money for the Government. 30 Op. O.L.C. at 121. (The same rationale applies to other GAO documents one commenter cites.)[4] The Department did not depart from that principle in the December 2020 Rule. Moreover, the Department has incorporated in some of the restrictions in the May 2022 Memorandum measures that address some of the other concerns raised in those Comptroller General opinions. The May 2022 Memorandum also explicitly incorporates the two criteria set forth in the *Softwood Lumber* OLC opinion—the ''settlement must be executed before an admission or finding of liability in favor of the United States, and the Justice Department and its client agencies must not retain post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement, except for ensuring that the parties comply with the settlement.'' May 2022 Memorandum at 3. Moreover, in all events, decisions of GAO and the Comptroller General ''are not binding on Executive Branch agencies''; instead, ''the opinions of the Attorney General and th[e] Office [of Legal Counsel] are controlling.'' *Prioritizing Programs to Exempt Small Businesses From Competition in Federal Contracts,* 33 Op. O.L.C. 284, 302 (2009).

Second, the *Softwood Lumber* opinion does not, contrary to commenters' views, limit its understanding of the criteria for consistency with the MRA to its own facts or to the specific examples it cites. It instead articulates the two criteria for compliance broadly and refers to them as ''general principles'' applicable regardless of whether the United States is a plaintiff or defendant. 30 Op. O.L.C. at 120. *See also* December 2020 OLC Memo at 2 (citing *Softwood Lumber* for the principle that the MRA generally permits ''certain payments to third parties'').

Third, it is irrelevant that one commenter deems unpersuasive two circuit-level decisions sometimes invoked to support the legality of settlement payments—*Public Interest Research Group* v. *Powell Duffryn Terminals, Inc.,* 913 F.2d 64, 81 (3d Cir. 1990), and *Sierra Club* v. *Electronic Controls Design,* 909 F.2d 1350, 1354 (1990). *Softwood Lumber* does not rely on these decisions. The commenter, moreover, criticizes these decisions in part on the ground that ''Congress has subsequently indicated that SEPs (and thus all Third-Party Payments) violate

[4] The Department also notes that these Comptroller General decisions did not address the MRA's applicability when the Federal Government does not ''retain post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement, except for ensuring that the parties comply with the settlement.'' *Softwood Lumber,* 30 Op. O.L.C. at 119. Moreover, all those decisions involved administrative agencies with statutory authority to both impose and also settle administrative penalties—a situation distinct from that addressed by the Department's May 2022 Memorandum and IFR. And those decisions focused on concerns raised when agencies enter settlements under which third parties carry out actions within the agencies' own statutory responsibilities, and with no nexus to the underlying violations—concerns that, again, the May 2022 Memorandum and the IFR address.

the MRA'' and the Anti-Deficiency Act (''ADA'') ''absent explicit congressional authorization,'' referring to Congress's express authorization of SEPs in 42 U.S.C. 16138. The Department disagrees with the commenter's reading of that provision, for reasons given below. Finally, the commenter claims that *Kokesh* v. *SEC,* 137 S. Ct. 1635 (2017), clarified that what constitutes a ''penalty'' is a functional inquiry. *Kokesh,* however, held that monetary disgorgement ordered by the SEC constitutes a penalty within the meaning of 28 U.S.C. 2462. *Id.* at 1641–45. *Kokesh* did not involve a settlement, and it is not relevant to when money paid under a settlement is received by the Federal Government under the MRA.

Fourth, when commenters contend that private defendants violate 31 U.S.C. 3302(c) by making third-party payments pursuant to settlements, they assume that funds in the hands of private defendants are ''public money'' subject to the MRA. Under *Softwood Lumber,* however, such funds are not public monies. And the commenters' argument improperly conflates funds in the hands of private litigants, before any determination of liability, with penalties imposed after trial that may in some circumstances constitute public money. *See Pub. Int. Rsch. Grp.,* 913 F.2d at 81 n.32 (noting that section 3302(c)(1) applies to penalties imposed after a trial, but recognizing that outside of penalties, ''a [private] party may compromise its claim however it sees fit''); *United States* v. *Smithfield Foods, Inc.,* 982 F. Supp. 373, 374 (E.D. Va. 1997) (finding with respect to a Clean Water Act penalty imposed after a trial that ''a penalty, which is imposed pursuant to a federal statute, in a suit brought by the federal government, . . . constitutes 'public money.' As such, it must be deposited with the Treasury, in accordance with the Miscellaneous Receipts Act, unless otherwise specified by Congress'').

Fifth, the Attorney General has not ''cherry-picked'' a favorable definition of ''constructive receipt'' to avoid violation of the MRA. To the contrary, the 1980 OLC opinion cited by the commenter applied the doctrine of ''constructive receipt'' as a ''practical'' constraint to guard against elevating form over substance in evaluating whether a settlement violated the MRA. *Effect of 31 U.S.C. 484,* 4B Op. O.L.C. at 688. In addition, as the comment itself acknowledges, there is no definitive version of the constructive receipt doctrine that is clearly applicable to the types of settlements at issue here and that differs from the Department's approach. Moreover, as *Effect of 31 U.S.C. 484* notes, the Department and Federal agencies had previously applied the same definition in other contexts, including to conclude that an individual in some circumstances does not ''accept'' funds when the individual does not retain control over the disposition of those funds. *Id.* at 688 n.11. That further undercuts the argument that the Department has chosen a particular version of the doctrine in order to permit circumvention of the MRA.

The Department also disagrees with the assertion that 42 U.S.C. 16138 (enacted in 2008) undercuts the legality of payments to third parties. That provision addresses EPA's authority to accept diesel emissions reduction SEPs. The commenter broadly states that the ''clear implication'' of this provision is that diesel emission SEPs (and accordingly all third-party payments) violate the MRA and the ADA absent express congressional authorization. But this claim ignores the text, context, and history of section 16138, which make clear that Congress enacted the 2008 provision to address a narrow concern that EPA then believed had newly arisen from Congress's express appropriations for diesel retrofit projects.

As an initial matter, nothing in the text of section 16138 indicates that it broadly prohibits the Federal Government from entering into settlement agreements that include payments to third parties. On the contrary, by its terms, it provides that the EPA ''may accept . . . diesel emissions reduction Supplemental Environmental Projects'' that meet certain criteria ''as part of a settlement of any alleged violates of environmental law.'' 42 U.S.C. 16138. To the extent that the commenter relies on the interpretive cannon *expressio unius est exclusio alterius*—that expressing one item of an associated group or series excludes another—that canon applies ''only when circumstances support a sensible inference that the term left out must have been meant to be excluded.'' *NLRB* v. *SW Gen., Inc.,* 580 U.S. 288, 302 (2017) (quotation marks and brackets omitted). Here, it is not ''sensible'' to ''infer[ ],'' *id.,* that Congress intended to disrupt the Federal Government's long-standing practice of entering into settlement agreements that include third-party payments from a provision that authorizes the Federal Government to agree to one such type of agreement—*i.e.,* those that include ''diesel emissions reduction Supplemental Environmental Projects,'' 42 U.S.C. 16138.

The history and context of section 16138 confirm this conclusion. As the Senate report accompanying the legislation states, SEPs had historically ''been an important funding stream for diesel retrofit projects.'' S. Rep. No. 110–266, at 2 (2008). The report notes that SEPs are ''projects [that] are undertaken by a defendant as part of a settlement in an environmental enforcement action . . . . They specifically do not include actions which a defendant is otherwise legally required to perform. So they generate environmental and public health benefits that would not have occurred without the settlement.'' *Id.* However, after Congress first funded the diesel retrofit program in 2005, the report continues, ''EPA apparently . . . concluded that the Agency generally should cease funding diesel retrofit projects via SEPs. EPA believes that allowing diesel retrofits to be funded by SEPs once Congress has specifically appropriated monies for that purpose could violate the Miscellaneous Receipts Act.'' *Id.* The Senate report explains that the new provision was ''intended to clarify that Congress did not intend the funding of the Diesel Emissions Reduction Act to affect EPA's ability to enter into SEPs that fund diesel retrofit projects.'' *Id.* Rather, ''Congress never intended the Diesel Emissions Reduction Act to limit EPA's ability to negotiate additional diesel retrofit projects as part of enforcement settlements.'' *Id.* at 3.

This history makes clear that Congress enacted the 2008 provision to address the narrow concern that, at the time, EPA believed had arisen from Congress's express appropriations in 2005 for diesel retrofit projects. Congress clarified that it had ''never intended'' to limit EPA's ability to negotiate SEPs when it funded the diesel retrofit program. *Id.* Neither the text nor the history or context of how section 16138 came about suggest that Congress understood SEPs to violate the MRA as a general matter. To the contrary, Congress was aware of EPA's and the Department's practice of using SEPs in environmental enforcement settlements and enacted this provision to support that practice and ensure that diesel retrofit projects would continue to be included. *See* S. Rep. No. 110–266, at 2.[5]

[5] Indeed, as one recent article put it, ''there is no evidence in the text or legislative history of the 2008 . . . amendment to show that Congress intended for the amendment to preclude EPA from accepting SEPs absent clear congressional authorization.'' Daniel Alvarez et al., *Clearing the*

Continued

The Department also disagrees with the same commenter's argument that 42 U.S.C. 7604(g)(2) undercuts the legality of payments to third parties in settlements, including SEPs. That provision allows a court to order that up to $100,000 of a penalty award in a citizen suit brought under the Clean Air Act to be used for ''beneficial mitigation projects which are consistent with'' the Clean Air Act and ''enhance the public health or the environment'' in lieu of being deposited in the U.S. Treasury. 42 U.S.C. 7604(g)(2). Like 42 U.S.C. 16138, nothing in the text of section 7604(g)(2) suggests that, in adopting that provision, Congress intended to upend the practice of agreeing to third-party payments as part of settlement agreements. Nor is that a ''sensible inference,'' *SW Gen.,* 580 U.S. at 302; section 7604(g)(2) is limited to cases brought by private citizens to abate pollution under the Clean Air Act and authorizes courts to order certain environmental projects in lieu of penalties—authority that, absent this provision, courts would lack.

The history of that provision confirms its limited scope. Section 7604(g)(2) was adopted as part of the Clean Air Act Amendments of 1990, Public Law 101–549, tit. VII, sec. 707, 104 Stat. 2399, 2682–83. One provision of that law, codified at 42 U.S.C. 7604(g)(1), created a special fund into which penalties imposed in Clean Air Act citizen suit actions ''shall be deposited''; the very next subsection, section 7604(g)(2), then provided that ''notwithstanding paragraph (1)'' courts had the authority to instead order the use of such civil penalty monies for beneficial mitigation projects. The close connection between these subsections—including the fact that section 7604(g)(2) twice cross-references section 7604(g)(1)—further indicates that section 7604(g)(2) was directed specifically to judicial remedies in citizen litigation under the Clean Air Act.[6] Congress's decision to authorize a court to order certain defined projects in the limited context of these private suits after a court determination of liability and penalty assessment has no bearing on the Government's authority to seek appropriate relief in a settlement.

In addition, the Department disagrees with commenters who contend that a third-party payment in the form of a SEP amounts to an agreement to trade back part of the penalty that would constitute public money subject to the MRA. Such trading back of penalties for third-party payments is not authorized by this rule or the May 2022 Memorandum. To the extent commenters suggest that such trade backs are permissible under the *2015 SEP Policy,* the Department notes that while that policy is beyond the scope of this rulemaking, it also does not authorize such trade backs. Nor does the Government violate the MRA simply because it settles a penalty claim that, if pursued to judgment, would have yielded public money subject to the MRA. Instead, the factors outlined in *Softwood Lumber* identify when the Government has constructively received money under the MRA.

Finally, the Department notes that the Clark Memorandum—which commenters cited in connection with this topic and for purposes of other topics—has been withdrawn and was not adopted more broadly by the Department. *See* Memorandum for ENRD Section Chiefs and Deputy Section Chiefs from Deputy Assistant Attorney General Jean E. Williams, Env't & Nat. Res. Div., U.S. Dep't of Just., *Withdrawal of Memoranda and Policy Documents* (Feb. 4, 2021), *https://www.justice.gov/enrd/page/file/1364716/dl* (last visited Oct. 31, 2024). Any related memoranda to the withdrawn Clark Memorandum and associated litigation filings also were not adopted more broadly by the Department. The Department has also addressed arguments made in the Clark Memorandum (which several commenters have repeated) elsewhere in this document.

2. The Anti-Deficiency Act

Comments: Some commenters state that the ADA, 31 U.S.C. 1341, was enacted to implement the Appropriations Clause of the U.S. Constitution. According to these commenters, it is a violation of the ADA for a settlement agreement to divert any funds from the U.S. Treasury into private hands without congressional authorization.

Other commenters state that there is no violation of the ADA because in these settlements, the Federal Government never received any funds to expend without congressional appropriation.

Response: The Department agrees that settlements that include third-party payments do not violate the ADA. The ADA generally prohibits any expenditure or obligation of public money exceeding an amount ''available in an appropriation or fund for the expenditure or obligation. . . .'' 31 U.S.C. 1341(a)(1)(A). As discussed above, *see supra* Part II.B.1, where a settlement is ''executed before an admission or finding of liability in favor of the United States'' and where the United States does not ''retain post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement, except for ensuring that the parties comply with the settlement,'' the Government has not '' 'received money for the Government.' '' *Softwood Lumber,* 30 Op. O.L.C. at 119 (quoting 31 U.S.C. 3302(b)). In such settlements, no Government official or employee expends public money or creates an obligation of the Government.

3. Constitutionality of the Department's Actions

Comments: Multiple commenters state that the power to tax and the power to spend are granted only to Congress under Article I of the Constitution. They state that under the Appropriations Clause, only Congress has the authority to direct how Federal dollars are spent, and that body enacts annual appropriations measures mandating how Federal agencies do so. These commenters contend that the long-standing practices of the Department reflected in the May 2022 Memorandum circumvent these constitutional obligations. Additionally, commenters argue that through these settlements, DOJ is usurping the role of the legislature, without clear direction from Congress to do so. One commenter also claims that SEPs and similar payments to third parties use ''lawful enforcement authority to extract unlawful settlements,'' which, in the commenters' view, is inconsistent with the requirement in Article II of the Constitution that ''the executive take Care that the Laws be faithfully executed.''

Response: Third-party settlements entered into consistent with *Softwood Lumber* and the May 2022 Memorandum are consistent with the Constitution, as well as the MRA. The Constitution provides that ''[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law,'' U.S. Const. art. I, sec. 9, cl. 7, and that ''[t]he Congress shall have

Air on Supplemental Environmental Projects, 54 Env't L. Rep. 10382, 10394 (2024).

[6] The two provisions were closely linked in the legislative history of the 1990 Clean Air Act Amendments. The conference report describes the two provisions together in a single sentence, stating that ''[t]he House amendment establishes a special treasury fund similar to the one created in the Senate bill, and also authorizes courts in citizen suits to order that penalties be used in beneficial mitigation projects'' and noting that ''[t]he conference agreement adopts the House position.'' Congressional Research Service, *A Legislative History of the Clean Air Act Amendments of 1990,* at 946 (1993). Again, nothing here suggests that Congress intended to upend the practice of agreeing to third-party payments as part of settlement agreements.

Power . . . to pay the Debts and provide for the common Defence and general Welfare of the United States,'' *id.* art. I, sec. 8, cl. 1. In such settlements, no money is ''drawn from the Treasury.'' Nor does Congress's authority to provide for the ''general Welfare'' preclude the Executive Branch from settling litigation on terms that are otherwise consistent with applicable law.

The MRA helps ''preserve[ ] Congress's constitutional control over the expenditure of public funds.'' *Applicability of the Miscellaneous Receipts Act to an Arbitral Award of Legal Costs,* 42 Op. O.L.C. __, at *3 (Mar. 6, 2018). Similar to how the Framers of the Constitution limited the Appropriations Clause's commands to ''Money . . . drawn from the Treasury,'' Congress limited the MRA to ''money'' ''receiv[ed] . . . for the Government.'' And as discussed above in the responses to commenters, *see supra* Parts II.B.1 and II.B.2, funds paid under settlements that include third-party payments are not ''drawn from the Treasury'' and have not been ''receiv[ed] . . . for the Government'' by the United States. Commenters are also incorrect that the May 2022 Memorandum circumvents the Appropriations Clause and the MRA; on the contrary, the May 2022 Memorandum goes beyond what the Appropriations Clause and the MRA require. *See* May 2022 Memorandum at 2–4. To the extent the constitutional arguments of commenters also rely on their interpretation of the MRA or ADA, the Department addresses those arguments above.

Moreover, appropriately structured third-party payments are consistent with the discretion the Constitution accords the Executive Branch in enforcing the statutes enacted by Congress, which—absent a limitation by Congress—includes the authority to resolve claims by settlement on appropriate terms. *Authority of the United States to Enter Settlements,* 23 Op. O.L.C. at 135 (''The settlement power is sweeping, but the Attorney General must still exercise her discretion in conformity with her obligation to 'enforce the Acts of Congress.' '' (citation omitted)). While the Take Care Clause can impose certain limitations on that power, *see id.* at 138, the commenter offers no explanation for why all third-party settlements violate that provision beyond the conclusory statement that they ''obviously'' do.

4. Revocation of the December 2020 Rule and Issuance of the May 2022 Memorandum as Arbitrary and Capricious

Comments: Several commenters argue that the revocation of the December 2020 Rule is arbitrary and capricious or not grounded in law, or otherwise claim that DOJ lacks sufficient bases to justify the action. They argue that DOJ's conclusion that the December 2020 Rule is ''more restrictive and less tailored than necessary,'' 87 FR 27937, does not support repealing the entire rule. They further argue that the Department's statement that settlement policies ''have traditionally been addressed through memoranda,'' *id.,* is not sufficient to justify repeal.

Commenters assert that the Department placed the prior policy in regulations and that failing to do so here is a ''bad system of management'' because there is ''no central repository'' where the public and officials could locate memos governing the agency. One commenter states further that the May 2022 Memorandum describing the Department's new policy cites to an OLC memorandum that has not been produced via a Freedom of Information Act (''FOIA'') request and so itself is not available to the public.

Response: It is well-established that ''[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'' *Encino Motorcars, LLC* v. *Navarro,* 579 U.S. 211, 221 (2016). ''When an agency changes its existing position, it 'need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.' '' *Id.* (quoting *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)). ''But the agency must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.' '' *Id.* (quoting *Fox Television Stations,* 556 U.S. at 515). The IFR and the May 2022 Memorandum describe sound reasons for the revocation of 28 CFR 50.28 and a change in policy. Appropriately tailored ''agreements providing for payments to third parties are lawful and allow the United States to more fully accomplish the primary goals of civil and criminal enforcement: Compensating victims, remedying harm, and punishing and deterring unlawful conduct.'' 87 FR 27937. ''For example, the harms caused by violations of Federal environmental statutes . . . can be difficult to redress directly in particular cases''; and in such circumstances, third-party payments (including SEPs) can ''help achieve an enforcement action's goals.'' *Id.* Please see the other responses in this document to comments raising specific legal and policy concerns, especially Parts II.B.1 and 5, that underscore the reasons the Department changed policy.

Turning to the question of the form of the new policy, the Department observes that the previous Administration itself recognized that 28 CFR 50.28 was '' 'limited to agency organization, management, or personnel matters'. . . .'' 85 FR 81410 (citing 5 U.S.C. 553(a)(2), (b), and (d)). The same is true with respect to the IFR and with respect to this final rule. In such areas, Federal agencies have flexibility as to how they act and memorialize their actions. *Cf. Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 101 (2015) (''Because an agency is not required to use notice-and-comment procedures [under the APA] to issue an initial interpretive rule, it is also not required to use those procedures when it amends or repeals that interpretive rule.''). Moreover, as the IFR states in announcing the revocation of 28 CFR 50.28, DOJ policies addressing the goals of settlements have ''traditionally'' been announced in memoranda. 87 FR 27937. Also of note, the previous Administration did not undertake a notice-and-comment rulemaking process; instead, it promulgated 28 CFR 50.28 as an immediately effective final rule. Likewise, in 2022, DOJ revoked this provision as an interim final rule and released simultaneously the May 2022 Memorandum and posted it to the DOJ website. *See https://www.justice.gov/media/1221546/dl?inline=* (last visited Oct. 31, 2024). At its discretion, the Department took the further step of requesting public comment as to those actions and is responding to significant submitted public comments in this final rule.

In response to the commenter who suggests that a memorandum is not appropriate because of the lack of a ''central repository'' for Department policy and states that the policy should be in the *Justice Manual* or *Code of Federal Regulations,* the Department notes that the memorandum is reflected in the *Justice Manual,* which is publicly available on the Justice.gov website. *See Settlement Agreements Involving Payments to Non-Governmental Third Parties,* section 1–17.000. Including these provisions in the *Justice Manual* is preferable because *Justice Manual* provisions can be readily amended, allowing the Department to adjust the guidance governing additional circumstances and fact patterns as needed. The *Justice Manual* governs the litigation practices of the Department

and is followed by Department litigators; a regulation is not needed for this purpose. Further, the Department has announced with this notice that it will make changes to these *Justice Manual* provisions, demonstrating the benefits of this approach.

Finally, as to the question of the release under FOIA of December 2020 OLC Memo, which is referenced in footnote two of the May 2022 Memorandum, DOJ did release this document (posted on February 16, 2023) and it is available in the FOIA Reading Room at *https://www.justice.gov/oip/foia-library/foia-processed/general_topics/settlement_guidelines_third_parties_2_14_23/download* (last visited Oct. 31, 2024).

5. The Attorney General's Guidelines and Limitations as Public Policy

5.1. Examples of Past Department of Justice Conduct as a Basis for Not Revoking the December 2020 Rule and Issuing the May 2022 Memorandum

Comments: Some commenters state that during the Clinton, Bush, and Obama Administrations, the Department entered into settlement agreements containing third-party payments that violated the statutory and constitutional provisions discussed in the previous topics; and further stated that these settlement agreements reflect bad public policy. Examples offered include settlements with financial institutions following the 2008–09 financial crisis; settlements addressing ''housing counseling assistance'' programs; cy pres settlements in other consumer and civil rights cases; and settlements in environmental cases. Commenters argued that these settlements demonstrate that case resolutions will lead to favoritism or ''cronyism.'' Several commenters further asserted that Congress declined to enact funding for some programs where similar activities were subsequently at least partially funded through third-party payments. Commenters also alleged that the Federal Government ''strong-armed'' defendants in some of these settlements to make payments to politically favored entities. Requiring defendants to donate to activist groups selected by the Department, they argue, raises serious legal and ethical issues, erodes public trust, and is analogous to ''corruption.'' Commenters also expressed concern about the ''lack of transparency'' surrounding third-party payments, and about decisions made by ''unaccountable bureaucrats.''

Response: Some of the points raised by commenters do not relate to the substance of the action on which the Department is seeking comment. For example, cy pres class action settlements are expressly outside the scope of the Department's action. *See* May 2022 Memorandum at 1 n.2.

A general prohibition by rule on third-party payments is unnecessary for several reasons. First, with respect to conflict-of-interest concerns, Department attorneys are subject to strict conflict of interest rules imposed by the Department and their respective State bars that apply in the context of litigation, including the settlement of claims. Second, the Department has concluded that, although the commenters' concerns are unfounded based on past settlements, it can best proactively address such concerns through the use of policies like the May 2022 Memorandum, or changes to the *Justice Manual,* rather than a less flexible rulemaking process. Indeed, the May 2022 Memorandum sets forth guidelines designed to ensure that third-party settlements are not used for improper purposes, including a requirement that projects ''have a strong connection to the underlying violation or violations of federal law at issue'' and a provision barring the Department and its client agencies from ''propos[ing] the selection of any particular third party to receive payments to implement any project carried out under any such settlement.'' May 2022 Memorandum at 3. These guidelines adequately guard against cronyism and political favoritism while preserving the benefits of third-party payments. Third (and relatedly), the Department notes that allowing for third-party payments can increase trust in the judicial process by, for example, allowing settlements to be more responsive to affected communities.

For similar reasons, the Department disagrees that a rule prohibiting third-party payments is necessary to ensure transparency. As detailed earlier in this preamble, *see supra* Part I.C, transparency concerns can be addressed through other means, including the revisions to the *Justice Manual* described there. Those revisions appropriately balance concerns of transparency and efficiency with the benefits that can accrue from third-party settlements in a way that a rule banning third-party settlements would not. Nor is a rule necessary to ensure that unaccountable actors are not making important settlement decisions. Rather, the Department can ensure accountability through other means, such as subjecting settlements that include third-party payments to approval requirements similar to those required for other significant departmental actions. *See* May 2022 Memorandum at 3–4 (settlements involving a payment to a non-governmental third party must obtain the approval of the Deputy Attorney General or the Associate Attorney General, with certain exceptions).

To the extent that commenters suggest that Congress's decision not to fund certain activities is evidence that it is improper for the Department to agree to third-party payments that would fund such activities, they have not provided any reason to draw an inference that Congress's inaction evinces an intent to affirmatively disapprove such settlements.

Some commenters identified particular past payments to third-party organizations that they view as inappropriate, including settlements involving allegations of lending discrimination that required the defendant to make payments to third-party organizations to conduct general public education and awareness projects and a 2006 environmental non-prosecution agreement requiring a third-party payment in the form of ''$1 million to the Alumni Association for the United States Coast Guard Academy, New London, Connecticut to fund an Endowed Chair of Environmental Studies.'' The Department, while not conceding to the commenters' characterizations of these settlements, is sensitive to the need to give the public confidence that settlements providing for payments to third parties are appropriately tailored. In that vein, the May 2022 Memorandum provides that ''[n]o such settlement shall require payments to non-governmental third parties solely for general public educational or awareness projects; solely in the form of contributions to generalized research, including at a college or university; or in the form of unrestricted cash donations.''

5.2. Selection of Third-Party Recipients

Comments: One commenter would revise the May 2022 Memorandum to allow DOJ and EPA to work with affected community members in two respects: to devise appropriate SEPs and to suggest appropriate third-party recipients. The commenter says that the May 2022 Memorandum can be read to give defendants ''sole control'' in selecting projects because it prohibits Department selection of a specific third party and allows the defendant to propose projects. The commenter argues that impacted communities may know how best to remedy harm done to them, and they should not be required to work directly with the party causing the harm. Such revisions, the comment

continues, would also help to prevent funding of organizations improperly favored by defendants.

Several commenters argue that under the May 2022 Memorandum, DOJ has too great a role in the selection of the recipients of third-party payments, which will lead to the funding of ''political allies.'' Other commenters similarly express concerns about ''steer[ing] settlement funds to political allies,'' ''picking winners,'' or funneling funds to ''advocacy groups'' for ''favored programs.''

Response: The Department acknowledges the concerns with allowing defendants sole authority to select third-party recipients, but in order to avoid the appearance that the Department is directing the inclusion of particular projects or third parties into a settlement, declines to adopt a policy under which the Department would make such selections. And the Department has addressed these concerns through other means to help ensure appropriate project selection. For example, under the May 2022 Memorandum, ''projects must have a strong connection to the underlying violation,'' ''be consistent with the underlying statute,'' and ''advance at least one of [the statute's] objectives.'' May 2022 Memorandum at 3. ''The project should also be designed to reduce the detrimental effects of the underlying violation . . . to the extent feasible and reduce the likelihood of similar violations in the future.'' *Id.* Moreover, the Department and its client agencies ''may specify the type of entity'' to be the beneficiary of any projects carried out, *id.,* and may ''disapprove of any third-party implementer or beneficiary that the defendant proposes'' provided that the disapproval is based upon objective criteria for assessing qualifications and fitness outlined in the settlement agreement. *Id.* The May 2022 Memorandum also expressly precludes certain payments that would ordinarily be too broad to satisfy the criteria above: Settlements may not ''require payments to non-governmental third parties solely for general public educational or awareness projects; solely in the form of contributions to generalized research . . . or in the form of unrestricted cash donations.'' *Id.* Thus, these provisions rule out Federal selection of any particular recipient but permit the United States to disapprove a particular recipient based on objective grounds laid out in the settlement agreement.

In addition, the Department can address the concerns about defendants selecting projects in other ways. The May 2022 Memorandum ''provides internal Justice Department guidance only.'' May 2022 Memorandum at 2. Nothing prevents a community from engaging with the defendant at any time, including regarding potential SEPs. Moreover, once a defendant expresses interest in or proposes a third-party payment as part of a judicial settlement, Department attorneys and their client agencies may encourage the defendant to seek input from affected communities on their proposal. Defendants may choose to consult with the community to identify the community's needs and concerns in advance of agreeing to a settlement, which would help satisfy the Department's requirement that third-party payments have a strong connection to the allegations and advance the underlying statutory purpose. The Department will also add a provision to *Justice Manual* section 1–17.000 that provides for public comment on certain settlements that include these types of payments, *see supra* Part I.C, so the public will be able to provide input on the particular remedies identified in the settlement.

Finally, with respect to concerns that the Department would steer settlement funds to political allies, pick winners, or funnel funds to favored groups and programs, the requirements detailed above operate to ensure, as stated in the May 2022 Memorandum, that third-party payments function properly as ''critical tools for addressing violations of federal law and remedying the harms those violations cause.'' May 2022 Memorandum at 2. The Department would not support the use of partisan or viewpoint-based criteria in determining how to implement a third-party payment, as those would not be ''objective criteria,'' *id.* at 3; such criteria could give rise to an inference that a potential recipient of a third-party payment was rejected based on the Department's disfavoring of that particular partisan characteristic or viewpoint.

5.3. Guidelines and Limitations: Adequacy To Constrain Settlement Discretion

Comment: One commenter views the May 2022 Memorandum as ''window-dressing that will reopen avenues of past abuse'' of the Department's settlement discretion. In this commenter's view, the guidelines still permit the Department to indicate the category of recipient of third-party payments and to disapprove specific recipients based on criteria the Department itself selects, and even the express prohibition of certain types of third-party payments can be circumvented by allowing some minimal funding of another type of activity or minimal statement of conditions for cash donations. The commenter made several further similar criticisms addressed below.

Response: The Department disagrees with the characterization that the May 2022 Memorandum does not sufficiently constrain its settlement discretion. On the contrary, the memorandum's provisions impose significant and appropriate constraints on the use of this tool. The guidelines and limitations operate together to ensure that settlement agreements providing for payments to non-governmental third parties are structured properly, and are consistent with applicable law. *See* May 2022 Memorandum at 2–3. The requirement that the Deputy Attorney General or Associate Attorney General approve a settlement containing a third-party payment also promotes consistency in application of the May 2022 Memorandum's terms. *See id.* at 3–4.

The commenter states that the prohibition on third-party payments ''solely'' for general public educational or awareness projects or generalized research is not constraining because a settlement could ''allocate *any* amount of the settlement money to some other activity that is not public education, awareness, or generalized research'' in order to ''skirt this limitation.'' That misunderstands the relevant limitation. The term ''solely'' is intended to recognize that a project that otherwise complies with the guidelines set forth in the May 2022 Memorandum could also have an incidental effect of public education or awareness or could have incidental benefits to generalized research. The Department now clarifies that no portion of a settlement may be directed at these prohibited purposes. For example, a settlement addressing the lead-based-paint violations of a commercial renovator may include a third-party payment in the form of a project to remediate lead-based paint in a nearby school. The settlement may have the incidental effect of educating school attendees, their families, and the local community about the dangers of lead paint, but no portion of the third-party project could be directly used for a public awareness campaign.

The commenter further argues that the requirement of a ''strong connection to the underlying violation or violations of federal law at issue in the enforcement action,'' May 2022 Memorandum at 3, is not a significant constraint. The commenter suggests that this provision requires only a connection to the broad purposes of the underlying statute,

which the commenter states is ''highly subjective.'' The Department disagrees. The same provision of the May 2022 Memorandum states that ''[t]he project should also be designed to reduce the detrimental effects of the violation or violations at issue to the extent feasible and reduce the likelihood of similar violations in the future.'' May 2022 Memorandum at 3. Linking the project to the detrimental effects of the violation (and preventing recurrence) requires a strong connection to the harms associated with the underlying violation; for violations that affect a particular geographic area, this requirement will also mandate that the project be linked to that area.

The commenter describes the limitation that a project ''should also be designed to reduce the detrimental effects of the underlying violation or violations at issue to the extent feasible and reduce the likelihood of similar violations in the future,'' *id.,* as expressing an ''aspirational preference, not a requirement of agency settlements.'' This is incorrect. The May 2022 Memorandum requires that a properly structured settlement must address this factor ''to the extent feasible.'' May 2022 Memorandum at 3. This qualification recognizes that, in some instances, it may be difficult to reduce the detrimental effects of a past violation of law where those effects are widely shared.

The commenter states that the provision limiting third-party payments for activities for which an agency receives a specific appropriation will not be effective, stating that ''[t]o sidestep these guidelines, an outside group need only describe the project for which it may receive settlement funds in a manner that differentiates the project from an agency's appropriations or statutory obligations.'' This is also incorrect. The Department will review any proposals for overlap between a project and appropriations that an agency receives and will not rely solely on the description of the project by the defendant or any other party.

The commenter also questions the benefits of the provisions of the May 2022 Memorandum providing for review and approval by the Deputy Attorney General or Associate Attorney General of settlements that include payments to non-governmental third parties. The Department has long required that certain significant settlements be approved by the Deputy Attorney General or Associate Attorney General. 28 CFR 0.160, 0.161. These requirements ensure that certain types of case resolution receive appropriate review and attention within the Department. The provisions of the May 2022 Memorandum requiring such approval for settlements including payments to non-governmental third parties are consistent with these longstanding provisions and will similarly ensure that the memorandum's provisions are applied consistently and uniformly.

The commenter also appears to presume that DOJ controls the development of third-party payment provisions. The Department will adopt a provision in *Justice Manual* section 1–17.000 clarifying that in negotiating a civil case resolution, the Department and its client agencies may condition a settlement on the inclusion of a third-party payment if the third-party payment constitutes relief that a court would have authority to order under applicable law or in equity, but that otherwise such provisions may only be included if the defendant expresses interest in doing so. Outside the context of relief that a court could order, then, these provisions will be included only where the defendant expresses interest in doing so. Second, the defendant has the lead on developing the proposed project, which must have a ''strong connection'' to the violation of Federal law underlying the case.

In addition, in many civil cases, following the conclusion of settlement negotiations, there is a public process for entry of a proposed Federal consent decree. 15 U.S.C. 16(b)–(h); 28 CFR 50.7. Once the United States files the proposed consent decree in Federal court, there is typically a period in which the general public may comment, including on any provisions addressing third-party payments. The Federal court then considers any resulting comments and exercises its own independent judgment in deciding whether to approve such a decree. The Department will add a provision to *Justice Manual* section 1–17.000 requiring a public comment process for certain civil third-party payments subject to the May 2022 Memorandum, so that the public will have additional opportunities for input on such provisions. This requirement will afford additional transparency for settlements including such remedies.

5.4. Guidelines and Limitations: Prohibition on Post-Settlement Control

Comment: According to one commenter, the recipients of third-party payments under the May 2022 Memorandum are not subject to reporting obligations to ensure oversight and accountability because DOJ and its client agencies cannot '' 'retai[n] post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement.' ''

Response: The prohibition against post-settlement control is designed to address the requirements of the MRA. *See supra* Part II.B.1. This does not mean, however, that DOJ will not oversee the settlement and ensure the defendant's compliance with it. In fact, the fourth guideline in the May 2022 Memorandum specifically allows for this:

> Any such settlement must be executed before an admission or finding of liability in favor of the United States, and the Justice Department and its client agencies must not retain post-settlement control over the disposition or management of the funds or any projects carried out under any such settlement, *except for ensuring that the parties comply with the settlement.*

May 2022 Memorandum at 3 (emphasis added) (citing *Softwood Lumber,* 30 Op. O.L.C. at 119).

In addition, Federal consent decrees and settlements in civil cases contain standard provisions to ensure compliance, typically including stipulated penalties for failure to complete required actions spelled out in the agreement. Settlement agreements including a third-party payment may also contain specific terms addressing implementation and compliance. The Government can seek enforcement of these provisions to ensure compliance with the terms of the settlement or consent decree. Furthermore, following the conclusion of settlement negotiations, the Department will require opportunity for public comment on certain settlements that incorporate third-party payments in *Justice Manual* section 1–17.000, which will provide a mechanism for additional accountability on such terms. *See supra* Part I.C. (Such a public process is often already required by law, 15 U.S.C. 16(b)–(h), 28 CFR 50.7.)

6. Comments Regarding SEPs

6.1. Characterization of SEPs in the May 2022 Memorandum

Comment: One commenter states that the May 2022 Memorandum and IFR appear to ''fundamentally misunderstan[d] what SEPs are and how they are designed to function'' by treating them as ''a remedy for the underlying violation.'' The commenter goes on to provide his understanding of what a SEP is by reference to EPA's *2015 SEP Policy* and in contrast to the remedy the commenter identifies as mitigation. The commenter made several further similar criticisms addressed below.

Response: This comment discusses one potential type of third-party

payment used in the environmental context, ''Supplemental Environmental Projects.'' EPA's *2015 SEP Policy* specifically addresses such projects. The Department's May 2022 Memorandum is distinct from EPA's *2015 SEP Policy,* and comments on EPA's policy are outside the scope of the Department's request for comments, although the Department notes in this respect that the EPA policy never characterizes, as the comment suggests, SEPs as projects undertaken ''in exchange for a lower civil penalty.'' Similarly, the May 2022 Memorandum does not authorize third-party payments in any context to be made ''in exchange for a lower civil penalty.''

The Department's memorandum does reference SEPs as one potential category of third-party payment that can be an appropriate remedy in a Department settlement. (Note that not all SEPs necessarily involve third-party payments, however.) The Department will respond to this comment to the extent that it addresses aspects of the May 2022 Memorandum, as distinct from EPA's *2015 SEP Policy.*

This commenter asks why ''[t]he May [2022] Memo and the Interim Final Rule do not explain why courts' equitable authority is insufficient to remedy the harms from violations of federal environmental law.'' At the outset, remedying harm is not the only purpose of these types of third-party payments; they also operate to ''punish and deter future violations.'' May 2022 Memorandum at 1. As to their function in remedying harm, the May 2022 Memorandum states that some categories of harms, including in environmental cases, ''can be difficult to redress directly in particular cases.'' *Id.* at 1–2. Where a violation has attenuated or indirect effects (such as the example where excess air pollution accelerated weathering and increased lead exposure from deteriorating lead-based paint), it may not be feasible to identify the scope of those affected with precision. In settling a case, litigants are not subject to the same limitations that apply to judicial remedies and can agree to remedies that may go beyond those that a court would typically order. *See, e.g., Frew* v. *Hawkins,* 540 U.S. 431 (2004); *Local No. 93, Int'l Ass'n of Firefighters, AFL–CIO* v. *City of Cleveland,* 478 U.S. 501 (1986); *United States* v. *Charles George Trucking,* 34 F.3d 1081 (1st Cir. 1994); *United States* v. *BP Prods. N. Am., Inc.,* No. 2:23–CV–166, 2023 WL 5125148 (N.D. Ill. Aug. 9, 2023). In *Firefighters,* the Supreme Court stated that when considering a consent decree that would resolve a matter within its jurisdiction and within the general scope of the case pleadings and would ''further the objectives of the law upon which the complaint was based,'' ''a federal court is not necessarily barred from entering [that] consent decree merely because the decree provides broader relief than the court could have awarded after a trial.'' 478 U.S. at 525.

The remedies that theoretically a court could order can require more precise accounting of effects and injuries than may be practicable in some instances. Further, to fully remedy the underlying harm caused by the violation(s) might require more remedial action than a court may order in a particular statutory scheme. The May 2022 Memorandum requires that any project funded by a defendant ''be consistent with the underlying statute being enforced and advance at least one of the objectives of that statute,'' ensuring that the project will be consistent with congressional intent in enacting the applicable statutory framework. May 2022 Memorandum at 3.

Indeed, some of the other commenters provided examples of types of harms that cannot be adequately addressed without remedies of this type. *See infra* Part II.B.6.2. These harms can arise over long time scales, in circumstances in which there are multiple sources of exposure; in addition, it may be apparent that a particular area or community has experienced unusual environmental harms, but difficult to apportion causation from any individual source. For example, in 2015, the United States, the State of Michigan, and AK Steel Corporation agreed to a settlement to resolve claims for particulate matter violations of the Clean Air Act at AK Steel's Dearborn, Michigan steel plant, which is located in a mixed industrial area with multiple sources of pollution affecting neighboring communities. The settlement required AK Steel to pay a $1.35 million civil penalty and implement injunctive relief to address the violations. The settlement also required AK Steel to perform a SEP, consisting of the purchase and installation of dynamic air filters in the air conditioning systems at the Salina elementary and middle schools. The projects, which cost $337,000, reduced students' exposure to fine particulates—from the steel plant but commingled with pollution from other sources in the airshed—while in school. Examples like this illustrate why the Department concluded that ''[w]hen used appropriately, these agreements allow the government to more fully compensate victims, remedy harm, and punish and deter future violations.'' May 2022 Memorandum at 1.

6.2. SEPs as Public Policy

Comments: A number of commenters express support for the IFR's restoration of the use of third-party payments in the form of SEPs in judicial environmental enforcement settlements. In the view of these commenters, SEPs serve to provide fuller mitigation for harm caused by violations and are a tailored approach to address challenges for communities who routinely face noncompliance from industries. As one commenter states, ''SEPs represent a unique opportunity in the environmental enforcement context to secure some form of restitution for communities harmed by violations given the difficulty of identifying and quantifying full individual harm from a violating pollution source to support adequate direct mitigation. It is often difficult, if not impossible, to fully trace all human ailments or natural problems to a particular pollution source, especially over long periods of time.'' Absent the availability of this settlement tool, another commenter notes, ''enforcement actions are less able to reduce or offset the detrimental effects that the unlawful behavior has already had on affected communities.'' Some commenters state that the Department's changes will support State efforts to address equity, public health, and welfare issues in communities adversely affected by environmental violations and at no additional cost to the taxpayer, and note that 37 States have SEP policies allowing such projects in settlements.

The Department received multiple comments discussing the benefits of the changes in policy reflected in the Department's May 2022 Memorandum for communities and others affected by violations of law. Commenters describe how third-party payments in the form of SEPs have been used to provide more complete relief for communities affected by environmental pollution, particularly overburdened communities. Some of these comments specifically note that environmental violations can cause harms that cannot be adequately addressed without this type of remedy.

Some commenters, however, view third-party payments, including SEPs, as ''corrupt'' tools inadequate to remedy public rights or deter violators, arguing that SEPs and third-party payments undercut deterrence, do not prevent pollution in the case of environmental enforcement, and incentivize ''corrupt'' actions by officials to reward favored entities with payments. Similarly, another commenter questions the

deterrent effect of settlement agreements containing third-party payments in the form of SEPs and characterizes SEPs as ''ad hoc'' and as presenting ''likely inefficient ways to combat pollution.''

Response: These comments discuss one particular type of settlement instrument, SEPs. As noted in DOJ's response to topic 6.1 above, *see supra* Part II.B.6.1, comments on the terms of the *2015 SEP Policy* are outside the scope of the Department's request for public comment.

That said, the Department agrees with commenters that SEPs can provide benefits. Federal environmental statutes seek to protect public health writ large but, as applied in the context of a violating facility, it is often the people who live near and downwind of that facility who bear more of the harm. These harms can arise over long time scales, in circumstances in which there are multiple sources of exposure; in addition, it may be apparent that a particular area or community has experienced unusual environmental harms, but difficult to show causation from any individual source, as discussed. Third-party payments may be crafted to ensure that the case resolution accounts for the reality on the ground.

The Department disagrees that SEPs decrease the deterrent effect of Federal law and that they are inefficient ways to combat pollution. The commenter does not provide data to support these statements. In fact, the ability to include third-party payments in case resolution—in addition to a civil penalty and injunctive relief—increases the deterrent value of the Department's enforcement actions by expediting and facilitating settlement, enabling the Department to prosecute more violators and ensuring that violators are held accountable for all harms, including those harms that may be intangible or difficult to quantify, or where victims are no longer available to pursue individual claims. Certain third-party payments may also serve to deter and prevent violations, such as providing air-monitoring equipment to a surrounding community in a Clean Air Act enforcement case.

In addition, the Department does not depend solely upon third-party payments to accomplish its litigation objectives. Resolving violations of environmental laws by settlement is a complicated task, involving the weighing of a variety of factors, which the Department undertakes in accordance with applicable law and Departmental policy. Key considerations for the Department include compensating victims, redressing harms, and punishing and deterring unlawful conduct without the costs and delay of trial. The Department assesses that third-party payments can support these goals, and the Department disagrees with some commenters' suggestion that limiting the Department's enforcement tools to civil penalties after judgment will maximize deterrence, much less optimally serve the many goals of the Department's enforcement activities.

Whether a third-party payment is appropriate as part of case resolution is only one consideration for the Department when negotiating a settlement but including such a payment may contribute to a resolution. Such settlement agreements can be significantly more efficient than litigating every case to judgment because they save agencies and taxpayers significant time and expense. Those savings allow the Department to pursue more cases that will deter more violators from more future unlawful conduct. With respect to the commenters' claims of favoritism, see the discussion in topics 5.1 and 5.2 above of such claims and of constraints on selection of third parties and projects. *See supra* Part II.B.5.1 and II.B.5.2.

Finally, the Department notes that courts have entered Federal consent decrees containing SEPs for decades. As one court stated when approving a settlement with U.S. Steel involving SEPs at a value of $1.9 million and a $2.2 million civil penalty:

> Could the agreement be different? Of course. Could it demand more from U.S. Steel by way of a fine, for example? Again, of course it could. But making such a demand may have caused U.S. Steel to walk away from the bargaining table and set the parties on a course of protracted litigation. This is to say that there is no single fair and reasonable resolution, but rather a range of them. And, in my judgment, the Consent Decree proposed in this case is plainly within that range.

United States v. *U.S. Steel Corp.,* No. 12–CV–304–PPS–APR, 2017 WL 1190953, at *3 (N.D. Ind. Mar. 30, 2017).

7. Implementation of the May 2022 Memorandum

7.1. Publication of Future Memoranda

Comment: One commenter requests that DOJ make publicly available all future memoranda addressing third-party payments in settlements because they have been ''highly controversial and problematic.''

Response: DOJ recognizes the importance of and greatly values transparency and public participation in enforcement matters where it is possible given the sensitivity of bringing specific litigation. The Department published the May 2022 Memorandum (see response to topic 4 above, *supra* Part II.B.4) and voluntarily sought public comment on it. The requirements of the May 2022 Memorandum are publicly available in *Justice Manual* section 1–17.000, as will be the Department's revisions to that section. The Department will provide in the new *Justice Manual* provision for a public process on certain civil settlements that incorporate third-party payments. *See supra* Part I.C. The Department is aware of the public interest in this topic and will seek to make future memoranda in this area public to the extent it is feasible to do so.

7.2. Including Affected Communities

Comments: Multiple commenters address ways in which impacted communities and individuals should participate more fully in the settlement process and be better supported in doing so. Several commenters asked DOJ and EPA specifically to affirm the continued validity of EPA's *2015 SEP* Policy and to update EPA's 2003 community engagement guidance with ''meaningful'' engagement practices or made similar suggestions on ways to increase engagement. *See* U.S. Environmental Protection Agency, *Interim Guidance for Community Involvement in Supplemental Environmental Projects* (2003). Several commenters also encourage continued implementation of the training and outreach practices in a recently issued Department memorandum.

Response: Commenters suggest a variety of mechanisms to increase the role of communities in selecting and implementing SEPs. DOJ recognizes the importance of remedying the harms to the communities most directly impacted by violations of the Federal environmental laws. As noted above, comments that relate to the details of the *2015 SEP Policy* or other EPA policies are outside the scope of this request for public comment.

The Department recently addressed the need for meaningful engagement with at least a subset of impacted communities in a memorandum entitled *Comprehensive Environmental Justice Enforcement Strategy. See* Memorandum for Heads of Department Components, United States Attorneys from the Associate Attorney General, *Comprehensive Environmental Justice Enforcement Strategy* (May 5, 2022) (''*Comprehensive Environmental Justice Enforcement Strategy* Memorandum''), *https://www.justice.gov/asg/file/1217741-0/dl?inline* (last visited Oct. 31, 2024). Pursuant to the strategy, all

litigating components at DOJ shall consider appropriate outreach efforts to identify areas of environmental justice concern in relevant communities. *Id.* at 6–7. As the commenter suggested, designated environmental justice coordinators in each U.S. Attorney's Office have been trained to serve as point people for community outreach. *Id.* at 3 and 6. And cases initiated under the strategy will include the development of case-specific community outreach plans to obtain input on community concerns or potential case remedies. *Id.* at 6–7.

Regarding comments addressing consideration of community input in the development of SEPs in enforcement actions, comments on EPA's policy are outside the scope of the Department's request for comments. But DOJ notes that in December 2023 EPA began piloting the use of an email inbox to receive ideas from the public concerning potential projects for settlement negotiations. Further information is available at U.S. Environmental Protection Agency, *Supplemental Environmental Projects (SEPs), https://www.epa.gov/enforcement/supplemental-environmental-projects-seps#sepidea* (''USEPA SEPs website'') (last visited Oct. 31, 2024).

The Department appreciates commenters' suggestions for potential assistance to impacted communities from the DOJ Environmental Crime Victim Assistance program, and for funding streams from DOJ and EPA to compensate community-based organizations for their expertise. However, these comments are outside the scope of the IFR.

7.3. Working With Tribal Governments

Comment: One commenter expresses general support for SEPs, urges DOJ and EPA to address the aspects of SEPs that are relevant to Federally recognized Indian Tribes (''Tribes'') in Indian country, and offers recommendations to the Department based on previous experiences with SEPs. The commenter suggests working with Tribes early to avoid SEPs that are ''rigid'' or ''unworkable,'' and to achieve environmental justice.

Response: The Department has a policy on *Tribal Consultation* (Nov. 30, 2022), which can be found at *https://www.justice.gov/d9/2022-12/doj-memorandum-tribal-consultation.pdf* (last visited Oct. 31, 2024). Consistent with this policy, DOJ is committed to engaging in ongoing communication with Tribes. While settlement negotiations fall outside of our formal consultation policy, DOJ engages in communication with Tribes beyond consultation such as listening sessions, meetings with individual Tribes, and informal discussions with Tribal leaders.

The Department is a co-plaintiff with Tribes in a number of environmental enforcement matters. In such cases, the co-plaintiff Tribe is an active participant in settlement negotiations and able to discuss SEPs as an element of relief for the claims the Tribe advances.

As noted in DOJ's previous response, *see supra* Part II.B.7.2, the Department recently addressed the need for meaningful engagement with impacted communities in its *Comprehensive Environmental Justice Enforcement Strategy* Memorandum. Consistent with the strategy, all parts of the Department shall consider appropriate outreach efforts to identify areas of environmental justice concern, including each U.S. Attorney's Office in communities within its district. Designated environmental justice coordinators in each U.S. Attorney's Office have been trained to serve as point people for community outreach. And cases initiated under the strategy will include the development of case-specific community outreach plan. In addition, the strategy requires certain Department components to consider how to: ''(1) facilitate consideration of these unique [Tribal environmental justice] issues in cases brought pursuant to this Strategy; (2) identify opportunities to work with the governments of Federally recognized Tribes, including consortia of such Tribes; (3) work with other Federal agencies to coordinate investigative resources and enforcement authorities; and (4) recommend ways to address and incorporate Tribal concerns into the Department's enforcement work.'' *Comprehensive Environmental Justice Enforcement Strategy* Memorandum at 3.

The Department appreciates the commenter's suggestions for Tribal set-asides, whether in the context of mitigation or a third-party payment, depending on the particular case, and greater transparency regarding the impact of emissions on tribal communities. These comments are outside the scope of the IFR, and the Department does not address them further.

7.4. Effectiveness of the 2015 SEP Policy

Comment: One commenter asks DOJ and EPA to affirm that EPA's *2015 SEP Policy* remains in effect or to readopt it if does not. The commenter indicates that even if it was never withdrawn or replaced, having administrative procedural clarity would be beneficial.

Response: Where DOJ is working with EPA as a client agency, the Department certainly discusses case resolution with it by reference to relevant EPA policy documents. Whether EPA continues to apply a particular policy, including its *2015 SEP Policy,* is within that agency's purview and beyond the scope of this action. DOJ understands the 2015 policy to be in effect as reflected in several responses to comments and points commenters to EPA's website, which itself cites the *2015 SEP Policy. See* USEPA SEPs website.

IV. Regulatory Certifications

A. Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, or practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. *See* 5 U.S.C. 553(a)(2), (b), and (d). The rule is effective upon signature. In its discretion, the Department sought post-promulgation public comment on the IFR and is responding to public comment.

B. Regulatory Flexibility Act

An analysis under the Regulatory Flexibility Act was not required for this rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. *See* 5 U.S.C. 601(2), 604(a).

C. Executive Orders 12866, 13563, and 14094—Regulatory Review

This rule has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b) of Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and Executive Order 14094, ''Modernizing Regulatory Review.''

This rule is ''limited to agency organization, management, or personnel matters'' and thus is not a ''rule'' for purposes of review by the Office of Management and Budget under section 3(d)(3) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

D. Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform.''

E. Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. It is a rule of internal agency practice and procedure. Therefore, in accordance with Executive Order 13132, ''Federalism,'' the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

G. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a ''rule'' as that term is used in the Congressional Review Act, 5 U.S.C. 804(3)(B), (C), and the reporting requirements of 5 U.S.C. 801 do not apply.

H. Paperwork Reduction Act of 1995

This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

List of Subjects in 28 CFR Part 50

Administrative practice and procedure.

Accordingly, for the reasons set forth in the preamble, the interim final rule amending 28 CFR part 50, which published at 87 FR 27936 on May 10, 2022, is adopted as final without change.

Dated: December 3, 2024.

Merrick B. Garland,

Attorney General.

[FR Doc. 2024–28866 Filed 12–6–24; 8:45 am]

BILLING CODE 4410–BB–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0999]

Special Local Regulations; Marine Events Within the Eleventh Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulations.

SUMMARY: The Coast Guard will enforce multiple special local regulations codified in federal regulations for recurring marine events taking place in December 2024 located in the Los Angeles Long Beach Captain of the Port Area. This action is necessary and intended to provide for the safety of life and property on navigable waterways during these events. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any official patrol vessel displaying a Coast Guard ensign.

DATES: The Coast Guard will enforce the regulations listed in 33 CFR 100.1104, for the locations described in event entries (5) through (16) in Table 1 to § 100.1104 during December 2024, according to the schedule listed in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kevin Kinsella, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 521–3860, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce multiple special local regulations for annual events in the Captain of the Port Los Angeles Long Beach Zone listed in 33 CFR 100.1104 Table 1 to § 100.1104 for events occurring in the month of December as listed.

1. Entry (5) Morro Bay Holiday Boat Parade (also known as (a.k.a.) Morro Bay Lighted Boat Parade). From 4 p.m. to 9 p.m. on December 7, 2024.

2. Entry (6) Santa Barbara Holiday Boat Parade (a.k.a. Santa Barbara Annual Boat Parade of Lights). From 5:30 p.m. to 9 p.m. on December 8, 2024.

3. Entry (7) Ventura Harbor Holiday Boat Parade (a.k.a. Ventura Harbor Parade of Lights). From 6:30 p.m. to 8 p.m. daily on December 13, 2024 and on December 14, 2024.

4. Entry (8) Channel Islands Harbor Holiday Boat Parade (a.k.a. Channel Islands Harbor Parade of Lights). From 7 p.m. to 9 p.m. on December 14, 2024.

5. Entry (9) Marina del Rey Holiday Boat Parade. From 5:30 p.m. to 10 p.m. on December 14, 2024.

6. Entry (10) King Harbor Holiday Boat Parade. From 4:30 p.m. to 10 p.m. on December 14, 2024.

7. Entry (11) Port of Los Angeles Holiday Boat Parade (a.k.a. LA Harbor Holiday Afloat Parade). From 5:30 p.m. to 9:30 p.m. on December 7, 2024.

8. Entry (12) Parade of 1,000 Lights (a.k.a. Shoreline Yacht Club Annual Christmas Boat Parade). From 5:30 p.m. to 7:30 p.m. on December 14, 2024.

9. Entry (13) Naples Island Holiday Boat Parade (a.k.a. Naples Boat Parade). From 6:30 p.m. to 7:30 p.m. on December 21, 2024.

10. Entry (14) Huntington Harbor Holiday Boat Parade (a.k.a. 62nd Annual Huntington Harbour Boat Parade). From 5 p.m. to 9 p.m. daily on December 14, 2024, and on December 15, 2024.

11. Entry (15) Newport Beach Holiday Boat Parade (a.k.a. 126th Annual Christmas Boat Parade). From 6:30 p.m. to 9 p.m. daily on December 18, 2024, and on December 22, 2024.

12. Entry (16) Dana Point Holiday in the Harbor (a.k.a. 49th Annual Dana Point Harbor Boat Parade of Lights). From 6:30 p.m. to 8:30 p.m. daily on December 13, 2024, December 14, 2024, and December 15, 2024.

Pursuant to 33 CFR 100.1104, all persons and vessels not registered with the sponsor as participants or as official patrol vessels are considered spectators. The ''official patrol'' consists of any Coast Guard; other Federal, state, or local law enforcement; and any public or sponsor-provided vessels assigned or approved by the cognizant Coast Guard Sector Commander to patrol each event. No spectator shall anchor, block, loiter, nor impede the through transit of participants or official patrol vessels in the regulated areas during all applicable effective dates and times unless cleared to do so by or through an official patrol vessel. When hailed and/or signaled by an official patrol vessel, any spectator located within a regulated area during all applicable effective dates and times shall come to an immediate stop. The Patrol Commander (PATCOM) is empowered to control the movement of all vessels in the regulated area or to restrict vessels from entering the regulated area. The Patrol Commander shall be designated by the cognizant Coast Guard Sector Commander; will be a U.S. Coast Guard commissioned officer, warrant officer, or petty officer

to act as the Sector Commander's official representative; and will be located aboard the lead official patrol vessel. As the Sector Commander's representative, the PATCOM may terminate the event any time it is deemed necessary for the protection of life and property. PATCOM may be reached on VHF–FM Channel 13 (156.65MHz) or 16 (156.8MHz) when required, by the call sign ''PATCOM.'' The Patrol Commander may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so. The Coast Guard may be assisted by other Federal, state, or local agencies.

This notice of enforcement is issued under authority of 33 CFR 100.1104 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via a Marine Safety Information Bulletin (MSIB) and a Broadcast Notice to Mariners (BNM). If the Captain of the Port Los Angeles Long Beach determines that the Special Local Regulations need not to be enforced for the full duration stated in this notice, the Captain of the Port may use a Broadcast Notice to Mariners to reflect the change.

Dated: December 3, 2024.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles—Long Beach.

[FR Doc. 2024–28751 Filed 12–5–24; 11:15 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0998]

Safety Zone; Los Angeles County Annual New Years Eve Fireworks Event

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce safety zones for the Los Angeles County Holiday Fireworks on December 14, 2024, and the Los Angeles County New Years Eve Fireworks on December 31, 2024 through January 1, 2025. These safety zones are to provide for the safety of life and property on the navigable waterways during these events. Our regulation for firework events within the Los Angeles Long Beach Captain of the Port Zone identifies the regulated areas for these firework events in Marina del Rey, CA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 165.1125 will be enforced for the locations identified in Table 1 to § 165.1125 Item Number 14, from 5:30 p.m. to 6:30 p.m. on December 14, 2024, and Item Number 15, from 8:00 p.m. on December 31, 2024, through 1:00 a.m. on January 1, 2025.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kevin Kinsella, U.S. Coast Guard; telephone 310–521–3860, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.1125 for the Los Angeles County Holiday Fireworks regulated area in Item Number 14 of Table 1 to § 165.1125 from 5:30 p.m. to 6:30 p.m. on December 14, 2024 and for the New Years Eve Fireworks regulated area in Item Number 15 of Table 1 to § 165.1125 from 8:00 p.m. on December 31, 2024, to 1:00 a.m. on January 1, 2025. This action will be taken to provide for the safety of life on navigable waterways during the events. Our regulation for fireworks events within the Los Angeles Long Beach Captain of the Port Zone, Table 1 to § 165.1125, Item Numbers 14 and 15, specifies the location of the regulated areas for the Los Angeles County Holiday Fireworks and the New Years Eve Fireworks, which encompasses portions of Marina del Rey. During the enforcement periods, § 165.1125 requires operators of a vessel in the regulated area to comply with directions from the Patrol Commander or Official Patrol, defined as any Coast Guard or other Federal, state, or local law enforcement assisting the Coast Guard in enforcing the regulated area.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via a Marine Safety Information Bulletin (MSIB) and a Broadcast Notice to Mariners (BNM).

Dated: December 3, 2024.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2024–28754 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1025]

RIN 1625–AA00

Safety Zone; Queensway Bay, Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters of Queensway Bay. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Los Angeles-Long Beach.

DATES: This rule is effective from 11 p.m. on December 31, 2024, through 12:30 a.m. January 1, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–1025 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Kevin Kinsella, U.S. Coast Guard Sector Los Angeles-Long Beach, Chief, Waterways Management Division; telephone (310) 521–3861, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a

notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive sufficient notice of this fireworks event in time to publish an NPRM. We must establish this safety zone by December 31, 2024 to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display. Accordingly, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to ensure potential safety hazards associated with fireworks do not impact the safety of the public and the marine environment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Los Angeles-Long Beach (COTP) has determined that potential hazards associated with a fireworks event on December 31, 2024, will be a safety concern for anyone within Queensway Bay. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks event.

IV. Discussion of the Rule

This rule establishes a safety zone from 11 p.m. on December 31, 2024, through 12:30 a.m. on January 1, 2025. The safety zone will cover all navigable waters within 500 feet of the fireworks launch site. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration and time-of-day of the safety zone. This safety zone will impact a small, designated area during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human

environment. This rule involves a safety zone lasting only two and a half hours that will prohibit entry within 500 feet of the fireworks launch site within Queensway Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T11–191 to read as follows:

§ 165.T11–191 Safety Zone; Queensway Bay, Long Beach, CA.

(a) *Location.* The following area is a safety zone: All waters of Queensway Bay, from surface to bottom, encompassed by a line connecting the points creating a 500-foot radius around the launch site located at 33°45′06.8″ N, 118°11′13.7″ and along the shoreline back to the beginning point. These coordinates are based on the WGS 84 datum.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM Channel 13 (156.65 MHz) or 16 (156.8 MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 11 p.m. on December 31, 2024, through 12:30 a.m. on January 1, 2025.

Dated: December 3, 2024.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2024–28756 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–1004]

RIN 1625–AA00

Safety Zone; Santa Barbara Harbor, Santa Barbara, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters of Santa Barbara Harbor. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Los Angeles-Long Beach.

DATES: This rule is effective from 6 p.m. through 7:30 p.m. December 8, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–1004 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Commander Kevin Kinsella, U.S. Coast Guard Sector Los Angeles-Long Beach, Chief, Waterways Management Division; telephone (310) 521–3861, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard did not receive sufficient notice of this fireworks event in time to publish an NPRM. We must establish this safety zone by December 8, 2024 to protect personnel, vessels, and the marine environment from potential hazards created by a fireworks display. Accordingly, it is impracticable to publish an NPRM because we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to ensure potential safety hazards associated with fireworks do not impact the safety of the public and the marine environment.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Los Angeles-Long Beach (COTP) has determined that potential hazards associated with a fireworks event on December 8, 2024, will be a safety concern for anyone within Santa Barbara Harbor. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks event.

IV. Discussion of the Rule

This rule establishes a safety zone from 6 p.m. through 7:30 p.m. on December 8, 2024. The safety zone will cover all navigable waters within Santa Barbara Harbor. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration and time-of-day of the safety zone. This safety zone will impact a small, designated area during the evening when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only one and a half hours that will prohibit entry within Santa Barbara Harbor. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T11–194 to read as follows:

§ 165.T11–194 Safety Zone; Santa Barbara Harbor, Santa Barbara, CA.

(a) *Location.* The following area is a safety zone: All waters of Santa Barbara Harbor, from surface to bottom, encompassed by a line connecting the following points beginning at 34°24′26″ N, 119°41′27″ W, thence to 34°24′28″ N, 119°41′15″ W, thence to 34°24′17″ N, 119°41′15″ W, thence to 34°24′29″ N, 119°41′06″ W, thence to 34°24′40″ N, 119°41′17″ W and along the shoreline back to the beginning point. These coordinates are based on the WGS 84 datum.

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Los Angeles-Long Beach (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM Channel 13 (156.65 MHz) or 16 (156.8MHz). Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6 p.m. through 7:30 p.m. on December 8, 2024.

Dated: December 3, 2024.

Stacey L. Crecy,

Captain, U.S. Coast Guard, Captain of the Port Los Angeles-Long Beach.

[FR Doc. 2024–28752 Filed 12–5–24; 11:15 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0603; FRL–11596–02–R9]

Air Plan Revisions; Arizona; Maricopa County Air Quality Department

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Maricopa County Air Quality Department (MCAQD or ''County'') portion of the Arizona State Implementation Plan (SIP). These revisions concern emissions of volatile organic compounds (VOC) from storage, transfer, or loading of organic liquids and gasoline. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act). We are also approving the MCAQD's reasonably available control technology (RACT) demonstration associated with these rules for the 2008 8-hour ozone national ambient air quality standards (NAAQS) in the Phoenix-Mesa ozone nonattainment area.

DATES: This rule is effective January 8, 2025.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2023–0603. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kira Wiesinger, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; phone: (415) 972–3827; email: *wiesinger.kira@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On August 19, 2024 (89 FR 67014), the EPA proposed to approve the following rules into the Arizona SIP.

Local agency	Rule No.	Rule title	Revised	Submitted
MCAQD	350	Storage and Transfer of Organic Liquids (Non-Gasoline) at an Organic Liquid Distribution (OLD) Facility.	11/18/2020	12/03/2020
MCAQD	351	Storage and Loading of Gasoline at Bulk Gasoline Plants and at Bulk Gasoline Terminals.	11/18/2020	12/03/2020

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. We also proposed to approve the MCAQD's RACT demonstration associated with these rules for the 2008 8-hour ozone NAAQS. Additionally, we proposed that the revised rules corrected the deficiencies identified in our previous conditional approval (85 FR 10986, February 26, 2020). Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received no comments.

III. EPA Action

No comments were submitted. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving MCAQD Rule 350 and Rule 351 into the Arizona SIP. The November 18, 2020 version of Rule 350 and Rule 351 will replace the conditionally approved version of these rules in the SIP. This action signifies that the State of Arizona has fulfilled its commitment

under the terms of the February 26, 2020 conditional approval (85 FR 10986) to submit revised versions of these rules, and the EPA is now removing the conditional approval text associated with these rules and CTG categories from 40 CFR 52.119(c)(1). The EPA is also approving MCAQD's RACT demonstration associated with these rules for the 2008 8-hour ozone NAAQS in the Phoenix-Mesa ozone nonattainment area.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of MCAQD Rule 350, ''Storage and Transfer of Organic Liquids (Non-Gasoline) at an Organic Liquid Distribution (OLD) Facility,'' revised on November 18, 2020, which regulates VOC emissions from organic liquid storage and transfer operations at organic liquid distribution facilities. The EPA is also finalizing the incorporation by reference of MCAQD Rule 351, ''Storage and Loading of Gasoline at Bulk Gasoline Plants and at Bulk Gasoline Terminals,'' revised on November 18, 2020, which regulates VOC emissions from gasoline storage and loading activities at bulk gasoline plants and terminals. Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1] The EPA has made, and will continue to make, these documents available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and permitted by law. Executive Order 14096 (Revitalizing Our Nation's Commitment to Environmental Justice for All, 88 FR 25251, April 26, 2023) builds on and supplements Executive Order 12898 and defines EJ as, among other things, ''the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision-making and other Federal activities that affect human health and the environment.''

The State did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Orders 12898 and 14096 of achieving EJ for communities with EJ concerns.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 7, 2025. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 2, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

For the reasons stated in the preamble, the EPA amends part 52, chapter I, Title 40 of the Code of Federal Regulations as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart D—Arizona

■ 2. In § 52.119:

[1] 62 FR 27968 (May 22, 1997).

■ a. Remove and reserve paragraphs (c)(1)(i) and (c)(1)(ii); and
■ b. Revise paragraph (c)(1)(v).
The revisions read as follows:

§ 52.119 Identification of plan—conditional approvals.

* * * * *

(c) * * *

(1) * * *

(v) The RACT demonstration titled ''Analysis of Reasonably Available Control Technology for the 2008 8-Hour Ozone National Ambient Air Quality Standard (NAAQS) State Implementation Plan (RACT SIP),'' only those portions of the document beginning with ''Gasoline Tank Trucks And Vapor Collection System Leaks'' on page 34 through the first full paragraph on page 35, and Appendix C: CTG RACT Spreadsheet, the rows beginning with ''Gasoline Tank Trucks and Vapor Collection System Leaks'' on page 65, through ''Service Stations—Stage I'' on pages 67–69. This demonstration represents the RACT requirement for the following source categories: Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems (EPA–450/2–78–051); and Design Criteria for Stage I Vapor Control Systems—Gasoline Service Stations (EPA–450/R–75–102).

* * * * *

■ 3. In § 52.120, paragraph (c), Table 4, revise the entries for ''Rule 350'' and ''Rule 351'' to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 4 TO PARAGRAPH (c)—EPA-APPROVED MARICOPA COUNTY AIR POLLUTION CONTROL REGULATIONS

County citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Post-July 1998 Rule Codification				
*	*	*	*	*
Regulation III—Control of Air Contaminants				
*	*	*	*	*
Rule 350	Storage and Transfer of Organic Liquids (Non-Gasoline) at an Organic Liquid Distribution (OLD) Facility.	November 18, 2020	December 9, 2024, [INSERT FIRST PAGE OF **FEDERAL REGISTER** CITATION].	Submitted electronically on December 3, 2020, as an attachment to a letter dated November 24, 2020.
Rule 351	Storage and Loading of Gasoline at Bulk Gasoline Plants and at Bulk Gasoline Terminals.	November 18, 2020	December 9, 2024, [INSERT FIRST PAGE OF **FEDERAL REGISTER** CITATION].	Submitted electronically on December 3, 2020, as an attachment to a letter dated November 24, 2020.
*	*	*	*	*

* * * * *

[FR Doc. 2024–28537 Filed 12–6–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R08–OAR–2024–0552; FRL–12458–01–R8]

Finding of Failure To Attain and Reclassification of an Area in Utah as Serious for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is determining that the Northern Wasatch Front, UT area failed to attain the 2015 ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date. The effect of failing to attain by the applicable attainment date is that the area will be reclassified by operation of law to ''Serious'' nonattainment for the 2015 ozone NAAQS on, the effective date of this final rule. This action fulfills the EPA's obligation under the Clean Air Act (CAA) to determine whether ozone nonattainment areas attained the NAAQS by the Moderate area attainment date and to publish a document in the **Federal Register** identifying each area that is determined as having failed to attain and identifying the reclassification.

DATES: This rule is effective January 8, 2025.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2024–0552. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Amanda Brimmer, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–AQ–R, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6323, email address: *brimmer.amanda@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Overview of Action

The EPA is required to determine whether areas designated nonattainment for an ozone NAAQS attained the standard by the applicable attainment date, and to take certain steps for areas that failed to attain (see CAA section 181(b)(2)). The EPA's determination of attainment for the 2015 ozone NAAQS is based on a nonattainment area's design value (DV) as of the attainment date.[1]

The 2015 ozone NAAQS is met at an EPA regulatory monitoring site when the DV does not exceed 0.070 parts per million (ppm). For Moderate nonattainment areas for the 2015 ozone NAAQS, such as the area addressed in this action, the attainment date was August 3, 2024. Because the DV is based on the three most recent, complete calendar years of data, attainment must occur no later than December 31 of the year before the attainment date (*i.e.,* December 31, 2023, in the case of Moderate nonattainment areas for the 2015 ozone NAAQS). Accordingly, the EPA's determinations for each Moderate area are based upon the complete, quality-assured, and certified ozone monitoring data from calendar years 2021, 2022, and 2023.

This action addresses the Northern Wasatch Front area in Utah, which was classified as Moderate for the 2015 ozone NAAQS as of the Moderate area attainment date of August 3, 2024. The EPA is finding that the Northern Wasatch Front Moderate area did not attain by the attainment date, because the area's 2021–2023 DV was 0.077 ppm which is greater than 0.070 ppm. Under CAA section 181(b)(2)(A), the effect of this determination is that this area will be reclassified by operation of law as Serious on the effective date of this final rule. The reclassified area will then be subject to the Serious area requirement to attain the 2015 ozone NAAQS as expeditiously as practicable, but not later than August 3, 2027.

As a result of the area's reclassification as Serious, Utah must submit to the EPA the state implementation plan (SIP) revisions for this area that satisfy the statutory and regulatory requirements applicable to Serious areas established in CAA section 182(c) and in the 2015 Ozone NAAQS SIP Requirements Rule (see 83 FR 62998, December 6, 2018). The EPA is establishing deadlines for submitting SIP revisions for these reclassified areas in a separate action.

II. What is the background for this action?

On October 26, 2015, the EPA issued its final action to revise the NAAQS for ozone to establish a new 8-hour standard (*see* 80 FR 65452, October 26, 2015). In that action, the EPA promulgated identical tighter primary and secondary ozone standards designed to protect public health and welfare that specified an 8-hour ozone level of 0.070 ppm. Specifically, the standards require that the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration may not exceed 0.070 ppm.

Effective on August 3, 2018, the EPA designated 52 areas throughout the country as nonattainment for the 2015 ozone NAAQS (see 83 FR 25776, June 4, 2018). In a separate action, the EPA assigned classification thresholds and attainment dates based on the severity of an area's ozone problem, determined by the area's DV (see 83 FR 10376, May 8, 2018). Consistent with CAA section 181(a), the EPA established the attainment date for Marginal, Moderate, and Serious nonattainment areas as 3 years, 6 years, and 9 years, respectively, from the effective date of the final designations. Thus, the attainment date for Marginal nonattainment areas for the 2015 ozone NAAQS was August 3, 2021, the attainment date for Moderate areas was August 3, 2024, and the attainment date for Serious areas is August 3, 2027. On October 7, 2022 (87 FR 60897), the EPA determined that 22 areas, including the Northern Wasatch Front area addressed in this action, did not attain the standards by the Marginal attainment date, and these areas were reclassified as Moderate by operation of law.

III. What is the statutory authority for this action?

The statutory authority for this determination is provided by the CAA, as amended (42 U.S.C. 7401 *et seq.*). Relevant portions of the CAA include sections 107, 181 and 182.

CAA section 107(d) provides that when the EPA establishes or revises a NAAQS, the agency must designate areas of the country as nonattainment, attainment, or unclassifiable based on whether each area is not meeting (or is contributing to air quality in a nearby area that is not meeting) the NAAQS, meeting the NAAQS, or cannot be classified as meeting or not meeting the NAAQS, respectively. Subpart 2 of part D of title I of the CAA governs the classification, state planning, and emissions control requirements for any areas designated as nonattainment for a revised primary ozone NAAQS. In particular, CAA section 181(a)(1) requires each area designated as nonattainment for a revised ozone NAAQS to be classified at the same time as the area is designated based on the extent of the ozone problem in the area (as determined based on the area's DV). Classifications for ozone nonattainment areas are ''Marginal,'' ''Moderate,'' ''Serious,'' ''Severe,'' and ''Extreme,'' in order of stringency. CAA section 182 provides the specific attainment planning and additional requirements that apply to each ozone nonattainment area based on its classification.

Section 181(b)(2)(A) of the CAA provides that within 6 months following the applicable attainment date, the EPA must determine whether an ozone nonattainment area attained the ozone standard based on the area's DV as of that date. Under CAA section 181(a)(5) and 40 CFR 51.1307, on application by any state, the EPA may grant a 1-year extension to the attainment date when certain criteria are met. One criterion for a first attainment date extension is that an area's fourth highest daily maximum 8-hour value for the attainment year must not exceed the level of the standard.

If an area fails to attain the ozone NAAQS by the applicable attainment date and is not granted a 1-year attainment date extension, CAA section 181(b)(2)(A) requires the EPA to make the determination that an ozone nonattainment area failed to attain the ozone standard by the applicable attainment date, and requires the area to be reclassified by operation of law to the higher of: (1) the next higher classification for the area, or (2) the classification applicable to the area's DV as of the determination of failure to attain.[2] Section 181(b)(2)(B) of the CAA requires the EPA to publish the determination of failure to attain and accompanying reclassification in the **Federal Register** no later than 6 months after the attainment date, which in the case of the Moderate nonattainment area considered in this determination is February 3, 2025.

Once an area is reclassified, each state that contains a reclassified area is

[1] A DV is a statistic used to compare data collected at an ambient air quality monitoring site to the applicable NAAQS to determine compliance with the standard. The data handling conventions for calculating DVs for the 2015 ozone NAAQS are specified in appendix U to 40 CFR part 50. The DV for the 2015 ozone NAAQS is the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration. The DV is calculated for each air quality monitor in an area, and the DV for an area is the highest DV among the individual monitoring sites located in the area.

[2] The nonattainment area named in this action that failed to attain by the attainment date is being classified to the next higher classification, Serious. It does not have a DV that would otherwise place it in a higher classification.

required to submit certain SIP revisions in accordance with the more stringent classification. The SIP revisions are intended to, among other things, demonstrate how the area will attain the NAAQS as expeditiously as practicable, but no later than August 3, 2027, the Serious area attainment date for the 2015 ozone NAAQS. Per CAA section 182(i), a state with a reclassified ozone nonattainment area must submit the applicable attainment plan requirements ''according to the schedules prescribed in connection with such requirements'' in CAA section 182(c) for Serious areas, but the EPA ''may adjust applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.'' EPA is addressing the SIP revision and implementation deadlines for newly reclassified Serious areas, as well as the continued applicability of Moderate area requirements that this area may not yet have met, in a separate rulemaking.

IV. How does EPA determine whether an area has attained the standard?

The level of the 2015 ozone NAAQS is 0.070 ppm.[3] Under EPA regulations at 40 CFR part 50, appendix U, the 2015 ozone NAAQS is attained at a site when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient ozone concentration (*i.e.,* the DV) does not exceed 0.070 ppm. When the DV does not exceed 0.070 ppm at each ambient air quality monitoring site within the area, the area is deemed to be attaining the ozone NAAQS. Each area's DV is determined by the highest DV among monitors with valid DVs.[4] The data handling convention in 40 CFR part 50 appendix U states that concentrations are to be reported in ppm to the third decimal place, with additional digits to the right being truncated. Thus, a 3-year average ozone concentration of 0.071 ppm is greater than 0.070 ppm and would exceed the standard, but a 3-year average ozone concentration of 0.0709 ppm is truncated to 0.070 ppm and attains the 2015 ozone NAAQS.

The EPA's determination of whether the Northern Wasatch Front attained the standard is based on hourly ozone concentration data for calendar years 2021, 2022 and 2023 that have been collected and quality-assured in accordance with 40 CFR part 58 and reported to the EPA's Air Quality System (AQS) database.[5]

State and local monitoring network plans are subject to approval by the EPA on an annual basis, and any interim modifications to those plans must also be approved by the EPA.[6] The annual monitoring network plan process is provided in 40 CFR 58.10 and the requirements governing system modifications and monitor discontinuations are laid out in 40 CFR 58.14. Where state or local agencies seek to modify the ambient air quality monitoring networks by discontinuing a monitor station, the EPA may approve such modifications subject to the criteria established in 40 CFR 58.14(c). The EPA may not approve such discontinuation if doing so would compromise data collection needed for implementation of a NAAQS. If a monitor has been discontinued subject to 40 CFR 58.14 such that the discontinuation results in insufficient data to calculate a valid DV according to appendix U to 40 CFR part 50, EPA will determine the applicable area's attainment status based on the remaining monitors in the area.

V. What is EPA's determination for the area?

The EPA is determining that the Northern Wasatch Front Moderate nonattainment area failed to attain the 2015 ozone NAAQS by the attainment date of August 3, 2024. As shown in table 1, at least one monitor in this area had a 2021–2023 DV greater than 0.070 ppm; in fact, *all* of the area's monitors had a 2021–2023 DV greater than 0.070 ppm. The EPA has further determined that this area did not meet the requirements under section 181(a)(5)(B) and 40 CFR 51.1307 necessary to grant a 1-year extension of the attainment date, because at least one monitor had a 2023 fourth highest daily maximum 8-hour average that was greater than 0.070 ppm. Table 1 shows the annual fourth highest daily maximum 8-hour average ozone concentration and 2021–2023 DV for each monitor in the Northern Wasatch Front area.

TABLE 1—2021–2023 FOURTH HIGHEST DAILY MAXIMUM 8-HOUR AVERAGE OZONE CONCENTRATIONS AND DESIGN VALUES AT ALL MONITORS IN THE NORTHERN WASATCH FRONT AREA

AQS site ID	County	Fourth highest daily maximum 8-hour average ozone concentration (ppm)			2021–2023 DV (ppm)
		2021	2022	2023	
490110004	Bountiful Viewmont	0.082	0.075	0.073	0.076
490352005	Copper View	0.086	0.074	0.073	0.077
490353006	Hawthorne	0.081	0.072	0.072	0.075
490353010	Rose Park	0.079	0.075	0.070	0.074
490353013	Herriman #3	0.087	0.071	0.068	0.075
490353014	Lake Park	0.082	0.072	0.072	0.075

[3] See 40 CFR 50.19.

[4] According to appendix U to 40 CFR part 50, ambient monitoring sites with a DV of 0.070 ppm or less must meet minimum data completeness requirements in order to be considered valid. These requirements are met for a 3-year period at a site if daily maximum 8-hour average ozone concentrations are available for at least 90% of the days within the ozone monitoring season, on average, for the 3-year period, with a minimum of at least 75% of the days within the ozone monitoring season in any one year. Ozone monitoring seasons are defined for each state in appendix D to 40 CFR part 58. DVs greater than 0.070 ppm are considered to be valid regardless of the data completeness.

[5] The EPA maintains the AQS, a database that contains ambient air pollution data collected by the EPA, state, local, and Tribal air pollution control agencies. The AQS also contains meteorological data, descriptive information about each monitoring station (including its geographic location and its operator) and data quality assurance/quality control information. The AQS data is used to (1) assess air quality, (2) assist in attainment/non-attainment designations, (3) evaluate SIPs for non-attainment areas, (4) perform modeling for permit review analysis, and (5) prepare reports for Congress as mandated by the CAA. Access is through the website at *https://www.epa.gov/aqs.*

[6] Annual monitoring network plans for each state are available at *https://www.epa.gov/amtic/state-monitoring-agency-annual-air-monitoring-plans-and-network-assessments.*

VI. What action is EPA taking?

Pursuant to CAA section 181(b)(2), the EPA is determining that the Northern Wasatch Front area failed to attain the 2015 ozone NAAQS by the applicable attainment date of August 3, 2024. Therefore, upon the effective date of this final action, this area will be reclassified by operation of law to Serious nonattainment for the 2015 ozone NAAQS. Once reclassified as Serious, this area will be required to attain the standard ''as expeditiously as practicable'' but no later than 9 years after the initial designation as nonattainment, which in this case would be no later than August 3, 2027.

The Administrative Procedure Act (APA) provides that when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. 5 U.S.C. 553(b)(B). The EPA has determined that there is good cause for making this final agency action without prior proposal and opportunity for comment, because our action to determine whether this area has attained the NAAQS by the attainment date is governed, per CAA section 181(b)(2)(A), solely by area design values as of that date. The area DVs relied upon in this document are calculations based on the certified air quality monitoring data governed by EPA's regulations at 40 CFR part 58 and involve no exercise of judgment or discretion. Thus, notice and public procedures are unnecessary to take this action. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Order 14094 (88 FR 21879, April 11, 2023).

B. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). This action does not contain any information collection activities and serves only to make a final determination that the Northern Wasatch Front nonattainment area failed to attain the 2015 ozone standards by the August 3, 2024, attainment date, as a result of which the area will be reclassified as Serious nonattainment for the 2015 ozone standards by operation of law upon the effective date of this final reclassification action.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This action will not impose any requirements on small entities. The determination of failure to attain the 2015 ozone standards (and resulting reclassifications), do not in and of themselves create any new requirements beyond what is mandated by the CAA. This final action would require the state to adopt and submit SIP revisions to satisfy CAA requirements and would not itself directly regulate any small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The division of responsibility between the Federal government and the states for purposes of implementing the NAAQS is established under the CAA.

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

This action has Tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law.

The EPA has identified one Tribal area within the nonattainment area covered by this final rule, that would potentially be affected by this rulemaking. Specifically, the Skull Valley Band of Goshute Indians is within the Northern Wasatch Front, Utah nonattainment area.

The EPA has concluded that the proposed rule may have Tribal implications for this Tribe for the purposes of Executive Order 13175 but would not impose substantial direct costs upon the Tribe, nor would it preempt Tribal law. As noted previously, a Tribe that is part of an area that is reclassified from Moderate to Serious nonattainment is not required to submit a Tribal Implementation Plan (TIP) revision to address new Serious area requirements. However, when the EPA finalizes the determinations of failure to attain in this action, the nonattainment new source review (NNSR) major source threshold and offset requirements would change for stationary sources seeking preconstruction permits in any nonattainment areas newly reclassified as Serious.

The EPA will communicate with the potentially affected Tribe located within the boundary of the Northern Wasatch Front nonattainment area addressed in this action, including offering government-to-government consultation, as appropriate.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal

agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on communities with environmental justice (EJ) concerns to the greatest extent practicable and permitted by law. Executive Order 14096 (Revitalizing Our Nation's Commitment to Environmental Justice for All, 88 FR 25251, April 26, 2023) builds on and supplements E.O. 12898 and defines EJ as, among other things, the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability in agency decision-making and other Federal activities that affect human health and the environment.

Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898/14096 of achieving environmental justice for communities with EJ concerns.

K. Congressional Review Act

This rule is exempt from the CRA because it is a rule of particular applicability. The rule makes factual determinations for an identified entity (Northern Wasatch Front, UT area), based on facts and circumstances specific to that entity. The determinations of attainment and failure to attain the 2015 ozone NAAQS do not in themselves create any new requirements beyond what is mandated by the CAA.

L. Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 7, 2025. Filing a petition for reconsideration by the Administrator of this action does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of this action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: December 4, 2024.

KC Becker,

Regional Administrator, Region 8.

For the reasons stated in the preamble, title 40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 2. In § 81.345, the table entitled ''Utah—2015 8-Hour Ozone NAAQS [Primary and Secondary]'' is amended by revising the entry for ''Northern Wasatch Front, UT'' to read as follows:

§ 81.345 Utah.

* * * * *

UTAH—2015 8-HOUR OZONE NAAQS

[Primary and Secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Northern Wasatch Front, UT	.....	Nonattainment	11/8/2025	Serious.
Weber County (part):				
All portions of Weber County west of and including Townships 5, 6, and that portion of 7 North Range 1 West that are west of the ridgeline that traces the Wasatch Mountains from the southeast corner of the township to the easternmost extension of the county boundary within the township.				
Tooele County (part):				
In Tooele County, the following Townships or portions thereof as noted (including Tooele City):				
Township 1 South Range 3 West.				
Township 2 South Range 3 West.				
Township 3 South Range 3 West.				
Township 3 South Range 4 West.				
Township 2 South Range 4 West.				
Township 2 South Range 5 West.				
Township 3 South Range 5 West.				
Township 3 South Range 6 West.				
Township 2 South Range 6 West.				
Township 1 South Range 6 West.				
Township 1 South Range 5 West.				
Township 1 South Range 4 West.				
Township 1 South Range 7 West.				
Township 2 South Range 7 West.				
Township 3 South Range 7 West.				
All sections within Township 4 South Range 7 West except for sections 29, 30, 31 and 32.				
Township 4 South Range 6 West.				
Township 4 South Range 5 West.				
Township 4 South Range 4 West.				
Township 4 South Range 3 West.				
Salt Lake County.				

UTAH—2015 8-HOUR OZONE NAAQS—Continued

[Primary and Secondary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Davis County.				
* * * * * * *				

[1] Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country.
[2] This date is August 3, 2018, unless otherwise noted.

* * * * *

[FR Doc. 2024–28851 Filed 12–6–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R07–UST–2024–0452; FRL–12274–03–R7]

Nebraska: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the State of Nebraska's Underground Storage Tank (UST) program submitted by the Nebraska State Marshal (NSFM). This action also codifies EPA's approval of Nebraska's State program and incorporates by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities under the RCRA and other applicable statutory and regulatory provisions.

DATES: This rule is effective February 7, 2025, unless EPA receives adverse comment by January 8, 2025. If EPA receives adverse comments, it will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of February 7, 2025, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: Submit your comments by one of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. *Email: blankenship.marie@epa.gov.*

Instructions: Direct your comments to Docket ID No. EPA–R07–UST–2024–0452.

EPA's policy is that all comments received will be included in the public docket without change and may be available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov,* or email. The Federal *https://www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and also with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. EPA encourages electronic submittals, but if you are unable to submit electronically, please reach out to the EPA contact person listed in the document for assistance.

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information might not be publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

IBR and supporting material: You can view and copy the documents that form the basis for this codification and associated publicly available materials either through *https://www.regulations.gov* or by contacting Marie Blankenship at (913) 551–7908 or *blankenship.marie@epa.gov.* Please call or email the contact listed above if you need access to material indexed but not provided in the docket.

FOR FURTHER INFORMATION CONTACT: Marie Blankenship, Tanks, Toxics, and Pesticides Branch, Land, Chemical, and Redevelopment Division, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7908; email address: *blankenship.marie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval of Revisions to Nebraska's Underground Storage Tank Program

A. Why are revisions to State programs necessary?

States that have received final approval from the EPA under section 9004(b) of RCRA, 42 U.S.C. 6991c(b), must maintain an underground storage tank program that is no less stringent than the Federal UST program. Either EPA or the approved State initiate program revision. When EPA makes revisions to the regulations that govern the UST program, States must revise their programs to comply with the updated regulations and submit these revisions to the EPA for approval. Program revision may be necessary when the controlling Federal or State statutory or regulatory authority is modified or when responsibility for the State program is shifted to a new agency or agencies.

B. What decisions has the EPA made in this rule?

On September 8, 2023, in accordance with 40 CFR 281.51(a), Nebraska submitted a complete program revision application seeking the EPA approval for its UST program revisions (State Application). Nebraska's revisions correspond to the EPA final rule published on July 15, 2015 (80 FR 41566), which revised the 1988 UST regulations and the 1988 State program approval (SPA) regulations (2015 Federal Revisions). As required by 40 CFR 281.20, the State Application contains the following: a transmittal letter requesting approval, a description of the program and operating procedures, a demonstration of the State's procedures ensure adequate enforcement, a Memorandum of Agreement outlining the roles and responsibilities of the EPA and the implementing agency, a statement of certification from the Attorney General, and copies of all relevant State statutes and regulations. We have reviewed the State Application and determined that the revisions to Nebraska's UST program are no less stringent than the corresponding Federal requirements in subpart C of 40 CFR part 281, and that the Nebraska program provides for adequate enforcement of compliance (40 CFR 281.11(b)). Therefore, the EPA grants Nebraska final approval to operate its UST program with the changes described in the program revision application and as outlined below in section I.G. of this document.

C. What is the effect of this approval decision?

This action does not impose additional requirements on the regulated community because the regulations being approved by this rule are already effective in Nebraska and they are not changed by this action. This action merely approves the existing State regulations as meeting the Federal requirements and renders them federally enforceable.

D. Why is EPA using a direct final rule?

EPA is publishing this direct final rule concurrent with a proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. EPA is providing an opportunity for public comment now.

E. What happens if the EPA receives comments that oppose this action?

Along with this direct final rule, the EPA is publishing a separate document in the ''Proposed Rules'' section of this issue of the **Federal Register** that serves as the proposal to approve the State's UST program revisions, providing opportunity for public comment. If EPA receives comments that oppose this approval, EPA will withdraw the direct final rule by publishing a document in the **Federal Register** before the rule becomes effective. The EPA will base any further decision on the approval of the State program changes after considering all comments received during the comment period. EPA will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this approval, you must do so at this time.

F. For what has Nebraska previously been approved?

On August 19, 2002, the EPA finalized a rule approving the Nebraska UST program, effective September 18, 2002, to operate in lieu of the Federal program. The State's program has not previously been codified.

G. What changes are we approving with this action?

On September 8, 2023, in accordance with 40 CFR 281.51(a), Nebraska submitted a complete application for final approval of its UST program revisions adopted on July 15, 2015. The EPA now makes an immediate final decision, subject to receipt of written comments that oppose this action, that Nebraska's UST program revisions satisfy all of the requirements necessary to qualify for final approval. Therefore, EPA grants Nebraska final approval for the following program changes:

Required Federal element	Implementing State authority
40 CFR 281.30, New UST Systems and Notification.	Title 159 NAC Chapter 2; Chapter 3, intro; Chapter 4, section 001; Chapter 6, section 001.
40 CFR 281.31, Upgrading Existing UST Systems.	Title 159 NAC Chapter 6.
40 CFR 281.32, General Operating Requirements.	Title 159 NAC Chapter 4, section 001, section 001.1A; Chapter 5; Chapter 6, sections 001–007; Chapter 7, section 006; Chapter 10, section 006.
40 CFR 281.33, Release Detection	Title 159 NAC Chapter 4; Chapter 7, sections 001–006; Chapter 14; Title 17 NAC Chapter 12.
40 CFR 281.34, Release Reporting, Investigation, and Confirmation.	Title 159 NAC Chapter 6, section 005; Chapter 8, section 001–005; Title 126 NAC Chapter 18, sections 002.01, 002.01C, 002.01D, 002.02–005, 007.02.
40 CFR 281.35, Release Response and Corrective Action.	Title 159 NAC Chapter 8, sections 001, 003–005; Title 126 NAC Chapter 18, sections 003–007; Title 118 NAC Chapter 1–2 6.002–7, 10–11 and appendix B; Title 115 NAC Chapter 3, sections 001, 001.02, 014, 016–018.
40 CFR 281.36, Out-of-service Systems and Closure.	Title 159 NAC Chapter 10, sections 001–005.
40 CFR 281.37, Financial Responsibility for USTs Containing Petroleum.	Title 159 NAC Chapter 9 as it references 40 CFR 280.90 through 280.115.
40 CFR 281.38 Lender Liability	Title 159 NAC Chapter 9, section 002.
40 CFR 281.39, Operator Training	Title 159 NAC Chapter 13, sections 001–002, 003.04–008.02.
40 CFR 281.40 Legal Authorities for Compliance Monitoring.	Title 159 NAC Chapter 6; Chapter 12; Chapter 13, section 002.
40 CFR 281.41, Legal Authorities for Enforcement Response.	Title 159 NAC Chapter 6; Title 126 NAC Chapter 18, section 008.

The State also demonstrates that its program provides adequate enforcement of compliance as described in 40 CFR 281.11(b) and part 281, subpart D. The Nebraska State Fire Marshal (NSFM) has broad statutory authority with respect to USTs to regulate installation, operation, maintenance, closure, and UST releases, and to the issuance of orders. These statutory authorities are found in Nebraska Revised Statutes, Chapters sections 81–15, 117 to 81–15, 127, sections 81–501 to 81–512, and section 66–1501 to 66–1531, and Nebraska Administrative Code, Title 159. The Nebraska Department of Environment and Energy (NDEE) has broad statutory authority for corrective action and the

administration of the State remedial action fund. These statutory authorities are found in: sections 81–1501 to 81–1532, N.R.S., and Titles 115, 118, 126, 178, and 200, NAC. These authorities address rules of practice and procedure, ground water quality standards and cleanup requirements, release reporting and follow-up, and the Petroleum Release Remedial Action Reimbursement Fund.

H. Where are the revised rules different from the Federal rules?

Broader in Scope Provisions

Where an approved State program has a greater scope of coverage than required by Federal law, the additional coverage is not part of the federally-approved program and is not federally enforceable (40 CFR 281.12(a)(3)(ii)). The following Nebraska requirements are considered ''broader in scope'' than the Federal program:

The NSFM has responsibilities with a greater scope of coverage than required by Federal law. NRS section 81–502.

The NSFM has responsibilities for rules and regulations; enforcement; and State procedure with a greater scope of coverage than required by Federal law. NRS section 81–502.04.

The NSFM has duties with a greater scope of coverage than required by Federal law. NRS section 81–503.01(a)–(g), (i).

The NSFM has its own authority to enter and conduct inspections when authorized. NRS section 81–512.

The Nebraska Protection Act defines terms not subject to the UST program. NRS sections 81–1502(1)–(5), (8)–(9), (12)–(13), (15)–(19), (23), (28)–(29), and (31)–(38).

The NDEE has duties with a greater scope of coverage than required by Federal law. NRS section 81–1504(1)–(30), (33)–(58).

The Nebraska Environmental Quality Council has responsibilities to adopt and promulgate rules and regulations; standards of air, land and water with a greater scope of coverage than required by Federal law. NRS section 81–1505.

The Director of the NDEE is authorized to bring State enforcement for violations of State law under a state authority for hearings and issuing orders, requiring monitoring, investigations and corrective action. NRS section 81–1507.

The NDEE is authorized to pursue State civil penalties and injunctive relief. NRS sections 81–1508, 81–1508.01, and 81–1508.02.

The NDEE is authorized to perform inspections and execute search warrants under State authority. NRS section 81–1511.

Portions of the Nebraska UST provisions are applicable to heating oil tanks of greater than 1,100 gallon capacity. NRS section 81–15, 119(10)(b).

Nebraska requires that owners of farm, residential, and heating oil tank systems of less than 1,100 gallon capacity to register such tank systems and pay a one-time registration fee. NRS sections 81–15,119(10)(a) and 81–15–120.

Nebraska establishes permitting requirements on owners and operators of UST systems (*e.g.,* registration, operating, installation, closure). NRS section 81–15, 121.

Nebraska establishes procedures for the denial or revocation of State issued permits. NRS section 81–15–122.

Nebraska establishes procedures for a permit and registration system for all tanks; an inspection fee; inventory-control procedures; procedures for notification of temporarily or permanently abandoned tanks; and procedures for licensing tank installation and removal contractors. NRS sections 81–15–123(2)–(3), (4)(b), (5), (10), and (12) as it refers to certification and subcontractors.

Nebraska sets deadlines for NDEE approval or disapproval of remedial action plans; establishes procedures for the reimbursement of expenses paid by the owner or operator; establishes procedures for the NDEE to prepare a remedial action plan and implement the plan in the event of an unknown or unavailable owner or operator of a facility causing a release; provides that the Environmental Quality Council establish standards; provides access under State law; provides for NDEE briefing and certificates of completion for work completed under a remedial action plan. NRS sections 81–15, 124(2) second and third sentence, 81–15, 124(3) second sentence and full second paragraph, 81–15, 124.01–81–15, 124.02, 81–15, 124.04–81–15, 124.07.

Nebraska establishes a process for penalties and actions to enjoin for violations of the Petroleum Products and Hazardous Substances Storage and Handling act under State law. NSR section 81–15, 125–81–15, 126.

Nebraska requires notice of registration and duty to provide the notice. NSR section 81–15, 127.

The Nebraska remedial fund is structured to reimburse owners and operators of both USTs and aboveground storage tanks for allowable costs of remedial action and third party claims. NRS section 66–1501, *et seq.*

Nebraska provides intervention in a matter in litigation under State law. NSR section 25–328.

Nebraska requires contractor licensure and certification for tank installation and removal contractors. Title 159 NAC Chapter 3.001–3.004.

Nebraska requires all owners and operators to comply with Nebraska financial responsibilities requirements for all categories of UST system owner or operators as of the effective date of the regulations with no extensions or deferrals or comply with the federal financial responsibility requirements. Title 159 NAC Chapter 9.001 and Title 200 NAC Chapter 1 [entire regulation].

Nebraska mandates that fuel distributors, or any person who deposits regulated substances in an UST system, are required to notify owners and operators of the registration requirements. Title 159 NAC Chapter 11.004.

Nebraska establishes approval standards for UST training courses and trainers. Title 159 NAC Chapter 13.003.01–13.003.03.

Nebraska establishes minimum requirements for public hearings for permit decisions which by statue or other agency regulations provide for public notice, public review and comment, and an opportunity to request a public hearing before making a final permit decision. Title 115 NAC Chapter 3.001.01, 3.002–3.013, and 3.015.

Nebraska establishes antidegradation; beneficial uses; narrative and numerical standards and sample collections. Title 118 NAC Chapter 3.

Nebraska has procedures to establish narrative and numerical standards for groundwater classification. Title 118 NAC Chapter 4.

Nebraska establishes procedures for changing a groundwater classification. Title 118 NAC Chapter 5.

Nebraska establishes remedial action provisions for point source pollution events for non-petroleum releases. Title 118 NAC Chapter 6.001 and appendix A.

Nebraska establishes definitions for the management of waste with a greater scope of coverage than required by Federal law. Title 126, NAC Chapter 1.002–1.004, 1.006–1.010, 1.012, 1.014–1.019, 1.023, 1.025–1.029, 1.030.02, 1.032, 1.035, 1.039, 1.041–1.044, 1.046–1.047.

Nebraska establishes provisions for waste management permits and licenses; land application of paunch; and fertilizer and pesticide wastewater with a greater scope of coverage than required by Federal law. Nebraska also reserves chapters for future use. Title 126 NAC Chapters 2–17, 19 and appendix I.

Nebraska establishes provisions for rules and regulations related to:

recreation camps; design construction; operation and maintenance of public swimming pools; rules, regulations and standards governing mobile home parks; clean indoor air; fees for inspection of private water supply or private sewage disposal facilities; rules and regulations governing a private well; licensure under the water well standards and contractors' practice act; fees under the water well standards and contractors' practice act; water well standards and contractors' licensing board; asbestos projects; lead based paint activities; and methamphetamine cleanups with a greater scope of coverage than required by Federal law. Nebraska also reserves chapters for future use. Title 178 NAC Chapters 1–11, 13–24.

The following definitions associated with well installation are not applicable to the UST program: Abandoned Water Well, Driven Sandpoint Well, Ground Water Heat Pump Well, Illegal Water Well, Inactive Status Water Well, Injection Well, Open Hole Well, Service connection, Special Irrigation District. Title 178 NAC Chapter 12–002.

Nebraska establishes procedures for the installation of potable well construction; non-potable well construction; public water supply systems; ground water heat pump wells; installation of pumps and pumping equipment as it relates to disinfection associated with potable wells; and procedures for driven sandpoint wells and closed loop heat pump wells. Nebraska further offers a Waiver of Disinfection. Title NAC 178 Chapter 12–04–12–05, 12–08, 12–10, 12–011.01B2, 12–012.08C, 12–012.08G, and Waiver of Disinfection.

Nebraska requires owners and operators of UST systems that permanently closed between December 22, 1988, and January 1, 1989, to close such UST systems when directed to do so by the NSFM. NFPA 30: Flammable and Combustible Liquids Code (21.7.4.3.1–21.7.4.3.3) 2012 Version.

Nebraska requires UST system owners and operators to have a tightness test performed on tanks and piping prior to placing the tank system back into service after receiving an extension to the 12-month temporary closure period. National Fire Protection Association 30: Flammable and Combustible Liquids Code (21.7.4.3.1–21.7.4.3.3) 2012 Version.

More Stringent Provisions

Nebraska limits the means by which owners and operators can demonstrate compliance with installation of a new UST system. Only an installer that has been certified or licensed by the State can provide certification of compliance on the UST notification form. Title 159 NAC Chapter 3 as it incorporates 40 CFR 280.20(e)(2).

Nebraska requires additional design and installation standards for new UST systems. Title 159 NAC Chapter 4.001.01–4.001.07.

The Federal program requires all cathodic protection systems to be tested within 6 months of installation. Nebraska general operating requirements for existing UST systems require annual testing for impressed current cathodic protection systems after the initial testing. Title 159 NAC Chapter 6.002.01A1.

Nebraska general operating requirements for existing UST systems requires repaired tanks, piping, overfill, and spill prevention equipment be tested prior to placing the system back into service, or 30 days following the date of completion of the repair, whichever occurs first. Title 159 NAC Chapter 6.004.01.

Nebraska general operating requirements for existing UST systems requires additional record-keeping and reporting. Title 159 NAC Chapter 6.005–6.006.

Nebraska general operating requirements for existing UST systems requires that if a ball float is to be abandoned in place, a drop tube shut off or audible alarm will be set at 85 percent tank capacity to prevent overfill. Title 159 NAC Chapter 6.006.01.

Nebraska excludes all UST systems larger than 1,100 gallons used to store heating oil from all release detection requirements except that they must instead perform the manual tank gauging procedures in 40 CFR 280.43(b) on a monthly basis from April 1 to November 1. Title 159 NAC Chapter 7.001.01.

Nebraska release detection requirements require owners and operators to conduct and record the daily product inventory control requirements as described in 40 CFR 280.43(a)(1)–(6) for all new and existing UST systems. However, UST systems eligible for and utilizing manual tank gauging in accordance with 40 CFR 280.43(b), do not need to meet the daily inventory requirement. Title 159 NAC Chapter 7.004.

Nebraska release and suspected release reporting requires notification to NSFM and NDEE within 24 hours by the owner and operator of the tank. Title 159 NAC Chapter 8.005.

Nebraska site assessment at closure or change-in-service requires sampling analysis, in- place closure assessment, removal closure assessment, tank excavation requirements, line excavation assessment, and reporting requirements. Title 159 NAC Chapter 10.003–10.004.

Nebraska operator training requirements for Class A, Class B, and Class C operators establish owner and operator responsibilities, operator training requirements, operator examination requirements, reciprocity, timing of operator training, operator retraining and owner and operator documentation. Title 159 NAC Chapter 13.001–13.002, 13.003.04–13.003.05, 13.004–13.008.

Nebraska establishes ground water quality standards and use classifications for ground water regulatory programs. Title 118 NAC Chapter 1–2, 6.002, 7, appendix B.

Nebraska establishes water well construction, pump installation and water well decommissioning standards for dewatering wells, ground water monitoring and recovery wells, and test holes. Nebraska further provides for declaratory orders about substantially equivalent procedures or materials and variances. Title 178 NAC Chapter 12.001, 12–03, 12–06–12–07, 12–09, 12–011.01–12–011.01B1, 12–011.01C–12–012.08B, 12–012.08D–12–012.08F2, 12–012.09–12–14, the tables and figures, and the following definitions found at Title 178, Chapter 12–002 Annular Fill, Annular Space, Aquifer, Aquifer Seal, Primary Aquifer Seal, Surface Seal, Backflow Preventer, Bentonite, Bentonite Seal, Bored or Dug Well, Casing, Cesspool, Clay, Community Water System, Confining Layer, Construction of Water Wells, Contamination, Decommissioned when used in relation to a water well, Department, Dewatering Well, Discharge Pipe, Distribution Piping, Good Cause, Gravel Pack, Ground Water, Grout, Installation of Pumps and Pumping Equipment, Monitoring Well, Non-potable Well, Observation Well, Person, Pitless Unit, Pollution, Potable Well, Primary Aquifer Seal, Public Water System, (Licensed) Pump Installation Contractor, (Licensed) Pump Installation Supervisor, Pumps and Pumping Equipment, Recovery Well, Sanitary Well Seal, Screen Apertures, Screened Vent, Secure Cover or Cap, Seepage Pit, Septic Tank, Soil Absorption System (Septic Lateral Field), Static Water Level, Substantially Equivalent, Subsurface Disposal System, Supervision or its derivatives, Surface Seal, Test Hole, Tremie Pipe, Watertight Casing, Watertight Secure Cover, Water Well, (Licensed) Water Well Contractor, (Licensed) Water Well Drilling Supervisor, Well Development, Well Pit, Well Screen.

II. Codification

A. What is codification?

Codification is the process of placing a State's statutes and regulations that comprise the State approved UST program into the CFR. Section 9004(b) of RCRA, as amended, allows the EPA to approve State UST programs to operate in lieu of the Federal program. The EPA codifies its authorization of State programs 40 CFR part 282 and incorporates by reference State statutes and regulations that the EPA will enforce under sections 9005 and 9006 of RCRA and any other applicable state provisions. The incorporation by reference of State authorized programs in the CFR should substantially enhance the public's ability to discern the current status of the approved State program and State requirements that can be federally enforced. This effort provides clear notice to the public of the scope of the approved program in each State.

B. What is the history of codification of Nebraska's UST program?

The EPA has not previously incorporated by reference and codified Nebraska's approved UST program. Through this action, the EPA is incorporating by reference and codifying Nebraska's State program in 40 CFR 282.77 to include the program and the approved revisions.

C. What codification decisions have we made in this rule?

Incorporation by reference: In this rule, we are finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are finalizing the incorporation by reference of the federally approved Nebraska UST program described in the amendments to 40 CFR part 282 set forth below. The EPA has made, and will continue to make, this document generally available through *https://www.regulations.gov* or by contacting the EPA Region 7 contact listed in the **ADDRESSES** section of this preamble.

The purpose of this **Federal Register** document is to codify Nebraska's approved UST program. The codification reflects the State program that would be in effect at the time EPA's approved revisions to the Nebraska UST program addressed in this direct final rule become final. The document incorporates by reference Nebraska's UST statutes and regulations and clarifies which of these provisions are included in the approved and federally enforceable program. By codifying the approved Nebraska program and by amending the CFR, the public will more easily be able to discern the status of the federally-approved requirements of the Nebraska program.

EPA is incorporating by reference the Nebraska approved UST program in 40 CFR 282.77. Section 282.77(d)(1)(i) incorporates by reference for enforcement purposes the State's statutes and regulations.

Section 282.77 also references the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are approved as part of the UST program under Subtitle I of RCRA. These documents are not incorporated by reference.

D. What is the effect of Nebraska's codification on enforcement?

The EPA retains the authority under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions and to issue orders in approved States. With respect to these actions, EPA will rely on Federal sanctions, Federal inspection authorities, and Federal procedures rather than the State authorized analogues to these provisions. Therefore, the EPA is not incorporating by reference such particular, approved Nebraska procedural and enforcement authorities. Section 282.77(d)(1)(ii) of 40 CFR lists those approved Nebraska authorities that would fall into this category.

E. What State provisions are not part of the codification?

The public also needs to be aware that some provisions of the State's UST program are not part of the federally approved State program. Such provisions are not part of the RCRA Subtitle I program because they are ''broader in scope'' than Subtitle I of RCRA. Section 281.12(a)(3)(ii) of 40 CFR states that where an approved State program has provisions that are broader in scope than the Federal program, those provisions are not a part of the federally approved program. As a result, State provisions which are broader in scope than the Federal program are not incorporated by reference for purposes of federal enforcement in part 282. Section 282.77(d)(1)(iii) lists for reference and clarity the Nebraska statutory and regulatory provisions which are broader in scope than the Federal program and which are not, therefore, part of the approved program being codified in this document. Provisions that are broader in scope cannot be enforced by EPA; the State, however, will continue to implement and enforce such provisions under State law.

III. Statutory and Executive Order Reviews

This action only applies to Nebraska's UST Program requirements pursuant to RCRA section 9004 and imposes no requirements other than those imposed by State law. It complies with applicable Executive Orders (EOs) and statutory provisions as follows:

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), because this action approves and codifies State requirements for the purpose of RCRA section 9004 and imposes no additional requirements beyond those imposed by State. Therefore, this action was not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.,* because this action authorizes State requirements pursuant to RCRA section 9004 and imposes no requirements beyond those imposed by State.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandates as described in UMRA, 2 U.S.C. 1501 *et seq.,* and does not significantly or uniquely affect small governments because this action approves and codifies pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State.

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

This action approves and codifies pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

F. Executive Order 13132: Federalism

This action will not have substantial direct effects on the States, on the relationship between the National Government and the State on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves and codifies State requirements as part of the State RCRA underground storage tank program without altering the relationship or the distribution of power and responsibilities established by RCRA.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it approves a State program.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a ''significant regulatory action'' as defined under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Under RCRA section 9004(b), EPA grants a State's application for approval as long as the States the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State approved application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of Section 12(d) of the NTTAA, 15 U.S.C. 272 note, do not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations; and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023) direct Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations. Because this action approves pre-existing State rules that are no less stringent than existing Federal requirements and imposes no additional requirements beyond those imposed by State and there are no anticipated significant adverse human health or environmental effects, this rule is not subject to Executive Order 12898 or Executive Order 14096.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report containing this document and other required information to each House of the Congress and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). However, this action will be effective February 7, 2025 because it is a direct final rule.

Authority: This rule is issued under the authority of sections 2002(a), 7004(b), and 9004 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

List of Subjects in 40 CFR Part 282

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Incorporation by reference, Indians-lands, Insurance, Intergovernmental relations, Oil pollution, Penalties, Petroleum, Reporting and recordkeeping requirements, State and local governments, Surety bonds, Underground storage tanks, Water pollution control, Water supply.

Dated: November 22, 2024.

Meghan A. McCollister,

Regional Administrator, EPA Region 7.

For the reasons set forth in the preamble, EPA is amending 40 CFR part 282 as follows:

PART 282—APPROVED UNDERGROUND STORAGE TANK PROGRAMS

■ 1. The authority citation for part 282 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

■ 2. Add § 282.77 to read as follows:

§ 282.77 Nebraska State-Administered Program.

(a) *History of the approval of Nebraska's program.* The State of Nebraska is approved to administer and enforce an underground storage tank program in lieu of the Federal program under Subtitle I of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6991 *et seq*. The State program, as administered by the Nebraska State Fire Marshal, was approved by EPA pursuant to 42 U.S.C. 6991c and part 281 of this Chapter. EPA approved the Nebraska program on August 19, 2002, and it was effective on September 18, 2002. A subsequent program revision application was approved by EPA and became effective on February 7, 2025.

(b) *Enforcement authority.* Nebraska has primary responsibility for administering and enforcing its federally approved underground storage tank program. However, EPA retains the authority to exercise its inspection and enforcement authorities under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, as well as under any other applicable statutory and regulatory provisions.

(c) *Retaining program approval.* To retain program approval, Nebraska must revise its approved program to adopt new changes to the federal Subtitle I program which makes it more stringent, in accordance with section 9004 of RCRA, 42 U.S.C. 6991c and 40 CFR part 281, subpart E. If Nebraska obtains approval for the revised requirements pursuant to section 9004 of RCRA, 42 U.S.C. 6991c, the newly approved statutory and regulatory provisions will be added to this subpart and notice of any change will be published in the **Federal Register**.

(d) *Final program approval.* Nebraska has final approval for the following elements of its program application originally submitted to EPA and approved on August 19, 2002 and effective September 18, 2002, and the program revision application approved by EPA, effective on February 7, 2025:

(1) *State statutes and regulations*—(i) *Incorporation by reference.* The provisions cited in this paragraph, and listed in appendix A to part 282, are incorporated by reference as part of the underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.* The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the Nebraska regulations and statutes that are incorporated by reference in this paragraph from the Nebraska State Fire Marshal website at: *https://sfm.nebraska.gov* or the Nebraska State Fire Marshal Agency, 246 South 14th Street, Suite 1, Lincoln, NE 68508–1804. You may inspect all approved material at the EPA Region 7 Office, 11201 Renner Boulevard, Lenexa, KS 66219; telephone number: (913) 551–7908; or the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

(A) EPA-Approved Nebraska Statutory Requirements Applicable to the Underground Storage Tank Program, September 2024.

(B) EPA-Approved Nebraska Regulatory Requirements Applicable to the Underground Storage Tank Program, September 2024.

(ii) *Legal basis.* EPA evaluated the following statutes and regulations, which provide the legal basis for the State's implementation of the underground storage tank program, but they are not being incorporated by reference for enforcement purposes and do not replace Federal authorities:

(A) Nebraska Revised Statutes section 81–502.

(B) Nebraska Revised Statutes section 81–502.04.

(C) Nebraska Revised Statutes section 81–503.01.

(D) Nebraska Revised Statutes section 81–512.

(E) Nebraska Revised Statutes section 81–1502.

(F) Nebraska Revised Statutes section 81–1504.

(G) Nebraska Revised Statutes section 81–1505.

(H) Nebraska Revised Statutes section 81–1507.

(I) Nebraska Revised Statutes sections 81–1508, 81–1508.01—81–1508.02.

(J) Nebraska Revised Statutes section 81–1511.

(K) Nebraska Revised Statutes section 81–15, 117.

(L) Nebraska Revised Statutes section 81–15, 118.

(M) Nebraska Revised Statutes section 81–15, 119.

(N) Nebraska Revised Statutes section 81–15, 120.

(O) Nebraska Revised Statutes section 81–15, 121.

(P) Nebraska Revised Statutes section 81–15, 122.

(Q) Nebraska Revised Statutes section 81–15, 123.

(R) Nebraska Revised Statutes sections 81–15, 124, 81–15, 124.01–81–15, 124.07.

(S) Nebraska Revised Statutes section 81–15, 125.

(T) Nebraska Revised Statutes section 81–15, 126.

(U) Nebraska Revised Statutes section 81–15, 127.

(V) Nebraska Revised Statutes section 66–1531, *et seq.*

(W) Nebraska Revised Statutes section 25–328.

(X) Nebraska Administrative Code Title 159 Chapters 1–14.

(Y) Nebraska Administrative Code Title 115 Chapter 3.

(Z) Nebraska Administrative Code Title 118 Chapters 1–7, appendix A and B.

(AA) Nebraska Administrative Code Title 126 Chapters 1–19, appendix A.

(BB) Nebraska Administrative Code Title 178 Chapters 1–24.

(CC) Nebraska Administrative Code Title 200 Chapter 1.

(DD) National Fire Protection Association 30: Flammable and Combustible Liquids Code (21.7.4.3.1–21.7.4.3.3) 2012 Version.

(iii) *Provisions not incorporated by reference.* The following statutory and regulatory provisions are broader in scope than the Federal program, are not part of the approved program, and are not incorporated by reference in this section for enforcement purposes:

(A) Nebraska Revised Statutes section 81–502.

(B) Nebraska Revised Statutes section 81–502.04.

(C) Nebraska Revised Statutes section 81–503.01(1)(a)–(g), (i).

(D) Nebraska Revised Statutes section 81–512.

(E) Nebraska Revised Statutes section 81–1502(1)–(5), (8)–(9), (12)–(13), (15)–(19), (23), (28)–(29), and (31)–(38).

(F) Nebraska Revised Statutes section 81–1504(1)–(30), (33)–(58).

(G) Nebraska Revised Statutes section 81–1505.

(H) Nebraska Revised Statutes section 81–1507.

(I) Nebraska Revised Statutes sections 81–1508, 81–1508.01, 81–1508.02.

(J) Nebraska Revised Statutes section 81–1511.

(K) Nebraska Revised Statutes section 81–15, 119(10)(a)–(b).

(L) Nebraska Revised Statutes section 81–15, 120.

(M) Nebraska Revised Statutes section 81–15, 121.

(N) Nebraska Revised Statutes section 81–15, 122.

(O) Nebraska Revised Statutes section 81–15, 123(2)–(3), (4)(b), (5), (10), (12) as it refers to certification and subcontractors.

(P) Nebraska Revised Statutes sections 81–15, 124(2) second and third sentence, 81–15,124(3) second sentence and full second paragraph, 81–15, 124.01–81–15, 124.02, 81–15, 124.04–81–15, 124.07.

(Q) Nebraska Revised Statutes section 81–15, 125.

(R) Nebraska Revised Statutes section 81–15, 126.

(S) Nebraska Revised Statutes section 81–15, 127.

(T) Nebraska Revised Statutes section 66–1501, *et seq.* [entire statute].

(U) Nebraska Revised Statutes section 25–328.

(V) Nebraska Administrative Code, Title 159 Chapter 3.001–3.004.

(W) Nebraska Administrative Code, Title 159 NAC Chapter 9.001.

(X) Nebraska Administrative Code, Title 159 Chapter 11.004.

(Y) Nebraska Administrative Code, Title 159 Chapter 13.003.01–13.003.03.

(Z) Nebraska Administrative Code Title 115 Chapter 3.001.01, 3.002–3.013, 3.015.

(AA) Nebraska Administrative Code Title 118 Chapter 3.

(BB) Nebraska Administrative Code Title 118 Chapter 4.

(CC) Nebraska Administrative Code Title 118 Chapter 5.

(DD) Nebraska Administrative Code Title 118 Chapter 6.001.

(EE) Nebraska Administrative Code Title 118 appendix A.

(FF) Nebraska Administrative Code Title 126 Chapter 1.002–1.004, 1.006–1.010, 1.012, 1.014–1.019, 1.023, 1.025–1.029, 1.030.02, 1.032, 1.035, 1.039, 1.041–1.044, 1.046–1.047.

(GG) Nebraska Administrative Code Title 126 Chapter 2.

(HH) Nebraska Administrative Code Title 126 Chapter 3.

(II) Nebraska Administrative Code Title 126 Chapter 4.

(JJ) Nebraska Administrative Code Title 126 Chapter 5.

(KK) Nebraska Administrative Code Title 126 Chapter 6.
(LL) Nebraska Administrative Code Title 126 Chapter 7.
(MM) Nebraska Administrative Code Title 126 Chapter 8.
(NN) Nebraska Administrative Code Title 126 Chapter 9.
(OO) Nebraska Administrative Code Title 126 Chapter 10.
(PP) Nebraska Administrative Code Title 126 Chapter 11.
(QQ) Nebraska Administrative Code Title 126 Chapter 12.
(RR) Nebraska Administrative Code Title 126 Chapter 13.
(SS) Nebraska Administrative Code Title 126 Chapter 14.
(TT) Nebraska Administrative Code Title 126 Chapter 15.
(UU) Nebraska Administrative Code Title 126 Chapter 16.
(VV) Nebraska Administrative Code Title 126 Chapter 17.
(WW) Nebraska Administrative Code Title 126 Chapter 19.
(XX) Nebraska Administrative Code Title 126 appendix I.
(YY) Nebraska Administrative Code Title 178 Chapter 1.
(ZZ) Nebraska Administrative Code Title 178 Chapter 2.
(AAA) Nebraska Administrative Code Title 178 Chapter 3.
(BBB) Nebraska Administrative Code Title 178 Chapter 4.
(CCC) Nebraska Administrative Code Title 178 Chapter 5.
(DDD) Nebraska Administrative Code Title 178 Chapter 6.
(EEE) Nebraska Administrative Code Title 178 Chapter 7.
(FFF) Nebraska Administrative Code Title 178 Chapter 8.
(GGG) Nebraska Administrative Code Title 178 Chapter 9.
(HHH) Nebraska Administrative Code Title 178 Chapter 10.
(III) Nebraska Administrative Code Title 178 Chapter 11.
(JJJ) Nebraska Administrative Code Title 178 Chapters 12–04–12–05, 12–08, 12–10, 12–011.01B2, 12–012.08C, 12–012.08G, the Waiver of Disinfection, and the following definitions found at Title 178, Chapter 12–002: Abandoned Water Well, Driven Sandpoint Well, Ground Water Heat Pump Well, Illegal Water Well, Inactive Status Water Well, Injection Well, Open Hole Well, Service connection, Special Irrigation District.
(KKK) Nebraska Administrative Code Title 178 Chapter 13.
(LLL) Nebraska Administrative Code Title 178 Chapter 14.
(MMM) Nebraska Administrative Code Title 178 Chapter 15.
(NNN) Nebraska Administrative Code Title 178 Chapter 16.
(OOO) Nebraska Administrative Code Title 178 Chapter 17.
(PPP) Nebraska Administrative Code Title 178 Chapter 18.
(QQQ) Nebraska Administrative Code Title 178 Chapter 19.
(RRR) Nebraska Administrative Code Title 178 Chapter 20.
(SSS) Nebraska Administrative Code Title 178 Chapter 21.
(TTT) Nebraska Administrative Code Title 178 Chapter 22.
(UUU) Nebraska Administrative Code Title 178 Chapter 23.
(VVV) Nebraska Administrative Code Title 178 Chapter 24.
(WWW) Nebraska Administrative Code Title 200 Chapter 1 [entire regulation].
(XXX) National Fire Protection Association 30: Flammable and Combustible Liquids Code (21.7.4.3.1–21.7.4.3.3) 2012 Version.

(2) *Statement of legal authority.* The ''State of Nebraska Office of the Attorney General Letter'', signed by the Nebraska Attorney General on August 17, 2022, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(3) *Demonstration of procedures for adequate enforcement.* The ''Demonstration of Adequate Enforcement Procedures'' submitted as part of the original application on September 8, 2023, and as part of the program revision application on September 8, 2023, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(4) *Program description.* The program description and any other material submitted as part of the original application on September 8, 2023, and as part of the program revision application on September 8, 2023, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(5) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region 7 and the Nebraska Department of Environmental Quality and the Nebraska State Fire Marshal's Office, signed by the EPA Regional Administrator on February 10, 2019, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

■ 3. Appendix A to part 282 is amended by adding an entry for ''Nebraska'' to read as follows:

Appendix A to Part 282—State Requirements Incorporated by Reference in Part 282 of the Code of Federal Regulations

* * * * *

Nebraska

(a) The statutory provisions include:
(1) Nebraska Revised Statutes section 81–503.01(1)(h).
(2) Nebraska Revised Statutes section 81–1502(6)–(7), (10)–(11), (14), (20)–(22), (24)–(27), and (30).
(3) Nebraska Revised Statutes section 81–1504(31)–(32).
(4) Nebraska Revised Statutes section 81–15, 117.
(5) Nebraska Revised Statutes section 81–15, 118.
(6) Nebraska Revised Statutes section 81–15, 119(1)–(10), (10)(c)–(11).
(7) Nebraska Revised Statutes section 81–15, 123(1), (4)(a), (6)–(9), (11), (12) as it refers to training operators.
(8) Nebraska Revised Statutes sections 81–15, 124(1)–(2) and (3) first sentence.
(9) Nebraska Revised Statutes sections 81–15, 124.03.
(b) The regulatory provisions include:
(1) Nebraska Administrative Code Title 159 Chapter 1.
(2) Nebraska Administrative Code Title 159 Chapter 2.
(3) Nebraska Administrative Code, Title 159 Chapter 3 as it references 40 CFR 80.20(e)(2).
(4) Nebraska Administrative Code Title 159 Chapter 4.
(5) Nebraska Administrative Code Title 159 Chapter 5.
(6) Nebraska Administrative Code Title 159 Chapter 6.
(7) Nebraska Administrative Code Title 159 Chapter 7.
(8) Nebraska Administrative Code Title 159 Chapter 8.
(9) Nebraska Administrative Code Title 159 Chapter 9 as it adopts 40 CFR 280.90 through 280.115 by reference and 9.002.
(10) Nebraska Administrative Code Title 159 Chapter 10.
(11) Nebraska Administrative Code Title 159 Chapter 11.001–11.0003.02.
(12) Nebraska Administrative Code Title 159 Chapter 12.
(13) Nebraska Administrative Code Title 159 Chapter 13.001–13.002, 13.004–13.008.
(14) Nebraska Administrative Code Title 159 Chapter 14.
(15) Nebraska Administrative Code Title 115 Chapter 3.001.02, 3.014, 3.016–3.018.
(16) Nebraska Administrative Code Title 118 Chapter 1.
(17) Nebraska Administrative Code Title 118 Chapter 2.
(18) Nebraska Administrative Code Title 118 Chapter 6.002.
(19) Nebraska Administrative Code Title 118 Chapter 7.
(20) Nebraska Administrative Code Title 118 appendix B.

(21) Nebraska Administrative Code Title 126 Chapter 1.001, 1.005, 1.011, 1.013, 1.020–1.022, 1.024, 1.030.01, 1.031, 1.033–1.034, 1.036–1.038, 1.040, 1.045.

(22) Nebraska Administrative Code Title 126 Chapter 18.

(23) Nebraska Administrative Code Title 178 Chapters 12.001, 12–03, 12–06—12–07, 12–09, 12–011.01—12–011.01B1, 12–011.01C—12–012.08B, 12–012.08D—12–012.08F2, 12–012.09—12–14, the tables and figures, and the following definitions found at Title 178, Chapter 12–002 Annular Fill, Annular Space, Aquifer, Aquifer Seal, Primary Aquifer Seal, Surface Seal, Backflow Preventer, Bentonite, Bentonite Seal, Bored or Dug Well, Casing, Cesspool, Clay, Community Water System, Confining Layer, Construction of Water Wells, Contamination, Decommissioned when used in relation to a water well, Department, Dewatering Well, Discharge Pipe, Distribution Piping, Good Cause, Gravel Pack, Ground Water, Grout, Installation of Pumps and Pumping Equipment, Monitoring Well, Non-potable Well, Observation Well, Person, Pitless Unit, Pollution, Potable Well, Primary Aquifer Seal, Public Water System, (Licensed) Pump Installation Contractor, (Licensed) Pump Installation Supervisor, Pumps and Pumping Equipment, Recovery Well, Sanitary Well Seal, Screen Apertures, Screened Vent, Secure Cover or Cap, Seepage Pit, Septic Tank, Soil Absorption System (Septic Lateral Field), Static Water Level, Substantially Equivalent, Subsurface Disposal System, Supervision or its derivatives, Surface Seal, Test Hole, Tremie Pipe, Watertight Casing, Watertight Secure Cover, Water Well, (Licensed) Water Well Contractor, (Licensed) Water Well Drilling Supervisor, Well Development, Well Pit, Well Screen.

[FR Doc. 2024–28140 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 11

[Docket No. NIH–2024–0001]

RIN 0925–AA71

Clinical Trials Registration and Results Information Submission

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Department of Health and Human Services (HHS), through the National Institutes of Health (NIH), is amending its regulation governing clinical trials registration and results information submission to update throughout the regulation the internet web address or uniform resource locator (URL) of the site that provides information about formatting of information for submission, procedures, and tools as specified in the regulation.

DATES: This final rule is effective December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, Division of Management Support, 6011 Executive Boulevard, Suite 601, Rockville, Maryland 20852–7669, telephone 301–435–3343, email *dhernandez@od.nih.gov*.

SUPPLEMENTARY INFORMATION: NIH is completing a multiyear initiative to modernize the *ClinicalTrials.gov* website to deliver an improved user experience on an updated platform that enhances efficiency. The modernized website integrates content from the *prsinfo.clinicaltrials.gov* website, which is referenced in several sections of 42 CFR part 11 as the web address for obtaining information on formatting and other guidance, into the centralized *ClinicalTrials.gov* website at *https://clinicaltrials.gov* for convenience and ease of access. This address change necessitates amending the regulation to update the URL for the *prsinfo.clinicaltrials.gov* successor site. NIH considered other options and concluded that this final rule technical amendment is necessary because the current codified URL is referenced throughout the regulation itself (*i.e.,* as opposed to the Preamble alone). Moreover, the ''or successor site'' modifier is not always used in the regulation; for example, 42 CFR 11.8 states ''Information submitted under this part must be submitted electronically to *ClinicalTrials.gov,* in the format specified at *https://prsinfo.clinicaltrials.gov*.''

The address change necessitates amending the regulation codified at 42 CFR part 11 by removing the URL address *https://prsinfo.clinicaltrials.gov* wherever it appears in part 11, and adding, in its place, the URL *https://clinicaltrials.gov* or successor site.

Specifically, this action results in removing the URL *https://prsinfo.clinicaltrials.gov* and adding, in its place, the URL *https://clinicaltrials.gov* or successor site in §§ 11.4(c)(2)(ii) and (c)(3), 11.8, 11.44(e)(3)(i), 11.48(a)(5) and (b), 11.54(a)(1) and (b)(1), and 11.64(b)(1) in part 11.

Amending the regulation is time sensitive, as NIH completed integration of content from the *prsinfo.clinicaltrials.gov* website into the modernized *ClinicalTrials.gov* website in June 2024. The address change is cost neutral, editorial in nature, and does not impose any new regulatory requirements on affected parties.

Matters of Regulatory Procedure

Administrative Procedure Act

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA generally exempts rules from the requirements of notice and comment rulemaking when an agency ''for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)).

HHS has determined that notice and public comment are unnecessary because this amendment to the regulation provides only technical or non-substantive, administrative changes to specify the location of information about formatting of information for submission, procedures, and tools as specified in the regulation.

Additionally, HHS finds good cause for these amendments to become effective on the date of publication of this rulemaking action. The APA allows an effective date of less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.SC. 553(d)(3). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, HHS finds good cause for this correction to become effective on the date of publication of this rulemaking action.

Further, it is in the public interest that correct and up-to-date information be contained in the affected sections of the regulation at 42 CFR part 11 as soon as possible.

Regulatory Impact Analysis

NIH examined the impacts of this rule under Executive Order 12866, Regulatory Planning and Review; Executive Order 13563, Improving Regulation and Regulatory Review; Executive Order 14094, Modernizing Regulatory Review; Executive Order 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601–612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''not significant'' under section 3(f) and does not meet the criteria set forth in 5 U.S.C. 804(2) under subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Thus, a RIA is unnecessary.

Executive Order 13132

Executive Order 13132, ''Federalism,'' requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Secretary, HHS, has reviewed this rule as required under the Executive order and determined that it will not have federalism implications. The Secretary, HHS, certifies that the rule will not have effect on the States or on the distribution of power and responsibilities among various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires agencies to analyze regulatory options that would minimize the significant economic impact of a rule on small entities. The Secretary has determined that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written statement, to include an assessment of anticipated costs and benefits, before proposing any rule that includes a Federal mandate that may result in the expenditure by State, local and Tribal governments or more, in the aggregate or by the private sector, of $100,000.000 [adjusted annually for inflation (with base year 1995)] in any 1 year. The current inflation-adjusted statutory threshold as of January 2024 is approximately $183 million based on the Bureau of Labor Statistics inflation calculator. The Secretary, HHS, certifies that that this rule does not mandate any spending by State, local, or Tribal government in the aggregate or by the private sector.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) is not applicable, because this rule does not contain any new information collection or record keeping requirements that require the approval of the Office of Management and Budget, and this rule does not impact information collection and recordkeeping requirements in part 11 that are already approved under OMB Control Number 0925–0586.

Congressional Review Act

The Secretary, HHS, has determined this rule is a non-major rule under the Congressional Review Act (5 U.S.C. chapter 8) and has provided a report thereon to the Senate, House of Representatives and General Accounting Office in accordance with that law.

List of Subjects in 42 CFR Part 11

Biologics, Drugs, Human research subjects, Information, Laboratories, Medical devises, Medical research, Reporting and recordkeeping requirements.

Accordingly, under the authority of 42 U.S.C. 216, the Department of Health and Human Services amends 42 CFR part 11 by making the following technical amendment:

PART 11—CLINICAL TRIALS REGISTRATION AND RESULTS INFORMATION SUBMISSION

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b).

§§ 11.4, 11.8, 11.44, 11.48, 11.54, and 11.64 [Amended]

■ 2. Amend §§ 11.4, 11.8, 11.44, 11.48, 11.54, and 11.64 by removing the URL ''*https://prsinfo.clinicaltrials.gov*'' wherever it appears, and adding, in its place, the text ''*https://clinicaltrials.gov* or successor site''.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–28475 Filed 12–6–24; 8:45 am]

BILLING CODE 4140–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[WP Docket No. 07–100; FCC 23–3; FR ID 261942]

Improving Public Safety Communications in the 4.9 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule, announcement of compliance date.

SUMMARY: In this document, the Federal Communications Commission (FCC) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collections associated with certain rules adopted in the Seventh Report and Order, in WP Docket No. 07–100; FCC 23–3. This document is consistent with the Seventh Report and Order, which directs the Public Safety and Homeland Security Bureau and the Wireless Telecommunications Bureau to publish a document in the **Federal Register** announcing a compliance date for the rule section and revise the rule accordingly.

DATES:

Effective Date: December 9, 2024.

Compliance Date: Compliance with 47 CFR 90.1207(e) and (f) published at 88 FR 12565 on February 28, 2023, is required as of December 9, 2024.

ADDRESSES: Federal Communications Commission, 45 L St. NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Brian Marenco of the Public Safety and

Homeland Security Bureau, at (202) 418–0838 or *Brian.Marenco@fcc.gov*. For additional information concerning the Paperwork Reduction Act information collection requirements contact Nicole Ongele at (202) 418–2991 or via email: *Nicole.Ongele@fcc.gov*.

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the information collection requirements in § 90.1207(e) and (f) on September 7, 2023. This rule section was adopted in the Commission's Seventh Report and Order, in WP Docket No. 07–100; FCC 23–3, published at 88 FR 12565, February 28, 2023. In this Seventh Report and Order, the Commission adopted a proposal to collect more granular data on public safety deployments in the 4.9 GHz band. The Commission also decided to continue using the Universal Licensing System (ULS) as the licensing database for public safety operations in the 4.9 GHz band. The Commission directed the Public Safety and Homeland Security Bureau and the Wireless Telecommunications Bureau (collectively the Bureaus) to make any necessary enhancements to ULS and obtain any necessary review under the Paperwork Reduction Act, and announce by a notice when ULS is prepared to accept the granular data specified in § 90.1207(e) and (f) on public safety operations in the 4.9 GHz band. The Commission also directed the Bureaus to announce the compliance date for § 90.1207(e) and (f) by a subsequent notice and to cause § 90.1207(g) to be revised accordingly. ULS will be prepared to accept the granular data on December 9, 2024. Therefore, consistent with instructions from the Seventh Report and Order, this document revises § 90.1207 by adding compliance dates to paragraph (g) which states that compliance with paragraphs (e) and (f) is not required until paragraph (g) is updated. The Commission publishes this document as a compliance date of the rule. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens cause thereby, please contact Nicole Ongele, Federal Communications Commission, 45 L Street NE, Washington, DC 20554. Please include OMB Control Number, 3060–1312, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov*.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received final OMB approval on September 7, 2023, for the information collection requirements contained in § 90.1207(e) and (f).

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number for the information collection requirements in this rule is 3060–1312.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1312.

OMB Approval Date: September 7, 2023.

OMB Expiration Date: September 30, 2026.

Title: Sections 90.1207(e) through (f), Amendment of Part 90 of the Commission's Rules.

Form Number: N/A.

Respondents: State, Local, or Tribal Governments.

Number of Respondents and Responses: 3,871 respondents; 3,871 responses.

Estimated Time per Response: 16–160 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7), and 1401–1473 of the Communications Act of 1934.

Total Annual Burden: 592,288 hours.

Total Annual Cost: $14,882,400.

Needs and Uses: On January 18, 2023, the Commission released a Seventh Report and Order in WP Docket No. 07–100 which adds new § 90.1207(e) and (f) to the Commission's rules requiring incumbent public safety licensees and public safety applicants in the 4940–4990 MHz (4.9 GHz) band to submit granular technical data into the Commission's Universal Licensing System (ULS). Section 90.1207(e) requires applicants seeking to license new or modify existing facilities to submit granular technical data on their proposed operations into ULS. Section 90.1207(f) requires incumbent licensees to perform a one-time submission into ULS of the granular data specified in paragraph (e) for their existing operations and gives incumbent licensees at least a one-year period to complete this one-time collection.

List of Subjects in 47 CFR Part 90

Private Land Mobile Radio Services.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 90 as follows:

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

■ 1. The authority citation for part 90 continues to read as follows:

Authority: 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7), 1401–1473.

■ 2. Amend § 90.1207 by revising paragraph (g) to read as follows:

§ 90.1207 Licensing.

* * * * *

(g) Compliance with paragraphs (e) and (f) in this section shall be required as of December 9, 2024. The deadline for submissions for licensees subject to paragraph (f) in this section is Monday, June 9, 2025.

[FR Doc. 2024–26893 Filed 12–6–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 231221–0314; RTID 0648–XE510]

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer From New York to North Carolina

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of New York is transferring a portion of their 2024 commercial bluefish quota to the State of North Carolina. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2024 commercial bluefish

quotas for New York and North Carolina.

DATES: Effective December 6, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2024 allocations were published on January 2, 2024 (89 FR 34).

The final rule implementing amendment 1 to the FMP, as published in the **Federal Register** on July 26, 2000 (65 FR 45844), provided a mechanism for transferring bluefish commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these criteria have been met for the transfers approved in this notification.

New York is transferring 50,000 pounds (lb) (22,680 kilograms (kg)) to North Carolina through mutual agreement of the States. This transfer was requested to ensure North Carolina would not exceed its 2024 State quota. The revised bluefish quotas for 2024 are: New York, 339,190 lb (153,854 kg) and North Carolina, 1,130,996 lb (513,011 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 3, 2024.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–28776 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 236
Monday, December 9, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2549; Project Identifier MCAI–2024–00359–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus SAS Model 330–200, A330–200 Freighter, and A330–300 series airplanes. This proposed AD was prompted by a report of contamination of the advanced pneumatic detector pressure switch of engine pylon fire detectors. This proposed AD would require replacement of the affected parts and would prohibit installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 23, 2025.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2549; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2024–2549.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2549; Project Identifier MCAI–2024–00359–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0119, dated June 27, 2024 (EASA AD 2024–0119) (also referred to as the MCAI), to correct an unsafe condition for certain Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, –343, and –743L airplanes. Model A330–743L airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states occurrences were reported of contamination of the advanced pneumatic detector pressure switch of engine pylon fire detectors.

The FAA is proposing this AD to address such contamination, which could affect the reliability of the engine pylon fire detector, possibly leading to an undetected fire and consequent reduced control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2549.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0119 specifies procedures for replacement of the affected engine pylon fire detector and prohibits installation of affected engine pylon fire detector. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0119 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0119 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0119 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0119 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0119. Material required by EASA AD 2024–0119 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–2549 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 6 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
7 work-hours × $85 per hour = $595	$828	Up to $1,423	Up to $8,538.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2024–2549; Project Identifier MCAI–2024–00359–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 23, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0119, dated June 27, 2024 (EASA AD 2024–0119).

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by a report of contamination of the advanced pneumatic detector pressure switch of engine pylon fire detectors. The FAA is issuing this AD to address this contamination. The unsafe condition, if not addressed, could affect the reliability of the engine pylon fire detector,

possibly leading to an undetected fire and consequent reduced control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0119.

(h) Exceptions to EASA AD 2024–0119

(1) Where EASA AD 2024–0119 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (1) of the EASA AD 2024–0119 states to ''replace each affected part with a serviceable part in accordance with the instructions of the SB'' this AD requires replacing that text with ''replace each affected part with a serviceable part in accordance with the applicable tasks for removal and installation of the affected parts as specified in the accomplishment instructions of the SB.''

(3) Where EASA AD 2024–0119 defines a serviceable part as ''Engine pylon fire detector, eligible for installation in accordance with Airbus instructions, which is not an affected part'' for this AD replace that text with ''Engine pylon fire detector, eligible for installation that is not an affected part.''

(4) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0119.

(i) No Return of Parts Requirement

Although the material referenced in EASA AD 2024–0119 specifies to send affected pylon fire detectors to Kidde Technologies Inc., this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i) of this AD, if any material contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0119, dated June 27, 2024.

(ii) [Reserved]

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

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

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

Issued on December 3, 2024.

Peter A. White,

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

[FR Doc. 2024–28759 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2548; Project Identifier MCAI–2024–00401–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A318 series airplanes, Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This proposed AD was prompted by cracks being found during full-scale fatigue testing of the keel beam bottom panel between the edge profile and stringer run-out at a certain frame and stringer. This proposed AD would require repetitive special detailed inspections (SDI) of the affected area, and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 23, 2025.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2548; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory

continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

• For EASA material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2024–2548.

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

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *Timothy.P.Dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2548; Project Identifier MCAI–2024–00401–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *Timothy.P.Dowling@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0135, dated July 10, 2024 (EASA AD 2024–0135) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes, Model A320–211, –212, –214, –215, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those airplanes in the applicability. The MCAI states that during full-scale fatigue testing, cracks were found on the keel beam bottom panel between the edge profile and stringer run-out at frame 46 and stringer 37, left- and right-hand sides. Crack propagation in this area could possibly result in reduced structural integrity of the airplane.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2548.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0135 specifies procedures for repetitive SDIs for discrepancies (cracks) of the keel beam bottom panel between the edge profile and stringer run-out at frame 46 and stringer 37, left-hand and right-hand sides. EASA AD 2024–0135 also specifies corrective actions including crack repair.

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

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0135 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0135 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0135 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0135 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0135. Material required by EASA AD 2024–0135 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–2548 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,920 airplanes of U.S. registry. The FAA

estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
16 work-hours × $85 per hour = $1,360	$0	$1,360	$2,611,200

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus SAS: Docket No. FAA–2024–2548; Project Identifier MCAI–2024–00401–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 23, 2025.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus SAS airplanes, certificated in any category, as identified in paragraphs (c)(1) through (4) of this AD and in European Union Aviation Safety Agency (EASA) AD 2024–0135, dated July 10, 2024 (EASA AD 2024–0135).

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by cracks being found during full-scale fatigue testing of the keel beam bottom panel between the edge profile and stringer run-out at frame 46 and stringer 37, left- and right-hand sides. The FAA is issuing this AD to address the unsafe condition on these products. The unsafe condition, if not addressed, could result in crack propagation, possibly resulting in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0135.

(h) Exceptions to EASA AD 2024–0135

(1) Where EASA AD 2024–0135 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (2) of EASA AD 2024–0135 specifies ''if, during any inspection as required by paragraph (1) of this AD, discrepancies are detected, as defined in the SB, before next flight, contact Airbus for approved repair instructions and accomplish those instructions accordingly,'' this AD requires replacing that text with ''if, during any inspection as required by paragraph (1) of this AD, any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(3) Where paragraph (3) of EASA AD 2024–0135 does not allow corrective action as terminating action for the repetitive inspection requirements ''unless otherwise stated in the repair instructions provided by Airbus,'' this AD requires that any terminating action be approved in accordance with the procedures specified in paragraph (j)(1) of this AD.

(4) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0135.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0135 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of AIR–520, Continued Operational Safety Branch, send it to the

attention of the person identified in paragraph (k) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any material contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Additional Information

For more information about this AD, contact Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3667; email *Timothy.P.Dowling@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0135, dated July 10, 2024.

(ii) [Reserved]

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

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

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

Issued on December 3, 2024.

Peter A. White,

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

[FR Doc. 2024–28758 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2591; Airspace Docket No. 24–AGL–26]

RIN 2120–AA66

Amendment of VOR Federal Airways V–38, V–133, and V–144, and Revocation of VOR Federal Airway V–214 in the Vicinity of Zanesville, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Very High Frequency Omnidirectional Range (VOR) Federal Airways V–38, V–133, and V–144; and to revoke VOR Federal Airway V–214. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Zanesville, OH (ZZV), VOR/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID). The Zanesville VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 23, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2591 and Airspace Docket No. 24–AGL–26 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Zanesville, OH, VOR/DME in October 2025. The Zanesville VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Zanesville VOR/DME is planned for decommissioning, the co-located DME portion of the NAVAID is being retained to support current and future NextGen PBN flight procedure requirements.

The VOR Federal Airways affected by the planned decommissioning of the Zanesville VOR are V–38, V–133, V–144, and V–214. With the planned decommissioning of the Zanesville VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–38 would result in an existing gap in the airway being expanded; to V–133 would result in one of two existing gaps in the airway being expanded; to V–144 would result in a gap being created in the airway; and to V–214 would result in the airway being revoked.

To address the proposed amendments and revocation to the affected airways, instrument flight rules (IFR) traffic could use VOR Federal Airways V–44, V–75, V–115, V–117, and V–166 to navigate around the area affected by the planned decommissioning of the Zanesville VOR. Additionally, IFR pilots with Area Navigation (RNAV)-equipped aircraft could navigate using RNAV Route T–323 or point-to-point using the existing Fixes and waypoints that will remain in place to support continued operations though the affected area. Visual flight rules pilots who elect to navigate via the affected airways could also take advantage of the adjacent airways listed above, as well as the listed RNAV route and point-to-point navigation, if properly equipped. Lastly, all aircraft have the option to request and receive radar vectors from air traffic control to transit the affected area.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending VOR Federal Airways V–38, V–133, and V–144, and revoking VOR Federal Airway V–262. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Zanesville, OH, VOR/DME NAVAID. The proposed airway actions are described below.

V–38: V–38 currently extends between the Moline, IL, VOR/DME and the intersection of the Fort Wayne, IN, VOR/Tactical Air Navigation (VORTAC) 091° and Rosewood, OH, VORTAC 334° radials (WINES Fix); and between the Appleton, OH, VORTAC and the Cape Charles, VA, VORTAC. The FAA proposes to remove the route segment between the Appleton VORTAC and the Parkersburg, WV, VOR/DME. As amended, the route would be changed to extend between the Moline VOR/DME and the intersection of the Fort Wayne VORTAC 091° and Rosewood VORTAC 334° radials (WINES Fix), and between the Parkersburg VOR/DME and the Cape Charles VORTAC.

V–133: V–133 currently extends between the intersection of the Charlotte, NC, VOR/DME 305° and Barretts Mountain, NC, VOR/DME 197° radials (LINCO Fix) and the Zanesville, OH, VOR/DME; between the Saginaw, MI, VOR/DME and the Houghton, MI, VOR/DME; and between the International Falls, MN, VOR/DME and the Red Lake, Ontario (ON), Canada, VOR. The airspace within Canada is excluded. The FAA proposes to remove the airway segment between the Charleston, WV, VOR/DME and the Zanesville VOR/DME. As amended, the airway would be changed to extend between the intersection of the Charlotte VOR/DME 305° and Barretts Mountain VOR/DME 197° radials (LINCO Fix) and the Charleston VOR/DME; between the Saginaw VOR/DME and the Houghton VOR/DME; and between the International Falls VOR/DME and the Red Lake, ON, Canada, VOR. The airspace within Canada would continue to be excluded.

V–144: V–144 currently extends between the Fort Wayne, IN, VORTAC and the Linden, VA, VORTAC. The FAA proposes to remove the airway segment between the Appleton, OH, VORTAC and the Morgantown, WV, VOR/DME. As amended, the airway would be changed to extend between the Fort Wayne VORTAC and the Appleton VORTAC, and between the Morgantown VOR/DME and the Linden VORTAC.

V–214: V–214 currently extends between the intersection of the Appleton, OH, VORTAC 236° and Zanesville, OH, VOR/DME 274° radials (GLOOM Fix) and the Bellaire, OH,

VOR/DME. The FAA proposes to remove the airway in its entirety.

All NAVAID radials listed in the airway descriptions in the regulatory text of this notice of proposed rulemaking are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–38 [Amended]

From Moline, IL; INT Moline 082° and Peotone, IL, 281° radials; Peotone; Fort Wayne, IN; to INT Fort Wayne 091° and Rosewood, OH, 334° radials. From Parkersburg, WV; Elkins, WV; Gordonsville, VA; Richmond, VA; Harcum, VA; to Cape Charles, VA.

* * * * *

V–133 [Amended]

From INT Charlotte, NC, 305° and Barretts Mountain, NC, 197° radials; Barretts Mountain; to Charleston, WV. From Saginaw, MI; Traverse City, MI; Escanaba, MI; Sawyer, MI; to Houghton, MI. From International Falls, MN; to Red Lake, ON, Canada. The airspace within Canada is excluded.

* * * * *

V–144 [Amended]

From Fort Wayne, IN; to Appleton, OH. From Morgantown, WV; Kessel, WV; to Linden, VA.

* * * * *

V–214 [Removed]

* * * * *

Issued in Washington, DC, on December 3, 2024.

Richard Lee Parks,

Manager (A), Rules and Regulations Group.

[FR Doc. 2024–28724 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2568; Airspace Docket No. 24–AGL–10]

RIN 2120–AA66

Amendment of Jet Routes J–60 and J–82, and VOR Federal Airways V–8, V–55, and V–221; and Revocation of VOR Federal Airways V–92 and V–126 in the Vicinity of Goshen, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Routes J–60 and J–82, and Very High Frequency Omnidirectional Range (VOR) Federal Airways V–8, V–55, and V–221; and revoke VOR Federal Airways V–92 and V–126. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Goshen, IN (GSH), VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Goshen VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 23, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2568 and Airspace Docket No. 24–AGL–10 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A,

Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX, 76177.

Incorporation by Reference

Jet Routes are published in paragraph 2004 and VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Goshen, IN, VORTAC in June 2025. The Goshen VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Goshen VORTAC is planned for decommissioning, the co-located Tactical Air Navigation (TACAN) portion of the NAVAID is being retained. The TACAN would continue to provide navigational service for military operations and Distance Measuring Equipment (DME) service supporting current and future NextGen PBN flight procedure requirements.

The Air Traffic Service (ATS) routes affected by the planned decommissioning of the Goshen VOR are J–60, J–82, V–8, V–55, V–92, V–126, and V–221. With the planned decommissioning of the Goshen VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected routes. As such, proposed modifications to J–82 and V–221 would result in the ATS routes being shortened; to J–60 would result in a gap in the route; to V–8 would result in an existing gap being expanded; to V–55 would result in an additional gap in the airway; and to V–92 and V–126 would result in the airways being revoked.

To address the proposed amendments to the affected ATS routes, instrument flight rules (IFR) traffic could use Jet Routes J–30, J–146, and J–584 in the high-altitude stratum or use VOR Federal Airways V–10, V–38, V–277, and V–526 in the low-altitude stratum to navigate around the area affected by the planned decommissioning of the Goshen VOR. Additionally, IFR pilots with Area Navigation (RNAV)-equipped aircraft could navigate using RNAV Route Q–62 in the high-altitude stratum, RNAV Routes T–215 and T–265 in the low-altitude stratum, or point-to-point using the existing Fixes and waypoints (WP) that would remain in place to support continued operations though the affected area. Visual flight rules pilots who elect to navigate via the affected ATS routes could also take advantage of the adjacent conventional airways listed above, as well as the listed RNAV routes and point-to-point navigation, if properly equipped. Lastly, all aircraft have the option to request and receive radar vectors from air traffic control to transit the affected area as well.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending Jet Routes J–60 and J–82, and VOR Federal Airways V–8, V–55, and V–221; and revoking VOR Federal Airways V–92 and V–126. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Goshen, IN, VORTAC NAVAID. The proposed ATS route actions are described below.

J–60: J–60 currently extends between the Los Angeles, CA, VORTAC and the Sparta, NJ, VORTAC. The FAA proposes to remove the route segment between the Joliet, IL, VOR/Distance Measuring Equipment (VOR/DME) and the Dryer, OH, VOR/DME. As amended, the route would be changed to extend between the Los Angeles VORTAC and the Joliet VOR/DME, and between the Dryer VOR/DME and the Sparta VORTAC.

J–82: J–82 currently extends between the Battle Ground, WA, VORTAC and the Sioux Falls, SD, VORTAC; and between the Dubuque, IA, VORTAC and the Goshen, IN, VORTAC. The FAA proposes to remove the route segment between the Joliet, IL, VOR/DME and the Goshen VORTAC. As amended, the route would be changed to extend

between the Battle Ground VORTAC and the Sioux Falls VORTAC, and between the Dubuque VORTAC and the Joliet VOR/DME.

V–8: V–8 currently extends between the intersection of the Seal Beach, CA, VORTAC 266° and Ventura, CA, VOR/DME 144° radials (DOYLE Fix) and the Flag City, OH, VORTAC; and between the Martinsburg, WV, VORTAC and the Washington, DC, VOR/DME. The portion of the airway outside the United States has no upper limit. The FAA proposes to remove the airway segment between the Chicago Heights, IL, VORTAC and the Flag City VORTAC. As amended, the airway would be changed to extend between the intersection of the Seal Beach VORTAC 266° and Ventura VOR/DME 144° radials (DOYLE Fix) and the Chicago Heights VORTAC, and between the Martinsburg VORTAC and the Washington VOR/DME.

V–55: V–55 currently extends between the Dayton, OH, VOR/DME and the Pullman, MI, VOR/DME; and between the Grand Forks, ND, VOR/DME and the Bismarck, ND, VOR/DME. The FAA proposes to remove the airway segment between the Fort Wayne, IN, VORTAC and the Gipper, MI, VORTAC. As amended, the airway would be changed to extend between the Dayton VOR/DME and the Fort Wayne VORTAC, between the Gipper VORTAC and the Pullman VOR/DME, and between the Grand Forks VOR/DME and the Bismarck VOR/DME.

V–92: V–92 currently extends between the Chicago Heights, IL, VORTAC and the Goshen, IN, VORTAC. The FAA proposes to remove the airway in its entirety.

V–126: V–126 currently extends between the Goshen, IN, VORTAC and the intersection of the Goshen VORTAC 092° and Fort Wayne, IN, VORTAC 016° radials (ILTON Fix). The FAA proposes to remove the airway in its entirety.

V–221: V–221 currently extends between the Bible Grove, IL, VORTAC and the intersection of the Fort Wayne, IN, VORTAC 016° and Goshen, IN, VORTAC 092° radials (ILTON Fix). The FAA proposes to remove the airway segment between the Fort Wayne VORTAC and the intersection of the Fort Wayne VORTAC 016° and Goshen VORTAC 092° radials (ILTON Fix). As amended, the airway would be changed to extend between the Bible Grove VORTAC and the Fort Wayne VORTAC.

All NAVAID radials listed in the ATS route descriptions in the regulatory text of this notice of proposed rulemaking are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–60 [Amended]

From Los Angeles, CA; Paradise, CA; Hector, CA; Boulder City, NV; Bryce Canyon, UT; Hanksville, UT; Red Table, CO; Mile High, CO; Hayes Center, NE; Lincoln, NE; Iowa City, IA; to Joliet, IL. From Dryer, OH; Philipsburg, PA; INT Philipsburg 100° and Sparta, NJ, 253° radials; to Sparta.

* * * * *

J–82 [Amended]

From Battle Ground, WA; Donnelly, ID; Dubois, ID; Crazy Woman, WY; Rapid City, SD; to Sioux Falls, SD. From Dubuque, IA; INT Dubuque 095° and Joliet, IL, 317° radials; to Joliet.

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–8 [Amended]

From INT Seal Beach, CA, 266° and Ventura, CA, 144° radials; Seal Beach; Paradise, CA; 35 miles, 7 miles wide (3 miles SE and 4 miles NW of centerline) Hector, CA; Goffs, CA; INT Goffs 033° and Morman Mesa, NV, 196° radials; Morman Mesa; Bryce Canyon, UT; Hanksville, UT; Grand Junction, CO; Rifle, CO; Kremmling, CO; Mile High, CO; Akron, CO; Hayes Center, NE; Grand Island, NE; Omaha, IA; Des Moines, IA; Iowa City, IA; Moline, IL; Joliet, IL; to Chicago Heights, IL. From Martinsburg, WV; to Washington, DC. The portion outside the United States has no upper limit.

* * * * *

V–55 [Amended]

From Dayton, OH; to Fort Wayne, IN. From Gipper, MI; Keeler, MI; to Pullman, MI. From Grand Forks, ND; INT Grand Forks 239° and Bismarck, ND, 067° radials; to Bismarck.

* * * * *

V–92 [Removed]

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V–126 [Removed]

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V–221 [Amended]

From Bible Grove, IL; Hoosier, IN; Shelbyville, IN; Muncie, IN; to Fort Wayne, IN.

* * * * *

Issued in Washington, DC, on December 3, 2024.

Richard Lee Parks,

Manager (A), Rules and Regulations Group.

[FR Doc. 2024–28726 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2588; Airspace Docket No. 24–AGL–17]

RIN 2120–AA66

Amendment of Jet Routes J–26, J–64 and J–181, and VOR Federal Airways V–10 and V–156; and Revocation of VOR Federal Airway V–262 in the Vicinity of Bradford, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Routes J–26, J–64, and J–181, and Very High Frequency Omnidirectional Range (VOR) Federal Airways V–10 and V–156; and to revoke VOR Federal Airway V–262. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Bradford, IL (BDF), VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Bradford VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 23, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2588 and Airspace Docket No. 24–AGL–17 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX, 76177.

Incorporation by Reference

Jet Routes are published in paragraph 2004 and VOR Federal Airways are published in paragraph 6010(a) of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Bradford, IL, VORTAC in August 2025. The Bradford VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, ''Provision of

Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Bradford VORTAC is planned for decommissioning, the co-located Tactical Air Navigation (TACAN) portion of the NAVAID is being retained. The TACAN would continue to provide navigational service for military operations and Distance Measuring Equipment (DME) service supporting current and future NextGen PBN flight procedure requirements.

The Air Traffic Service (ATS) routes affected by the planned decommissioning of the Bradford VOR are J–26, J–64, J–181, V–10, V–156, and V–262. With the planned decommissioning of the Bradford VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected routes. As such, proposed modifications to J–26, J–181, and V–156 would result in the ATS routes being shortened; to J–64 and V–10 would result in an existing gap in the ATS routes being expanded; and to V–262 would result in the airway being revoked.

To address the proposed amendments and revocation to the affected ATS routes, instrument flight rules (IFR) traffic could use Jet Routes J–18, J–87, J–96, and J–232 in the high-altitude stratum or use VOR Federal Airways V–8, V–38, V–48, and V–434 in the low-altitude stratum to navigate around the area affected by the planned decommissioning of the Bradford VOR. Additionally, IFR pilots with Area Navigation (RNAV)-equipped aircraft could navigate using RNAV Route Q–42 in the high-altitude stratum and RNAV Routes T–215, T–325 and T–354 in the low-altitude stratum, or point-to-point using the existing Fixes and Waypoints (WP) that would remain in place to support continued operations though the affected area. Visual flight rules pilots who elect to navigate via the affected ATS routes could also take advantage of the adjacent conventional routes and airways listed above, as well as the listed RNAV routes and point-to-point navigation, if properly equipped. Lastly, all aircraft have the option to request and receive radar vectors from air traffic control to transit the affected area as well.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending Jet Routes J–26, J–64, and J–181, and VOR Federal Airways V–10 and V–156; and revoking VOR Federal Airway V–262. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Bradford, IL, VORTAC NAVAID. The proposed ATS route actions are described below.

J–26: J–26 currently extends between the Ciudad Juarez, Mexico, VOR/DME and the Joliet, IL, VOR/DME. The airspace within Mexico is excluded. The FAA proposes to remove the route segment between the Kirksville, MO, VORTAC and the Joliet VOR/DME. As amended, the route would be changed to extend between the Ciudad Juarez, Mexico, VOR/DME and the Kirksville VORTAC. The airspace within Mexico would remain excluded.

J–64: J–64 currently extends between the Los Angeles, CA, VORTAC and the Hill City, KS, VORTAC; and between the Lamoni, IA, VOR/DME and the intersection of the Ravine, PA, VORTAC 102° and Lancaster, PA, VOR/DME 044° radials (SARAA Fix). The FAA proposes to remove the route segment between the Lamoni VOR/DME and the Fort Wayne, IN, VORTAC. As amended, the route would be changed to extend between the Los Angeles VORTAC and the Hill City VORTAC, and between the Fort Wayne VORTAC and the intersection of the Ravine VORTAC 102° and Lancaster VOR/DME 044° radials (SARAA Fix).

J–181: J–181 currently extends between the Ranger, TX, VORTAC and the Okmulgee, OK, VOR/DME; and between the Hallsville, MO, VORTAC and the Bradford, IL, VORTAC. The FAA proposes to remove the route segment between the Hallsville VORTAC and the Bradford VORTAC. As amended, the route would be changed to extend between the Ranger VORTAC and the Okmulgee VOR/DME.

V–10: V–10 currently extends between the Pueblo, CO, VORTAC and the intersection of the Bradford, IL, VORTAC 058° and Joliet, IL, VOR/DME 287° radials (PLANO Fix); and between the intersection of the Chicago Heights, IL, VORTAC 358° and Gipper, MI, VORTAC 271° radials (NILES Fix) and the Gipper VORTAC. The FAA proposes to remove the airway segment between the Burlington, IA, VOR/DME and the intersection of the Bradford VORTAC 058° and Joliet VOR/DME 287° radials (PLANO Fix). Additionally, the FAA proposes to remove the legacy airway floor altitude information in the description between the Pueblo VORTAC and the Lamar, CO, VOR/DME route points as it is no longer required. As amended, the airway would be changed to extend between the Pueblo VORTAC and the Burlington VOR/DME, and between the intersection of the Chicago Heights VORTAC 358° and Gipper VORTAC 271° radials (NILES Fix) and the Gipper VORTAC.

V–156: V–156 currently extends between the Cedar Rapids, IA, VOR/DME and the Peotone, IL, VORTAC. The FAA proposes to remove the airway segment between the Moline, IL, VOR/DME and the Peotone VORTAC. As amended, the airway would be changed to extend between the Cedar Rapids VOR/DME and the Moline VOR/DME.

V–262: V–262 currently extends between the Peoria, IL, VORTAC and the Joliet, IL, VOR/DME. The FAA proposes to remove the airway in its entirety. However, the airway segment between the intersection of the Bradford, IL, VORTAC 085° and Joliet VOR/DME 204° radials (MOTIF Fix) and the Joliet VOR/DME would remain as V–69 and V–586.

All NAVAID radials listed in the ATS route descriptions in the regulatory text of this notice of proposed rulemaking are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration

proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–26 [Amended]

From Ciudad Juarez, Mexico; El Paso, TX; INT El Paso 070° and Chisum, NM, 215° radials; Chisum; Panhandle, TX; Mitbee, OK; Wichita, KS; Kansas City, MO; to Kirksville, MO. The airspace within Mexico is excluded.

* * * * *

J–64 [Amended]

From Los Angeles, CA; INT Los Angeles 083° and Hector, CA, 226° radials; Hector; Peach Springs, AZ; Tuba City, AZ; Rattlesnake, NM; Pueblo, CO; to Hill City, KS. From Fort Wayne, IN; Ellwood City, PA; Ravine, PA; to INT Ravine 102° and Lancaster, PA, 044° radials.

* * * * *

J–181 [Amended]

From Ranger, TX; to Okmulgee, OK.

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–10 [Amended]

From Pueblo, CO; Lamar, CO; Garden City, KS; Dodge City, KS; Hutchinson, KS; Emporia, KS; INT Emporia 063° and Napoleon, MO, 243° radials; Napoleon; Kirksville, MO; to Burlington, IA. From INT Chicago Heights, IL, 358° and Gipper, MI, 271° radials; to Gipper.

* * * * *

V–156 [Amended]

From Cedar Rapids, IA; to Moline, IL.

* * * * *

V–262 [Removed]

* * * * *

Issued in Washington, DC, on December 3, 2024.

Richard Lee Parks,

Manager (A), Rules and Regulations Group.

[FR Doc. 2024–28725 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–2573; Airspace Docket No. 23–AGL–20]

RIN 2120–AA66

Amendment of Jet Route J–538 and VOR Federal Airways V–129; Establishment of Canadian RNAV Routes Q–828, Q–945, Q–971, and T–797; and Revocation of Jet Routes J–483 and J–562; Northcentral United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Route J–538 and Very High Frequency Omnidirectional Range (VOR) Federal Airway V–129; establish Canadian Area Navigation (RNAV) Routes Q–828, Q–945, Q–971, and T–797 within United States (U.S.) airspace; and revoke Jet Routes J–483 and J–562. The FAA is proposing this action due to NAV CANADA's decommissioning of the Sioux Narrows (VBI), Ontario (ON), Canada, Very High Frequency Omnidirectional Range (VOR)/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID) and the planned decommissioning of the Lumsden (VLN), Saskatchewan (SK), Canada, VOR/Tactical Air Navigation (VORTAC) and Brandon (YBR), Manitoba (MB), Canada, VORTAC NAVAIDs. This action is proposed in support of NAV CANADA's NAVAID Modernization Program within Canada.

DATES: Comments must be received on or before January 23, 2025.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–2573 and Airspace Docket No. 23–AGL–20 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System (NAS) as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed

electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Jet Routes are published in paragraph 2004, Canadian Area Navigation Routes (Q-routes) are published in paragraph 2007, VOR Federal Airways are published in paragraph 6010(a), and Canadian Area Navigation Routes (T-routes) are published in paragraph 6013 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, dated July 31, 2024, and effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

NAV CANADA, which operates Canada's civil air navigation service, is implementing changes to Canada's instrument flight rules (IFR) navigation infrastructure as part of their NAVAID Modernization Program. This modernization program is designed to enhance the efficiency of Canada's flying operations by taking advantage of performance-based navigation and RNAV avionics capabilities. The changes being implemented by NAV CANADA affect Jet Routes J–483, J–538, and J–562, and VOR Federal Airway V–129. These Air Traffic Service (ATS) routes provide cross-border connectivity between the U.S. and Canada.

NAV CANADA has decommissioned the Sioux Narrows, ON, VOR/DME and plans to decommission the Lumsden, SK, VORTAC and Brandon, MB, VORTAC as part of their NAVAID Modernization Program. As a result, amendments to J–538 and V–129, and revocation of J–483 and J–562 in U.S. airspace are required due to the loss of navigational guidance provided by the Sioux Narrows, ON; Lumsden, SK; and Brandon, MB, VORs and to match airway changes NAV CANADA is making within Canadian airspace. NAV CANADA has established Canadian RNAV Routes Q–828 in the high-altitude enroute structure and T–797 in the low-altitude enroute structure already and plans to establish Canadian RNAV Routes Q–945 and Q–971 in the high-altitude enroute structure as mitigations for the affected ATS routes within Canadian and U.S. airspace.

To mitigate the proposed loss of J–538 and V–129 route segments and proposed revocation of J–483 and J–562, and to support NAV CANADA's planned RNAV route replacements for these affected ATS routes, the FAA must establish portions of Canadian RNAV Routes Q–828, Q–945, Q–971, and T–797 within U.S. airspace. The new Canadian RNAV route segments in U.S. airspace would provide airway continuity with NAV CANADA's RNAV Routes that are established or being established within Canadian airspace and provide cross-border airway connectivity between the U.S. and Canada. Existing NAVAIDs that provide conventional enroute structure in the affected area are limited and alternate, parallel, or adjacent Jet Routes or VOR Federal Airways to use as mitigations are not available. To compensate for the loss of the conventional enroute structure, IFR pilots with RNAV-equipped aircraft could navigate using the Canadian RNAV Routes proposed in this action or fly point-to-point using the Fixes and Waypoints (WP) that would remain in place. Additionally, IFR pilots could request air traffic control (ATC) radar vectors to fly through or around the affected areas. Visual flight rules pilots who elect to navigate via airways could also take advantage of the ATC services listed previously.

The Proposal

The FAA is proposing to amend 14 CFR part 71 by amending Jet Route J–538 and VOR Federal Airway V–129; establishing Canadian RNAV Routes Q–828, Q–945, Q–971, and T–797 in U.S. airspace; and revoking Jet Routes J–483 and J–562. The FAA is proposing this action due to the decommissioning of the Sioux Narrows, ON, Canada, VOR/DME and the planned decommissioning of the Lumsden, SK, Canada, VORTAC and Brandon, MB, Canada, VORTAC by NAV CANADA in support of their NAVAID Modernization Program. The proposed ATS route actions are described below.

J–483: J–483 currently extends between the Minot, ND, VOR/DME and the Lumsden, SK, Canada, VORTAC. The airspace within Canada is excluded. The FAA proposes to remove the route in its entirety.

J–538: J–538 currently extends between the Sioux Narrows, ON, Canada, VOR/DME and the Badger, WI, VOR/DME. The airspace within Canada is excluded. The FAA proposes to remove the route segment between the Sioux Narrows, ON, VOR/DME and the Duluth, MN, VORTAC. As amended, the route would be changed to extend between the Duluth VORTAC and the Badger VOR/DME.

J–562: J–562 currently extends between the Dickinson, ND, VORTAC and the Brandon, MB, Canada, VORTAC. The airspace within Canada is excluded. The FAA proposes to remove the route in its entirety.

Q–828: Q–828 is a new Canadian RNAV route proposed to be established within U.S. airspace extending between the Duluth, MN, VORTAC and the FARID, MN, WP that would replace the ''CFCJN'' Computer Navigation Fix (CNF) on the U.S./Canada border. The new RNAV route would mitigate the proposed J–538 amendment and provide route continuity and cross-border connectivity with the RNAV Route Q–828 established by NAV CANADA within Canadian airspace.

Q–945: Q–945 is a new Canadian RNAV route proposed to be established within U.S. airspace extending between the Dickinson, ND, VORTAC and the OSMEE, ND, WP that would replace the ''CFMSZ'' CNF on the U.S./Canada border. The new RNAV route would mitigate the proposed J–562 revocation and provide route continuity and cross-border connectivity with the RNAV Route Q–945 being established by NAV CANADA within Canadian airspace.

Q–971: Q–971 is a new Canadian RNAV route proposed to be established within U.S. airspace extending between the Minot, ND, VOR/DME and the CIPTA, ND, WP that would replace the ''CFHLT'' CNF on the U.S./Canada border. The new RNAV route would mitigate the proposed J–483 revocation and provide route continuity and cross-border connectivity with the RNAV Route Q–971 being established by NAV CANADA within Canadian airspace.

V–129: V–129 currently extends between the Spinner, IL, VORTAC and the intersection of the International Falls, MN, VOR/DME 335° radial and United States/Canadian border. The FAA proposes to remove the airway segment between the International Falls VOR/DME and the intersection of the International Falls VOR/DME 335° radial and United States/Canadian border. As amended, the airway would be changed to extend between the Spinner VORTAC and the International Falls VOR/DME.

T–797: T–797 is a new Canadian RNAV route proposed to be established within U.S. airspace extending between the International Falls, MN, VOR/DME and the WUGOR, MN, WP replacing the ''CFDTS'' CNF on the U.S./Canada border. The new RNAV route would mitigate the proposed V–129 airway segment removal and provide route continuity and cross-border connectivity with the RNAV Route T–797 established by NAV CANADA within Canadian airspace.

The NAVAID radials listed in the VOR Federal Airway V–129 description in the regulatory text of this NPRM are unchanged and stated in degrees True north.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–483 [Removed]

* * * * *

J–538 [Amended]

From Duluth, MN; Dells, WI; to Badger, WI.

* * * * *

J–562 [Removed]

* * * * *

Paragraph 2007 Canadian Area Navigation Routes.

* * * * *

Q–828 Duluth, MN (DLH) to FARID, MN [New]

Duluth, MN (DLH)	VORTAC	(Lat. 46°48′07.79″ N, long. 092°12′10.33″ W)
FARID, MN	WP	(Lat. 48°36′13.96″ N, long. 093°25′16.09″ W)

* * * * *

Q–945 Dickinson, ND (DIK) to OSMEE, ND [New]

Dickinson, ND (DIK)	VORTAC	(Lat. 46°51′36.14″ N, long. 102°46′24.60″ W)
OSMEE, ND	WP	(Lat. 48°59′59.19″ N, long. 100°49′57.63″ W)

* * * * *

Q–971 Minot, ND (MOT) to CIPTA, ND [New]

Minot, ND (MOT)	VOR/DME	(Lat. 48°15′37.21″ N, long. 101°17′13.46″ W)
CIPTA, ND	WP	(Lat. 48°59′55.84″ N, long. 102°20′17.11″ W)

Paragraph 6010(a) VOR Federal Airways.

* * * * *

V–129 [Amended]

From Spinner, IL; Peoria, IL; Davenport, IA; Dubuque, IA; INT Dubuque 348° and Nodine, MN, 150° radials; Nodine; Eau Claire, WI; Duluth, MN; Hibbing, MN; to International Falls, MN.

* * * * *

Paragraph 6013 Canadian Area Navigation Routes.

* * * * *

T–797 International Falls, MN (INL) to WUGOR, MN [New]		
International Falls, MN (INL)	VOR/DME	(Lat. 48°33′56.87″ N, long. 093°24′20.44″ W)
WUGOR, MN	WP	(Lat. 48°35′58.85″ N, long. 093°25′44.53″ W)

Issued in Washington, DC, on December 3, 2024.

Richard Lee Parks,

Manager (A), Rules and Regulations Group.

[FR Doc. 2024–28727 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0059; FRL–11682–10–OCSPP]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities (October 2024)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of filing of petition and request for comment.

SUMMARY: This document announces the Agency's receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before January 8, 2025.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2024–0059, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (RD) (7505T), main telephone number: (202) 566–1030, email address: *RDFRNotices@epa.gov.* The mailing address is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available at *https://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notification of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

A. Notice of Filing—Amended Tolerances for Non-Inerts

PP 4F9153. EPA–HQ–OPP–2024–0509. BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requests to amend the existing tolerance established in 40 CFR 180.700 for residues of the insecticide afidopyropen in or on Strawberry from 0.15 parts per million (ppm) to 0.3 ppm. In their initial assessment of afidopyropen (DP No. 441491), EPA–HED indicated the existing methods and

accompanying independent method validations were sufficient to support afidopyropen tolerances. EPA's ROCKS stated that the submitted analytical method for plant commodities can adequately detect parent afidopyropen (as well as its dimer M440I007) for the purposes of tolerance enforcement. *Contact:* RD.

B. Notice of Filing—New Tolerances for Non-Inerts

1. *PP 1F8969.* EPA–HQ–OPP–2023–0009. Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419, requests to amend tolerance in 40 CFR part 180.571 for residues of the herbicide, mesotrione, in or on soybean at 0.02 ppm. The high-performance liquid chromatography (HPLC) with tandem mass-spectrometry (MS/MS) is used to measure and evaluate the chemical mesotrione. *Contact:* RD.

2. *PP 3F9073.* EPA–HQ–OPP–2024–0212. K–I CHEMICAL U.S.A., Inc. c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, pyroxasulfone, including its metabolites M–1, M–3, M–25, and M–28 calculated as the stoichiometric equivalent of pyroxasulfone, in or on almond, hulls at 0.15 ppm, fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.07 ppm, and nut, tree, group 14–12 at 0.07 ppm. The Liquid Chromatography-Mass Spectrometry/Mass Spectrometry (LC–MS/MS) is used to measure and evaluate the chemical pyroxasulfone. *Contact:* RD.

3. *PP 1F8969.* EPA–HQ–OPP–2023–0009. Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419, requests to amend tolerance in 40 CFR part 180.571 for residues of the herbicide, mesotrione, in or on soybean at 0.02 ppm. The HPLC with MS/MS is used to measure and evaluate the chemical mesotrione. *Contact:* RD.

4. *PP 3F9073.* EPA–HQ–OPP–2024–0212. K–I CHEMICAL U.S.A., Inc. c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, pyroxasulfone, including its metabolites M–1, M–3, M–25, and M–28 calculated as the stoichiometric equivalent of pyroxasulfone, in or on almond, hulls at 0.15 ppm, fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.07 ppm, and nut, tree, group 14–12 at 0.07 ppm. The LC–MS/MS is used to measure and evaluate the chemical pyroxasulfone. *Contact:* RD.

5. *PP 3F9086.* EPA–HQ–OPP–2024–0415. Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, bicyclopyrone in or on soybean, seed at .01 ppm, and soybean, meal at .02 ppm. The analytical methods GRM030.05A, GRM030.05B, and GRM030.08A are used to measure and evaluate the chemical bicyclopyrone. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: November 19, 2024.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2024–28805 Filed 12–6–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R07–UST–2024–0452; FRL–12274–01–R7]

Nebraska: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is proposing to approve revisions to the State of Nebraska's Underground Storage Tank (UST) program submitted by the Nebraska State Fire Marshal (NSFM). This action is based on the EPA's determination that these revisions satisfy all requirements needed for program approval. This action also proposes to codify EPA's approval of Nebraska's State program and incorporate by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities under the RCRA and other applicable statutory and regulatory provisions.

DATES: Comments on this proposed rule must be received on or before January 8, 2025.

ADDRESSES: Submit comments, identified by Docket ID Number EPA–R07–UST–2024–0452, by one of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. *Email: blankenship.marie@epa.gov.*

Instructions: Direct your comments to Docket ID No. EPA–R07–UST–2024–0452. EPA's policy is that all comments received will be included in the public docket without change and may be available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov,* or email. The Federal *https://www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and also with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. EPA encourages electronic submittals, but if you are unable to submit electronically, please reach out to the EPA contact person listed in the document for assistance. You can view and copy the documents that form the basis for this codification and associated publicly available materials either through *https://www.regulations.gov* or by contacting Marie Blankenship at (913) 551–7908 or *blankenship.marie@epa.gov.* Please call or email the contact listed above if you need access to material indexed but not provided in the docket.

FOR FURTHER INFORMATION CONTACT: Marie Blankenship, Tanks, Toxics and Pesticides Branch, Land, Chemical, and Redevelopment Division, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 6; telephone number: (913) 551–7908; email address: *blankenship.marie@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has explained the reasons for this action in the preamble to the direct final rule. For additional information, see the direct final rule published in the ''Rules and Regulations'' section of this issue of the **Federal Register**.

Authority: This proposed rule is issued under the authority of sections 2002(a), 7004(b), and 9004 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

Dated: November 22, 2024.

Meghan A. McCollister,

Regional Administrator, EPA Region 7.

[FR Doc. 2024–28139 Filed 12–6–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2021–0093]

RIN 2105–AF28

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Transportation (DOT) proposes to revise its drug testing procedures rule, which became effective on June 1, 2023, to provide interim provisions to require the conduct of directly observed urine tests in situations where oral fluid tests are currently required, but oral fluid testing is not yet available.

DATES: Comments must be received on or before January 8, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. DOT–OST–2021–0093, at *https://www.regulations.gov/*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. DOT may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. For additional submission methods and general guidance on making effective comments, please visit *https://www.transportation.gov/regulations/rulemaking-process.*

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, Deputy Director, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone number 202–366–3784; *ODAPCwebmail@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is DOT proposing this rule?

DOT proposes to revise its drug testing regulation, Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR part 40), to address unforeseen circumstances rendering it impossible to comply with requirements in the final rule.

II. General Information

DOT published a final rule amending the procedures for its drug testing program (49 CFR part 40) on May 2, 2023 (88 FR 27596) (May 2023 Final Rule). The May 2023 Final Rule went into effect on June 1, 2023. The May 2023 Final Rule authorized oral fluid drug testing as an additional methodology for employers to use as a means of achieving the safety goals of the program. In the May 2023 Final Rule, we required an oral fluid test to be conducted in certain circumstances where an observed collection is required. However, because oral fluid testing is not yet available, DOT proposes to amend DOT's regulations to require the conduct of directly observed urine collections in those circumstances for an interim period. This rulemaking would correct the inadvertent factual impossibility created by the May 2023 Final Rule.

Section 40.67 When and how is a directly observed urine collection conducted?

DOT regulations at § 40.67 require that a collection be directly observed in certain circumstances, *e.g.,* if the original sample was invalid without adequate medical explanation or the test is for a return to duty. In the May 2023 Final Rule, DOT codified a procedure requiring the directly observed collection to be an oral fluid test rather than a urine test in certain situations. However, oral fluid testing cannot be implemented until the Department of Health and Human Services (HHS) certifies at least two laboratories, one to serve as a primary laboratory, and a second to serve as a split specimen laboratory. Because no oral fluid laboratories have been certified, it is not yet possible to comply with this provision.

In the interim, it is necessary to ensure that directly observed collections can still be conducted when required. DOT proposes to require directly observed urine collections in the situations specified in § 40.67(g)(3) if an oral fluid collection is not yet available. We emphasize that the responsibility of ensuring the collection takes place has always been a requirement the employer must satisfy. If a directly observed urine collection is required, the burden—as is currently the case—remains on the employer to provide an observer as specified in § 40.67(g) if the collection site cannot do so.

We intend this provision to require directly observed urine tests in situations where an oral fluid collection is required, but is not yet available, to be a temporary, short-term solution because there are currently no certified oral fluid laboratories. This provision will sunset one year after HHS publishes a **Federal Register** notice that it certified the second oral fluid drug testing laboratory. So that all are aware of the date when this provision will sunset, we will publish a **Federal Register** document specifying the date the second oral fluid laboratory is certified by HHS. If, during the interim period, a collection site is able to conduct an oral fluid collection (HHS has certified at least two oral fluid drug testing laboratories, and both a qualified oral fluid collector and a conforming oral fluid collection device are available at the collection site), an oral fluid collection would be required to be conducted.

In the May 2023 Final Rule, we added § 40.67(g)(3) to address situations where an observer who meets the regulatory requirements cannot be found at the collection site, but mistakenly used the term ''collector'' instead of ''observer'' in the regulatory text of that section. In this rule, we propose to correct the error.

III. Regulatory Notices and Analyses

Executive Orders 12866, 13563, and 14094

This proposed rule is a non-significant rule for purposes of Executive Order (E.O.) 12886, as supplemented by E.O. 13563 and amended by E.O. 14094, and will not impose any significant costs or have any significant impacts. Given the uncertainty of testing costs and lack of data on other aspects of testing, DOT did not estimate cost savings or other benefits for the May 2023 Final Rule that permitted oral fluid testing as an alternative to urine testing in most scenarios. In the regulatory analyses for the May 2023 Final Rule, DOT stated that ''Oral fluid testing is optional in all but very rare cases . . .'' However, and because oral fluid testing is not yet

available, this proposed rule requires that a directly observed urine collection be conducted in those ''very rare cases'' where an oral fluid test is required but is not available. As an amendment to establish a temporary requirement to conduct directly observed urine collections in situations where oral fluid collections are required but oral fluid testing is not yet available, which was the requirement in existence before issuance of the May 2023 Final Rule, this proposed rule will not affect a significant number of drug tests, and as such, will not impose any significant costs or have any significant impacts on the DOT testing program.

Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA)

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with a population of less than 50,000. For this rulemaking, potentially affected small entities include drug testing companies (U.S. Small Business Administration (SBA) North American Industry Classification System (NAICS) Sector 54 (Professional, Scientific and Technical Services), Code 541380 (Testing Laboratories and Services)) as well as DOT-regulated entities (SBA NAICS Sectors 48–49 (Transportation and Warehousing)).

The Department does not expect that the proposed rule would have a significant economic impact on a substantial number of small entities. The proposed rule, if adopted, would establish a temporary requirement to conduct directly observed urine collections in situations where oral fluid collections are required but oral fluid testing is not yet available. Urine testing was the requirement in existence before issuance of the May 2023 Final Rule, and regulated entities are therefore familiar with the procedure for directly observed urine tests. Because oral fluid testing is not yet available for use in DOT's drug testing programs, regulated entities also likely still have the collection devices and other equipment necessary to conduct urine testing. In addition, the temporary procedures proposed in this rulemaking would be used only in the specific circumstances in § 40.67(g) where urine testing is currently required and would thus not affect a significant number of drug tests. As a result, the temporary amendments would not, if adopted, impose significant costs. For these reasons, I certify that the proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. DOT requests comment on its certification and the expected economic impacts of the proposed rule.

Unfunded Mandates

The Secretary has examined the impact of this proposed rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This proposed rule does not trigger the requirement for a written statement under sec. 202(a) of the UMRA because this rulemaking does not impose a mandate that results in an expenditure of $200 million or more by either State, local, and Tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The DOT has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, ''Procedures for Considering Environmental Impacts'' (44 FR 56420, October 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). This proposed rule would amend the transportation industry drug testing program procedures regulation to establish a temporary requirement to conduct directly observed urine collections in situations where oral fluid collections are required but oral fluid testing is not yet available. This action is covered by the categorical exclusion listed at 23 CFR 771.118(c)(4), ''[p]lanning and administrative activities that do not involve or lead directly to construction, such as: . . . promulgation of rules, regulations, directives . . .'' The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Executive Order 13132: Federalism

The Secretary has analyzed the proposed rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Most of the regulated parties under the Department's drug testing program are private entities. Some regulated entities are public entities (*e.g.,* transit authorities and public works departments); however, the Secretary has determined that the proposed rule, which would provide temporary procedures to require the conduct of directly observed urine testing where oral fluid testing is not available, does not contain policies that have federalism implications.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires Federal agencies to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This proposed rule does not have Tribal implications. The proposed rule will also not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public. This proposed rule would not require any new collection of information under the PRA. Notwithstanding any other provision of

law, no person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a currently valid Office of Management and Budget (OMB) control number.

Privacy Act

Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

Rule Summary

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule can be found at *regulations.gov,* Docket DOT–OST–2021–0093, in the **SUMMARY** section of this document.

Pay-As-You-Go Act of 2023

In accordance with Compliance with Pay-As-You-Go Act of 2023 (Fiscal Responsibility Act of 2023, Pub. L. 118–5, div. B, title III) and OMB Memorandum (M–23–21) dated September 1, 2023, the Department has determined that this proposed rule is not subject to the Pay-As-You-Go Act of 2023 because it will not increase direct spending beyond specified thresholds.

List of Subjects in 49 CFR Part 40

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Laboratories, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, DOT proposes to amend 49 CFR part 40 as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

■ 1. The authority for 49 CFR part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 54101 *et seq.*

■ 2. In § 40.67:

■ a. In paragraph (g)(3) introductory text, remove the word ''collector'' and add in its place ''observer''; and

■ b. Add paragraph (g)(4).

The addition reads as follows:

§ 40.67 When and how is a directly observed urine collection conducted?

* * * * *

(g) * * *

(4) Notwithstanding paragraphs (g)(3)(i) and (ii) of this section, until otherwise specified (one year after HHS publishes a **Federal Register** notification of the second certified oral fluid drug testing laboratory), you must conduct an oral fluid collection if possible (*i.e.,* HHS has certified at least two oral fluid drug testing laboratories, and both a qualified oral fluid collector and a conforming oral fluid collection device are available at the collection site). Otherwise, you must conduct a directly observed urine collection as required in this section.

* * * * *

Signed pursuant to authority delegated at 49 CFR 1.27(c) in Washington, DC.

Subash Iyer,

Acting General Counsel.

[FR Doc. 2024–28561 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–9X–P

Notices

Federal Register
Vol. 89, No. 236
Monday, December 9, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, December 13, 2024, 10:00 a.m. EST.

ADDRESSES: Meeting to take place virtually and is open to the public via livestream on the Commission's YouTube page: *https://www.youtube.com/user/USCCR/videos.*

FOR FURTHER INFORMATION CONTACT: Joe Kim: 202–376–8371; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Government in Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on December 13, 2024, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

I. Approval of Agenda

II. Business Meeting

A. A Discussion and Vote on the planning documents for the 2025 Briefing Report Topic on Language Access, led by Commissioner Magpantay.

B. Management and Operations.

- Staff Director's Report.

III. Adjourn Meeting

Dated: December 5, 2024.

David Mussatt,

USCCR Chief of Regional Programs Unit.

[FR Doc. 2024–29013 Filed 12–5–24; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; High-Frequency Surveys Program/Household Trends and Outlook Pulse Survey (HTOPS)

On July 22, 2024, the Department of Commerce received clearance from the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 to conduct Phase 4.2 of the Household Pulse Survey (OMB No. 0607–1029, Exp. 01/31/27) and on July 12, 2024, clearance was received to conduct the tenth, eleventh, and twelfth Census Household Panel topical operations (OMB No. 0607–1025, Exp. 6/30/26). The Household Trends and Outlook Pulse Survey (HTOPS) is designed to ensure availability of frequent data collection for nationwide estimates on a variety of topics for a variety of subgroups of the population. This notice serves to inform of the Department's intent to request clearance from OMB to conduct HTOPS sample replenishment and January and February topical operations.

The purpose of the sample replenishment baseline instrument is to recruit a nationally representative survey panel and also collect data on a variety of topics of interest. The topical survey that will field in January will include a household roster update and a section of assistance program income questions that will be used to test several possible changes being made in preparation for the transition to a multimode version of the Survey of Income and Program Participation (SIPP) the SIPP redesign effort on a larger representative respondent sample. The results of this test will be for internal use only. The February topical survey will include content from the Household Pulse Survey. The Household Pulse Survey will continue to serve as an experimental endeavor coordinated with other federal agencies to produce near real-time data to understand the effects of current events, including health events, natural disaster events, or other social or economic events facing the nation or a significant portion of the nation.

It is the Department's intention to commence data collection using the revised instrument on or about July 23, 2024. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on February 15, 2024 (OMB No. 0607–1029) during a 30-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: High Frequency Surveys Program/Household Trends and Outlook Pulse Survey.

OMB Control Number: 0607–1029.

Form Number(s): Not yet determined.

Type of Request: Regular submission. Request for a Revision of a Currently Approved Collection.

Number of Respondents: Baseline: 18,000 respondents/Topicals 17,812 panel members.

Average Hours per Response: Baseline: .400 (24 minutes); Topicals: .333 (20 minutes).

Burden Hours: Baseline: 7,200/Topical 3,300 per month.

Needs and Uses: The High-Frequency Surveys Program was established as a natural progression from the creation of the Household Pulse Survey. The Household Trends and Outlook Pulse Survey (HTOPS) is a probability-based nationwide nationally representative survey panel designed to test the methods to collect data on a variety of topics of interest, and for conducting experimentation on alternative question wording and methodological approaches. The goal of the HTOPS is to ensure availability of frequent data collection for nationwide estimates on a variety of topics and a variety of subgroups of the population, meeting standards for transparent quality reporting of the Federal Statistical

Agencies and the Office of Management and Budget (OMB).

Panelists and households selected for the HTOPS were recruited from the Census Bureau's gold standard Master Address File. This ensures that HTOPS is rooted in this rigorously developed and maintained frame and available for linkage to administrative records securely maintained and curated by the Census Bureau. Invitations to complete the monthly surveys will be sent via email and SMS messages. Questionnaires will be mainly internet self-response. The HTOPS will maintain representativeness by allowing respondents who do not use the internet to respond via computer-assisted telephone interviewing (CATI). All panelists will receive an incentive for each complete questionnaire. Periodic replenishment samples will maintain representativeness and panelists will be replaced after a period of three years.

Affected Public: Households.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: 13 U.S.C. 141, 182 and 193.

This information collection request may be viewed at *www.reginfo.gov*. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–1025.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–28849 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 241127–0304]

RIN 0694–XC110

Impact of the Implementation of the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving ''Schedule 1'' Chemicals (Including ''Schedule 1'' Chemicals Produced as Intermediates) During Calendar Year 2024

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact that implementation of the Chemical Weapons Convention (CWC or ''the Convention''), through the Chemical Weapons Convention Implementation Act of 1998 and the Chemical Weapons Convention Regulations (CWCR), has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2024. The purpose of this notice of inquiry is to collect information to assist BIS in its preparation of the annual certification to the Congress on whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms are harmed by such implementation. This certification is required under Condition 9 of Senate Resolution 75 (April 24, 1997), in which the Senate gave its advice and consent to the ratification of the CWC.

DATES: Comments must be received by January 8, 2025.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking portal at: *www.regulations.gov.* The *regulations.gov* ID for this rule is: BIS–2024–0054. Please refer to RIN 0694–XC110 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The corresponding non-confidential version of those comments must be clearly marked ''PUBLIC.'' The file name of the non-confidential version should begin with the character ''P.'' Any submissions with file names that do not begin with either a ''BC'' or a ''P'' will be assumed to be public and will be made publicly available at: *https://www.regulations.gov.*

Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT:

For questions on the Chemical Weapons Convention requirements for ''Schedule 1'' chemicals, contact David Johnston, Treaty Compliance Division, (202) 482–2450, Email: David *Johnston@bis.doc.gov.*

For questions on the submission of comments, contact Logan Norton, Regulatory Policy Division, (202) 482–2440; Email: *RPD2@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction (CWC or ''the Convention''), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 9, titled ''Protection of Advanced Biotechnology,'' calls for the President to certify to Congress on an annual basis that ''the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1.'' On July 8, 2004, President George W. Bush, by Executive Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization

for the Prohibition of Chemical Weapons (OPCW). In order to achieve the object and purpose of the Convention and the implementation of its provisions, the CWC imposes certain obligations on countries that have ratified the Convention (*i.e.,* States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC. In the United States, the Chemical Weapons Convention Implementation Act of 1998 (22 U.S.C. 6701 *et seq.*) implements the provisions of the CWC.

''Schedule 1'' chemicals consist of those toxic chemicals and precursors set forth in the CWC ''Annex on Chemicals'' and in ''Supplement No. 1 to part 712—SCHEDULE 1 CHEMICALS'' of the CWCR (15 CFR parts 710–722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the ''Verification Annex'') restricts the production of ''Schedule 1'' chemicals for protective purposes to two facilities per State Party: a single small-scale facility and a facility for production in quantities not exceeding 10 kilograms (kg) per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103–21 defined the term ''protective purposes'' to mean ''used for determining the adequacy of defense equipment and measures.'' Consistent with this definition and as authorized by Presidential Decision Directive (PDD) 70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DoD) was assigned the responsibility to operate these two facilities. DoD maintains strict controls on ''Schedule 1'' chemicals produced at its facilities in order to ensure accountability for such chemicals, as well as their proper use, consistent with the object and purpose of the Convention. Although this assignment of responsibility to DoD under PDD–70 effectively precluded commercial production of ''Schedule 1'' chemicals for ''protective purposes'' in the United States, it did not establish any limitations on ''Schedule 1'' chemical activities that are not prohibited by the CWC.

The provisions of the CWC that affect commercial activities involving ''Schedule 1'' chemicals are implemented in the CWCR (see 15 CFR part 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR part 745), both of which are administered by BIS. Pursuant to CWC requirements, the CWCR restrict commercial production of ''Schedule 1'' chemicals to research, medical, or pharmaceutical purposes. The CWCR prohibit commercial production of ''Schedule 1'' chemicals for ''protective purposes'' because such production is effectively precluded per PDD–70, as described above (see 15 CFR 712.2(a)).

The CWCR also contain other requirements and prohibitions that apply to ''Schedule 1'' chemicals and/or ''Schedule 1'' facilities. Specifically, the CWCR:

(1) Prohibit the import of ''Schedule 1'' chemicals from States not Party to the Convention (15 CFR 712.2(b));

(2) Require annual declarations by certain facilities engaged in the production of ''Schedule 1'' chemicals in excess of 100 grams aggregate per calendar year (*i.e.,* declared ''Schedule 1'' facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));

(3) Provide for government approval of ''declared Schedule 1'' facilities (15 CFR 712.5(f));

(4) Require 200 days advance notification of the establishment of new ''Schedule 1'' production facilities producing greater than 100 grams aggregate of ''Schedule 1'' chemicals per calendar year (15 CFR 712.4);

(5) Provide that ''declared Schedule 1'' facilities are subject to initial and routine inspection by the OPCW (15 CFR 712.5(e) and 716.1(b)(1));

(6) Require advance notification and annual reporting of all imports and exports of ''Schedule 1'' chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of ''Schedule 1'' chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see the definition of ''production'' in 15 CFR 710.1), the phrase ''production of a Schedule 1 chemical'' means the formation of ''Schedule 1'' chemicals through chemical synthesis, as well as processing to extract and isolate ''Schedule 1'' chemicals. The phrase also encompasses the formation of a chemical through chemical reaction, including by a biochemical or biologically mediated reaction. ''Production of a Schedule 1 chemical'' is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Request for Comments

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, ''Schedule 1'' chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the CWC, through the Chemical Weapons Convention Implementation Act of 1998 and the CWCR, has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2024. To allow BIS to properly evaluate the significance of any harm to commercial activities involving ''Schedule 1'' chemicals, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice and in accordance with the instructions provided herein. BIS will consider all comments received on or before January 8, 2025.

Matthew S. Borman,

Principal Deputy Assistant Secretary for Strategic Trade and Technology Security.

[FR Doc. 2024–28755 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–852]

Melamine From Germany: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that melamine from Germany is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Noah Wetzel, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7466.

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2024, Commerce published in the **Federal Register** its preliminary determination in the LTFV investigation of melamine from Germany and invited interested parties to comment.[1] No interested party submitted comments. Accordingly, the final determination remains unchanged from the *Preliminary Determination* and no decision memoranda accompany this notice. The *Preliminary Determination* is hereby adopted in this final determination. Commerce conducted this LTFV investigation in accordance with section 735 of the Tariff Act of 1930, as amended (the Act).

Scope of the Investigation

The product covered by this investigation is melamine from Germany. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As stated in the *Preliminary Determination,* after being selected as the sole mandatory respondent, LAT Nitrogen Piesteritz GmbH (LAT Nitrogen), declined to participate and did not provide information requested by Commerce. Accordingly, Commerce based the *Preliminary Determination* entirely on the application of facts available with adverse inferences (AFA), and did not conduct verification under section 782(i) of the Act.

Use of Adverse Facts Available

As discussed in the *Preliminary Determination,* we assigned LAT Nitrogen an estimated weighted-average dumping margin based entirely on AFA, pursuant to sections 776(a) and (b) of Act.[2] There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination.* Accordingly, for this final determination, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to LAT Nitrogen.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In the *Preliminary Determination,* we assigned a dumping margin of 179.24 percent as the all-others rate based on a simple average of the calculated rates in the petition, pursuant to section 735(c)(5)(B) of the Act.[3] As noted above, we received no comments on our *Preliminary Determination;* thus, we continue to assign a dumping margin of 179.24 percent as the all-others rate for this final determination.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
LAT Nitrogen Piesteritz GmbH	*218.73
All Others	179.24

*Rate based on facts available with adverse inferences.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b).

However, because Commerce received no comments on the *Preliminary Determination,* it is adopting the *Preliminary Determination* as the final determination in this investigation. Consequently, there are no new calculations to disclose.

Suspension of Liquidation

In accordance with section 735(c)(4) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in the appendix to this notice, entered, or withdrawn from warehouse, for consumption, on or after September 24, 2024, which is the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), where appropriate, Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate as follows: (1) the cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of melamine from Germany no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded, and suspension of liquidation will be lifted. If the ITC determines that material injury, or the threat of material injury, exists, Commerce will issue an

[1] *See Melamine from Germany: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 89 FR 77822 (September 24, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *Id.,* 89 FR 77822.

[3] *Id.*

antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Suspension of Liquidation'' section above.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C3 H6 N6). Melamine is also known as 2,4,6-triamino-striazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2024–28800 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–428–853]

Melamine From Germany: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of melamine from the Federal Republic of Germany (Germany). The period of investigation is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Faris Montgomery, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–1537, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2024, Commerce published the *Preliminary Determination* in the **Federal Register**.[1] Commerce invited parties to comment on the *Preliminary Determination*.[2] We received no comments from interested parties and have accordingly made no changes to the *Preliminary Determination.* Accordingly, no decision memoranda accompany this notice. The *Preliminary Determination* is hereby adopted in this final determination. In the *Preliminary Determination,* and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final countervailing duty (CVD) determination with the final antidumping duty determination.[3] On July 22, 2024, Commerce tolled certain deadlines in this proceeding by seven days.[4] The deadline for the final determination is now December 2, 2024.

Scope of the Investigation

The product covered by this investigation is melamine from Germany. For a complete description of the scope of this investigation, *see* Appendix.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[5]

In making this final determination, Commerce relied on facts otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of adverse facts available, *see* the *Preliminary Determination.*

Verification

Because the examined respondents in this investigation did not provide information requested by Commerce and Commerce preliminarily determined each of the examined respondents to have been uncooperative, Commerce did not conduct verification.[6]

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act.

Pursuant to section 705(c)(5)(A)(ii) of the Act, if the individual estimated countervailable subsidy rates established for all exporters and producers individually examined are zero, *de minimis,* or determined based

[1] *See Melamine from Germany: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 89 FR 59053 (July 22, 2024), and accompanying Preliminary Decision Memorandum (PDM).

[2] *Id.,* 89 FR 59053.

[3] *Id.,* 89 FR 59053–59054.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] *See Preliminary Determination,* 89 FR 39054.

entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated subsidy rate for all other producers or exporters. Commerce has determined the individually estimated subsidy rate for the individually examined respondent under section 776 of the Act. Consequently, as a reasonable method, Commerce is determining the all-others rate based on the rate determined for LAT Nitrogen Piesteritz GmbH (LAT Nitrogen), the mandatory respondent in this investigation, as determined under section 776 of the Act.[7] For a full description of the methodology underlying Commerce's analysis, *see* the *Preliminary Decision Memorandum*.[8]

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Producer/exporter	Subsidy rate (percent *ad valorem*)
LAT Nitrogen Piesteritz GmbH	29.72
All Others	29.72

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce received no comments on the *Preliminary Determination,* it is adopting the *Preliminary Determination* as the final determination in this investigation. Consequently, there are no new calculations to disclose.

[7] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 21909, 21912 (April 23, 2008), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Sodium Nitrite from the Federal Republic of Germany,* 73 FR 38986, 38987 (July 8, 2008), and accompanying Issues and Decision Memorandum at Comment 2*; see also Notice of Final Determination of Sales at Less Than Fair Value: Raw Flexible Magnets from Taiwan,* 73 FR 39673, 39674 (July 10, 2008); and *Steel Threaded Rod from Thailand: Preliminary Determination of Sales at Less Than Fair Value and Affirmative Preliminary Determination of Critical Circumstances,* 78 FR 79670, 79671 (December 31, 2013), unchanged in *Steel Threaded Rod from Thailand: Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances,* 79 FR 14476, 14477 (March 14, 2014).

[8] *See Preliminary Determination* PDM at 8–14.

Suspension of Liquidation

As a result of our *Preliminary Determination,* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after July 22, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**.

In accordance with section 703(d) of the Act, effective November 20, 2024, we instructed CBP to discontinue the suspension of liquidation of all entries at that time, but to continue the suspension of liquidation of all entries between July 22, 2024, and November 19, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for such entries of subject merchandise. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of melamine from Germany. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of melamine from Germany. In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Administrative Protective Order

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to the APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C_3 H_6 N_6). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2024–28801 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–937]

Citric Acid and Certain Citrate Salts From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that RZBC Group Co., Ltd., RZBC Co., Ltd., RZBC Import & Export Co., Ltd., and RZBC (Juxian) Co., Ltd. (collectively, RZBC) did not sell subject merchandise in the United States at prices below normal value during the May 1, 2022, through April 30, 2023 period of review (POR).

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Maisha Cryor, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5831.

SUPPLEMENTARY INFORMATION:

Background

On June 6, 2024, Commerce published the *Preliminary Results* of the 2022–2023 administrative review of the antidumping duty order on citric acid and certain citrate salts (citric acid) from the People's Republic of China (China) [1] in the **Federal Register** and invited interested parties to comment.[2] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[3] On October 8, 2024, Commerce extended the deadline for the final results of this administrative review until December 10, 2024.[4] For a summary of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[5] Commerce conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the *Order* is citric acid from China. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

The issue raised in an interested party's case brief is addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on an analysis of the comment received, we made six changes to the margin calculation from the *Preliminary Results* for RZBC.[6]

The China-Wide Entity

Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[7] we did not conduct a review of the China-wide entity. Thus, the weighted-average dumping margin for the China-wide entity (*i.e.,* 156.87 percent) [8] is not subject to change as a result of this review.

Final Results of Review

We determine that the following weighted-average dumping margin exists for the period May 1, 2022, through April 30, 2023:

Exporter	Weighted-average dumping margin (percent)
RZBC Import & Export Co., Ltd	0.00

Disclosure

We intend to disclose the calculations performed for these final results of review to interested parties within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Tariff Act of 1930, amended (the Act) and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered this review. Because the respondent's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP to liquidate entries without regard to antidumping duties.[9] The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[10]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Where the respondent reported reliable entered values, Commerce will calculate importer/customer-specific ad valorem assessment rates by aggregating the amount of dumping calculated for all U.S. sales to the importer/customer and dividing this amount by the total entered value of the merchandise sold to the importer/customer.[11] Where an importer- (or customer-) specific assessment rate is zero or *de minimis* (*i.e.,* less than 0.50 percent), Commerce

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[1] *See Citric Acid and Certain Citrate Salts from Canada and the People's Republic of China: Antidumping Duty Orders,* 74 FR 25703 (May 29, 2009) (*Order*).

[2] *See Citric Acid and Certain Citrate Salts from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review; 2022–2023,* 89 FR 48377 (June 6, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[3] See Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[4] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2022–2023'' dated October 8, 2024.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Citric Acid and Certain Citrate Salts from the People's Republic of China; 2023–2023,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] *See* Issues and Decision Memorandum at 2–3.

[7] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[8] *See Order.*

[9] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102–03 (February 14, 2012); *see also* 19 CFR 351.106(c)(2).

[10] *See* section 751(a)(2)(C) of the Act.

[11] *See* 19 CFR 351.212(b)(1).

will instruct CBP to assess that importer's (or customer's) entries of subject merchandise without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). For entries that were not reported in the U.S. sales database submitted by RZBC during this review, Commerce will instruct CBP to liquidate such entries at the antidumping duty assessment rate for the China-wide entity (*i.e.,* 156.87 percent).[12]

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for RZBC the cash deposit rate will be the margin listed above; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be equal to the weighted- average dumping margin for the China-wide entity (*i.e.,* 156.87 percent); and (4) for all non- Chinese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.

[12] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing the final results of this review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 3, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28858 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–901]

Organic Soybean Meal From India: Final Results and Partial Rescission of Antidumping Duty Administrative Review; 2021–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that Shanti Worldwide (Shanti) made sales of subject merchandise at less than normal value during the period of review (POR) November 2, 2021, through April 30, 2023. Additionally, we are rescinding the review with respect to Shri Sumati Industries Pvt. Ltd. (Sumati), because we find that they did not make *bona fide* sales during the POR.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah Keith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0264.

SUPPLEMENTARY INFORMATION:

Background

On June 5, 2024, Commerce published the preliminary results of the 2021–2023 administrative review of the antidumping duty order on organic soybean meal from India.[1] We invited interested parties to comment on the *Preliminary Results*.[2] No interested parties submitted comments; thus, no decision memorandum accompanies this notice. The *Preliminary Results* are hereby adopted as the final results of this review. Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The merchandise subject to the *Order* is organic soybean meal from India. A full description of the scope of the *Order* is provided in the *Preliminary Results*.[4]

Recission of Administrative Review, in Part

In the *Preliminary Results,* we stated that we intended to rescind this review with respect to Sumati for which we preliminarily found that Sumati did not make a *bona fide* sale of organic soybean meal during the POR.[5] No party filed comments with respect to this preliminary finding. Therefore, we are rescinding the administrative review with respect to this company.

Final Results of the Review

We determine the following estimated weighted-average dumping margins for the period November 2, 2021, through April 30, 2023.

[1] *See Organic Soybean Meal from India: Preliminary Results, Preliminary Intent to Rescind, in part, and Partial Rescission of Antidumping Duty Administrative Review; 2021–2023,* 89 FR 48147 (June 5, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Results.*

[3] *See Organic Soybean Meal from India: Antidumping Duty Order,* 87 FR 29737 (May 16, 2022) (*Order*).

[4] *See Preliminary Results* PDM at 3.

[5] *See* Memorandum, ''Preliminary *Bona Fide* Sales Analysis for Shri Sumat Industries Pvt. Ltd.,'' (June 5, 2024); *see also Preliminary Results* PDM at 4–5.

Exporter/producer	Weight-average dumping margin (percent)
Shanti Worldwide	18.80

Disclosure

Because Commerce received no comments on the *Preliminary Results,* we have not modified our analysis. Consequently, there are no calculations to disclose in accordance with 19 CFR 351.224(b) for these final results.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. If the weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent), upon completion of the final results, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[6] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. Where the weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[7]

For entries of subject merchandise during the POR produced by Shanti for which it did not know that the merchandise it sold to the intermediary (*e.g.,* reseller, trading company, or exporter) was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[8]

For the company for which we are rescinding this review, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue these rescission instructions to CBP no earlier than 35 days after the publication of this notice in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies under review will equal to the dumping margin established in the final results of this review for each respondent (except, if that rate is *de minimis,* then the cash deposit rate will be zero); (2) for producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review or a prior segment of the proceeding but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.07 percent, the all-others rate established in the less-than-fair-value investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing the final results of this review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–28757 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See* 19 CFR 351.212(b)(1).

[7] *See* 19 CFR 352.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[8] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–421–817]

Melamine From the Netherlands: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that melamine from the Netherlands is

being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924.

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2024, Commerce published in the **Federal Register** its preliminary determination in the LTFV investigation of melamine from the Netherlands and invited interested parties to comment.[1] No interested party submitted comments. Accordingly, the final determination remains unchanged from the *Preliminary Determination* and no decision memoranda accompany this notice. The *Preliminary Determination* is hereby adopted in this final determination. Commerce conducted this LTFV investigation in accordance with section 735 of the Tariff Act of 1930, as amended (the Act).

Scope of the Investigation

The product covered by this investigation is melamine from the Netherlands. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As stated in the *Preliminary Determination,* after being selected as the sole mandatory respondent, OCI Nitrogen B.V. (OCI Nitrogen), discontinued its participation in this investigation. Accordingly, Commerce based the *Preliminary Determination* entirely on the application of facts available with adverse inferences (AFA), and did not conduct verification under section 782(i) of the Act.

Use of Adverse Facts Available

As discussed in the *Preliminary Determination,* we assigned OCI Nitrogen an estimated weighted-average dumping margin based entirely on AFA, pursuant to sections 776(a) and (b) of Act.[2] There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination.* Accordingly, for this final determination, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to OCI Nitrogen.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In the *Preliminary Determination,* we assigned an estimated weighted-average dumping margin of 53.50 percent as the all-others rate based on a simple average of the dumping margins alleged in the petition, pursuant to section 735(c)(5)(B) of the Act.[3] As noted above, we received no comments on our *Preliminary Determination;* thus, we continue to assign an estimated weighted-average dumping margin of 53.50 percent to all other producers and exporters for this final determination.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter or producer	Weighted-average dumping margin (percent)
OCI Nitrogen B.V	*72.16
All Others	53.50

*Rate based on facts available with adverse inferences.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce received no comments on the *Preliminary Determination,* it is adopting the *Preliminary Determination* as the final determination in this investigation. Consequently, there are no new calculations to disclose.

Suspension of Liquidation

In accordance with section 735(c)(4) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in the appendix to this notice, entered, or withdrawn from warehouse, for consumption, on or after September 24, 2024, which is the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), where appropriate, Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate as follows: (1) the cash deposit rate for merchandise produced or exported by OCI Nitrogen will be equal to OCI Nitrogen's company-specific estimated weighted-average dumping margin determined in this final determination; (2) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin as determined in the final determination. These suspension of liquidation instructions and cash deposit requirements will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of melamine from the Netherlands no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded, and suspension of liquidation will be lifted. If the ITC determines that material injury, or the threat of material injury, exists, Commerce will issue an antidumping order directing CBP to assess, upon further instruction by

[1] *See Melamine from the Netherlands: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 89 FR 77829 (September 24, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *Id.,* 89 FR 77830.

[3] *Id.*

Commerce, antidumping duties on all imports of the subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Suspension of Liquidation'' section.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula $C_3 H_6 N_6$). Melamine is also known as 2,4,6-triamino-striazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2024–28795 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–518–001]

Melamine From Qatar: Final Negative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that melamine from Qatar is not being, or is not likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Andrew Hart, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1058.

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2024, Commerce published in the **Federal Register** its preliminary negative determination in the LTFV investigation of melamine from Qatar and invited interested parties to comment on the *Preliminary Determination*.[1]

A summary of the events that occurred since Commerce published its *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

[1] *See Melamine from Qatar: Preliminary Negative Determination of Sales at Less Than Fair Value,* 89 FR 77824 (September 24, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Negative Determination in the Less-Than-Fair-Value Investigation of Melamine from Qatar,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Final Negative Determination of Critical Circumstances

We continue to find that critical circumstances do not exist for imports of melamine from Qatar for all producers and exporters pursuant to section 733(e)(1)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.206. For a discussion and analysis of comments regarding Commerce's critical circumstances analysis, *see* the Issues and Decision Memorandum.

Scope of the Investigation

The product covered by this investigation is melamine from Qatar. For a complete description of the scope of this investigation, *see* Appendix I to this notice.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i)(1) of the Act, in October 2024, we verified the sales and cost information submitted by QMC/Muntajat [3] for use in our final determination. We used standard verification procedures, including an examination of relevant sales and accounting records, and original source documents provided by QMC/Muntajat.[4]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs submitted by interested parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached as Appendix II to this notice.

[3] As discussed in the *Preliminary Determination,* Commerce preliminarily collapsed the following companies and treated them as a single entity: Qatar Melamine Company (QMC); Qatar Chemical and Petrochemical marketing and Distribution Company (Muntajat) Q.P.J.S.C. (Muntajat) (collectively QMC/Muntajat); and Qatar Fertiliser Company P.S.C. (QAFCO). Commerce continues to collapse these companies and treat them as a single entity for the final determination.

[4] *See* Memoranda, ''Verification of the Sales Response of Qatar Melamine Company and Qatar Chemical and Petrochemical Marketing and Distribution Company Q.P.J.S.C. in the Antidumping Duty Investigation of Melamine from Qatar,'' dated October 17, 2024 (Sales Verification Report); and ''Verification of the Cost Responses of Qatar Melamine Company in the Antidumping Duty Investigation of Melamine from Qatar,'' dated November 1, 2024 (Cost Verification Report).

Changes Since the Preliminary Determination

We made certain changes to the margin calculation for QMC/Muntajat, since the *Preliminary Determination*.[5] For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Determination

Commerce determines that the following estimated weighted-average dumping margins exist for the period, January 1, 2023, through December 31, 2023:

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Qatar Melamine Company; Qatar Chemical and Petrochemical Marketing and Distribution Company (Muntajat) Q.P.J.S.C.; Qatar Fertiliser Company (P.S.C.).	0.00	Not Applicable.

Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters pursuant to sections 735(c)(1)(B) and (c)(5) of the Act, because it has not made a final affirmative determination of sales at LTFV.

Disclosure

Commerce intends to disclose the calculations performed in connection with this final determination to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the publication of the notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In the *Preliminary Determination,* the estimated weighted-average dumping margin for QMC/Muntajat was *de minimis* and, therefore, we did not suspend liquidation of entries of melamine from Qatar. Because Commerce has made a final negative determination of sales at LTFV with regard to the subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation or to require cash deposit of estimated antidumping duties for entries of melamine from Qatar.

U.S. International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the U.S. international Trade Commission of its final negative determination of sales at LTFV. As our final determination is negative, this proceeding is terminated in accordance with section 735(c)(2) of the Act.

Administrative Protective Order

This notice serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination and this notice are issued and published in accordance with sections 735(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula $C_3 H_6 N_6$). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28796 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–518–002]

Melamine From Qatar: Final Affirmative Countervailing Duty Determination and Final Negative Critical Circumstances Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of melamine from Qatar. The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

[5] *See* Memorandum, ''Analysis for the Final Determination for Qatar Melamine Company and Qatar Chemical and Petrochemical Marketing and Distribution Company Q.P.J.S.C.,'' dated concurrently with this notice.

FOR FURTHER INFORMATION CONTACT: Samantha Kinney and Sofia Pedrelli, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2285 and (202)-482–4310, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2024, Commerce published in the **Federal Register** its preliminary determination in the countervailing duty (CVD) investigation of melamine from Qatar and invited interested parties to comment.[1] In the *Preliminary Determination,* and in accordance with section 705(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(4), Commerce aligned the final CVD determination with the final antidumping duty determination of melamine from Qater.[2] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[3] The deadline for the final determination is now December 2, 2024. On September 12, 2024, Commerce released its Post-Preliminary Decision.[4]

For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[5] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is melamine from Qatar. For a complete description of the scope of the investigation, *see* Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As provided in section 782(i) of the Act, in September 2024, Commerce verified all information reported by Qatar Melamine Company (QMC), Qatar Chemical and Petrochemical Marketing and Distribution Company (Muntajat) Q.P.J.S.C (Muntajat), and its cross-owned affiliates, QAFCO, Industries Qatar, and QatarEnergy (collectively, QMC/Muntajat),[6] and the Government of Qatar (GOQ). We used standard verification procedures, including an examination of relevant account records and original source documents provided by QMC/Muntajat.[7]

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case and rebuttal briefs by interested parties in this investigation, are discussed in the Issues and Decision Memorandum. For a list of the issues raised by parties, and to which we responded in the Issues and Decision Memorandum, *see* Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[8] Commerce notes that, in making these findings, it relied, in part, on facts available and, because it finds that QMC/Muntajat did not act to the best of its ability to respond to Commerce's requests for information, Commerce drew an adverse inference where appropriate in selecting from among the facts otherwise available.[9] For further information, *see* the ''Use of Facts Otherwise Available and Adverse Inferences'' section in the Preliminary Decision Memorandum. For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

Final Negative Determination of Critical Circumstances

Commerce determines that critical circumstances do not exist within the meaning of 703(e)(1) of the Act. For further information, *see* the Issues and Decision Memorandum.

Changes Since the Preliminary Determination and Post-Preliminary Analysis

Based on our review and analysis of the information received during verification and comments received from interested parties, for this final determination, we made certain changes to the countervailable subsidy rate calculations for QMC/Muntajat, and for all other producers/exporters. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual estimated countervailable subsidy rate for the mandatory respondent, QMC/Muntajat. Section 705(c)(5)(A)(i) of the Act states that, for companies not individually investigated, Commerce will determine an all-others rate equal to the weighted-average countervailable subsidy rates established for exporters and/or producers individually investigated, excluding any zero and *de minimis* countervailable subsidy rates, and any rates determined entirely under section 776 of the Act.

In this investigation, we continue to calculate an individual total net countervailable subsidy rate for QMC/Muntajat that is not zero, *de minimis,* or based entirely on facts otherwise available. Because QMC/Muntajat's individual total net countervailable subsidy rate is the only rate calculated in this investigation, the all-others rate is the individual estimated subsidy rate calculated for the examined respondent (QMC/Muntajat), in accordance with section 705(c)(5)(A)(i) of the Act.

[1] *See Melamine from Qatar: Preliminary Affirmative Countervailable Duty Determination, Preliminary Negative Determination of Critical Circumstances, and Alignment of Final Determination With the Final Antidumping Duty Determination,* 89 FR 59045 (July 22, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Determination,* 89 FR 59046.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[4] *See* Memorandum, ''Post Preliminary Analysis Memorandum for the Countervailing Duty Investigation of Melamine from Qatar,'' dated September 12, 2024 (Post-Preliminary Analysis Memorandum).

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Melamine from Qatar,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] Commerce continues to determine that QMC is cross owned with Muntajat, Qatar Fertiliser Company (P.S.C.) (QAFCO), Industries Qatar Q.P.S.C. (Industries Qatar) and QatarEnergy. *See Preliminary Determination* PDM at 7–9; *see also* Post-Preliminary Analysis Memorandum at 3.

[7] *See* Memoranda, ''Verification of the Questionnaire Responses of Qatar Melamine Company and Muntajat,'' dated October 30, 2024; and ''Verification of the Questionnaire Responses of the Government of Qatar,'' dated October 30, 2024.

[8] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[9] *See* sections 776(a) and (b) of the Act.

Final Determination

Commerce determines that the following estimated net countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023:

Company	Subsidy rate (percent *ad valorem*)
Qatar Melamine Company; Qatar Chemical and Petrochemical Marketing and Distribution Company (Muntajat) Q.P.J.S.C.; Qatar Fertiliser Company (P.S.C.); Industries Qatar Q.P.S.C.; QatarEnergy	41.91
All Others	41.91

Disclosure

Commerce intends to disclose its calculations performed to interested parties in this final determination within five days of its public announcement or, if there is no public announcement, within five days of the date of the publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination,* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after July 22, 2024, the date of publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse, on or after November 19, 2024, but to continue the suspension of liquidation of all entries of subject merchandise on or before November 18, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. Pursuant to section 705(c)(2) of the Act, if the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled.

ITC Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its final affirmative determination that countervailable subsidies are being provided to producers and exporters of melamine from Qatar. As Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will determine, within 45 days of our final determination, whether the domestic industry in the United States is materially injured, or threated with material injury, by reason of imports of melamine from Qatar. In addition, we are making available to the ITC all non-privileged and non-proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order

This notice will serve as the only reminder to parties subject to the APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula $C_3 H_6 N_6$). Melamine is also known as 2,4,6-triamino-s-triazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28797 Filed 12–6–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–824]

Oil Country Tubular Goods From Argentina: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that Siderca S.A.I.C. (Siderca) made sales of subject merchandise at less than normal value (NV) during the period of review (POR) May 11, 2022, through October 31, 2023. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0665.

SUPPLEMENTARY INFORMATION:

Background

On November 21, 2022, Commerce published in the **Federal Register** the antidumping duty order on oil country tubular goods (OCTG) from Argentina.[1] On November 2, 2023, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.[2] On December 29, 2023, based on timely requests for an administrative review, Commerce initiated an administrative review of the *Order*.[3] On January 25, 2024, Commerce identified Siderca as the sole mandatory respondent in this administrative review.[4] On July 9, 2024, Commerce extended the time limit for these preliminary results to November 29, 2024.[5] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[6] The deadline for the preliminary results is now December 6, 2024.

For a complete description of the events that occurred since the initiation of this review, *see* the Preliminary Decision Memorandum.[7]

Scope of the Order

The products covered by the *Order* are OCTG from Argentina. For a complete description of the scope of this *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). We calculated constructed export price and NV in accordance with sections 772 and 773 of the Act, respectively. For a complete description of the methodology in these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached in the appendix to this notice. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

We preliminarily determine that the following estimated weighted-average dumping margin exists for the period May 11, 2022, through October 31, 2023:

Producer or exporter	Weighted-average dumping margin (percent)
Siderca S.A.I.C	6.8

Disclosure

We intend to disclose the calculations and analysis performed for these preliminary results to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice.[8]

Public Comment

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Interested parties who submit case or rebuttal briefs in this administrative review must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this administrative review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[11] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the

[1] *See Oil Country Tubular Goods from Argentina, Mexico, and the Russian Federation: Antidumping Duty Orders and Amended Final Affirmative Antidumping Duty Determination for the Russian Federation,* 87 FR 70785 (November 21, 2022) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 75270 (November 2, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 90168 (December 29, 2023).

[4] *See* Memorandum, ''Company to be Individually Examined,'' dated January 25, 2024.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated July 9, 2024.

[6] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Oil Country Tubular Goods from Argentina; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[8] *See* 19 CFR 351.224(b).

[9] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

issues and decision memorandum that will accompany the final results of this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance via ACCESS within 30 days after the date of publication of this notice. Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised at the hearing will be limited to those raised in the case and rebuttal briefs. If a hearing request is made, parties will be notified of the date and time of the hearing.[12] Parties should confirm the date and time of the hearing two days before the scheduled date.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[13] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in written briefs, no later than 120 days after the date of publication of this notice in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon completion of the final results of this administrative review, pursuant to section 751(a)(2)(A) of the Act, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review.[15] If Siderca's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we intend to calculate an importer-specific assessment rate for antidumping duties based on the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[16] If Siderca's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of this review, we intend to instruct CBP to liquidate relevant entries without regards to antidumping duties.

For entries of subject merchandise during the POR produced by Siderca for which it did not know that the merchandise was destined to the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[17]

The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[18] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired, *i.e.,* within 90 days of publication.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of the final results of this administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided in section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Siderca will be equal to the weighted-average dumping margin established in the final results of this administrative review, except, if that rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), then the cash deposit rate will be zero; (2) for merchandise exported by a company not covered in this review but covered in a prior completed segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the investigation but the producer is, then the cash deposit rate will be the company-specific rate established in the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 78.30 percent, the all-others rate established in the original less-than-fair-value investigation.[19] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(1), (3), and (h)(2), and 19 CFR 351.221(b)(4).

Dated: December 3, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–28859 Filed 12–6–24; 8:45 am]

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[12] *See* 19 CFR 351.310(d).

[13] *See* 19 CFR 351.303.

[14] *See APO and Service Final Rule.*

[15] *See* 19 CFR 351.212(b)(1).

[16] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[17] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[18] *See* section 751(a)(2)(C) of the Act; and 19 CFR 351.212(b).

[19] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–274–810]

Melamine From Trinidad and Tobago: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that melamine from Trinidad and Tobago is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2024, Commerce published in the **Federal Register** its preliminary determination in the LTFV investigation of melamine from Trinidad and Tobago and invited interested parties to comment.[1] No interested party submitted comments. Accordingly, the final determination remains unchanged from the *Preliminary Determination* and no decision memoranda accompany this notice. The *Preliminary Determination* is hereby adopted in this final determination. Commerce conducted this LTFV investigation in accordance with section 735 of the Tariff Act of 1930, as amended (the Act).

Scope of the Investigation

The product covered by this investigation is melamine from Trinidad and Tobago. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As stated in the *Preliminary Determination,* after being selected as the sole mandatory respondent, Methanol Holdings (Trinidad) Limited (MHTL) discontinued its participation in this investigation. Accordingly, Commerce based the *Preliminary Determination* entirely on the application of facts available with adverse inferences (AFA), and did not conduct verification under section 782(i) of the Act.

Final Affirmative Determination of Critical Circumstances, in Part

We continue to find that critical circumstances exist for imports of melamine from Trinidad and Tobago for the mandatory respondent MHTL but do not exist for all other producers and exporters pursuant to sections 735(a)(3)(A) and (B) of the Act and 19 CFR 351.206.[2]

Use of Adverse Facts Available

As discussed in the *Preliminary Determination,* we assigned MHTL an estimated weighted-average dumping margin based entirely on AFA, pursuant to sections 776(a) and (b) of Act.[3] There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination.* Accordingly, for this final determination, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to MHTL.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In the *Preliminary Determination,* we assigned a dumping margin of 98.32 percent as the all-others rate based on a simple average of the calculated rates in the petition, pursuant to section 735(c)(5)(B) of the Act.[4] As noted above, we received no comments on our *Preliminary Determination;* thus, we continue to assign a dumping margin of 98.32 percent as the all-others rate for this final determination.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/Producer	Weighted-average dumping margin (percent) *
Methanol Holdings (Trinidad) Limited	** 146.85
All Others	98.32

* Consistent with the *Preliminary Determination,* because the companion countervailing duty investigation found no export subsidies, we have not offset the weighted-average dumping margins.

** Rate based on facts available with adverse inferences.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce received no comments on the *Preliminary Determination,* it is adopting the *Preliminary Determination* as the final determination in this investigation. Consequently, there are no new calculations to disclose.

Suspension of Liquidation

In accordance with section 735(c)(4) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in the appendix to this notice, entered, or withdrawn from warehouse, for consumption, on or after June 26, 2024, which is 90 days prior to the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), where appropriate, Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate as follows: (1) the cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit

[1] *See Melamine from Trinidad and Tobago: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Affirmative Determination of Critical Circumstances, In Part,* 89 FR 77814 (September 24, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Determination* PDM at 9–13.

[3] *See Preliminary Determination,* 89 FR 77815.

[4] *Id.*

rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of melamine from Trinidad and Tobago no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded, and suspension of liquidation will be lifted. If the ITC determines that material injury, or the threat of material injury, exists, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Suspension of Liquidation'' section.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C3 H6 N6). Melamine is also known as 2,4,6-triamino-striazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2024–28799 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–274–811]

Melamine From Trinidad and Tobago: Final Affirmative Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of melamine from Trinidad & Tobago. The period of investigation is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Megan Goins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0884.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2024, Commerce published its *Preliminary Determination* in the **Federal Register** and invited interested parties to comment.[1] Also on July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] The deadline for the final determination is now December 2, 2024.

A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum.[3] The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is melamine from Trinidad and Tobago. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation, and the issues raised in the case brief that was submitted by a party in this investigation, are discussed in the Issues and Decision

[1] *See Melamine from Trinidad and Tobago: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination,* 89 FR 59057 (July 22 2024) (*Preliminary Determination*), and accompanying Preliminary Determination Memorandum (PDM).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Countervailing Duty Investigation of Melamine from Trinidad and Tobago,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Memorandum. For a list of the issues raised by that interested party and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[4] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making this final determination, Commerce relied on facts otherwise available, including with an adverse inference (AFA), pursuant to sections 776(a) and (b) of the Act. For a full discussion of our application of AFA, *see* the *Preliminary Determination,*[5] and the Issues and Decision Memorandum section entitled ''Use of Facts Otherwise Available and Application of Adverse Inferences.''

Verification

Because the examined respondent in this investigation did not provide information requested by Commerce and Commerce preliminarily determined the examined respondent to have been uncooperative, Commerce did not conduct verification.[6]

All-Others Rate

As discussed in the *Preliminary Determination,* Commerce based the selection of the all-others rate on the countervailable subsidy rate established for the mandatory respondent, in accordance with section 703(d) of the Act.[7] Consistent with section 705(c)(5)(A)(ii) of the Act, we made no changes to the selection of the all-others rate for this final determination.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
Methanol Holdings (Trinidad) Ltd	*7.43
All Others	7.43

*Rate based on AFA.

Disclosure

Commerce normally discloses to interested parties the calculations and analysis performed in a final determination within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce applied total AFA to the respondent in this investigation, in accordance with section 776 of the Act, and the applied AFA rates are based on rates calculated in prior proceedings, there are no calculations to disclose.

Suspension of Liquidation

As a result of our *Preliminary Determination,* and pursuant to sections 703(d)(1)(B) and (d)(2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to collect cash deposits and suspend liquidation of entries of subject merchandise from Trinidad and Tobago that were entered, or withdrawn from warehouse, for consumption, on or after July 22, 2024, the date of the publication of the *Preliminary Determination* in the **Federal Register**. In accordance with section 703(d) of the Act, we also instructed CBP to discontinue the suspension of liquidation of all entries of subject merchandise entered or withdrawn from warehouse on, or after November 19, 2024, but to continue the suspension of liquidation of all entries of subject merchandise between July 22, 2024, and November 18, 2024.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a countervailing duty order, reinstate the suspension of liquidation under section 706(a) of the Act, and require a cash deposit of estimated countervailing duties for entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of melamine from Trinidad and Tobago. Because the final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of melamine from Trinidad and Tobago no later than 45 days after our final determination. In addition, we are making available to the ITC all non-privileged and nonproprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final determination in accordance with sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

[4] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; *see also* section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[5] *See Preliminary Determination* PDM at 5–9.

[6] *See Preliminary Determination,* 89 FR 59058.

[7] *Id.*

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C3 H6 N6). Melamine is also known as 2,4,6- triamino-s-triazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. A ll melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–28798 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–882]

Melamine From Japan: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, In Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that melamine from Japan is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2023, through December 31, 2023.

DATES: Applicable December 9, 2024.

FOR FURTHER INFORMATION CONTACT: George McMahon, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1167.

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2024, Commerce published in the **Federal Register** its preliminary determination in the LTFV investigation of melamine from Japan and invited interested parties to comment.[1] No interested party submitted comments. Accordingly, the final determination remains unchanged from the *Preliminary Determination* and no decision memoranda accompany this notice. The *Preliminary Determination* is hereby adopted in this final determination. Commerce conducted this LTFV investigation in accordance with section 735 of the Tariff Act of 1930, as amended (the Act).

Scope of the Investigation

The product covered by this investigation is melamine from Japan. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Scope Comments

We received no comments from interested parties on the scope of the investigation as it appeared in the *Preliminary Determination.* Therefore, we made no changes to the scope of the investigation.

Verification

As stated in the *Preliminary Determination,* after being selected as the sole mandatory respondent, Mitsui Chemicals, Inc. (Mitsui Chemicals), declined to participate and did not provide information requested by Commerce. Accordingly, Commerce based the *Preliminary Determination* entirely on the application of facts available with adverse inferences (AFA), and did not conduct verification under section 782(i) of the Act.

Final Affirmative Determination of Critical Circumstances, in Part

We continue to find that critical circumstances exist for imports of melamine from Japan for the mandatory respondent Mitsui Chemicals but do not exist for all other producers and exporters pursuant to sections 735(a)(3)(A) and (B) of the Act and 19 CFR 351.206.[2]

Use of Adverse Facts Available

As discussed in the *Preliminary Determination,* we assigned Mitsui Chemicals an estimated weighted-average dumping margin based entirely on AFA, pursuant to sections 776(a) and (b) of Act.[3] There is no new information on the record that would cause us to revisit our decision in the *Preliminary Determination.* Accordingly, for this final determination, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to Mitsui Chemicals.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In the *Preliminary Determination,* we assigned a dumping margin of 115.11 percent as the all-others rate based on a simple average of the calculated rates in the petition, pursuant to section 735(c)(5)(B) of the Act.[4] As noted above, we received no comments on our *Preliminary Determination;* thus, we

[1] *See Melamine from Japan: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Affirmative Determination of Critical Circumstances, In Part,* 89 FR 77819 (September 24, 2024) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See Preliminary Determination,* 89 FR 77820.

[3] *Id.*

[4] *Id.*

continue to assign a dumping margin of 115.11 percent as the all-others rate for this final determination.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Mitsui Chemicals, Inc	* 127.69
All Others	115.11

* Rate is based on facts available with adverse inferences.

Disclosure

Normally, Commerce will disclose to the parties in a proceeding the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce received no comments on the *Preliminary Determination,* it is adopting the *Preliminary Determination* as the final determination in this investigation. Consequently, there are no new calculations to disclose.

Suspension of Liquidation

In accordance with section 735(c)(4) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of subject merchandise, as described in the appendix to this notice, entered, or withdrawn from warehouse, for consumption, on or after June 26, 2024, which is 90 days prior to the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), where appropriate, Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate as follows: (1) the cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

U.S. International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of melamine from Japan no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits will be refunded, and suspension of liquidation will be lifted. If the ITC determines that material injury, or the threat of material injury, exists, Commerce will issue an antidumping order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation as discussed above in the ''Suspension of Liquidation'' section.

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: December 2, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The merchandise subject to this investigation is melamine (Chemical Abstracts Service (CAS) registry number 108–78–01, molecular formula C_3 H_6 N_6). Melamine is also known as 2,4,6-triamino-striazine; 1,3,5-Triazine-2,4,6- triamine; Cyanurotriamide; Cyanurotriamine; Cyanuramide; and by various brand names. Melamine is a crystalline powder or granule. All melamine is covered by the scope of this investigation irrespective of purity, particle size, or physical form. Melamine that has been blended with other products is included within this scope when such blends include constituent parts that have been intermingled, but that have not been chemically reacted with each other to produce a different product. For such blends, only the melamine component of the mixture is covered by the scope of this investigation. Melamine that is otherwise subject to this investigation is not excluded when commingled with melamine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

The subject merchandise is provided for in subheading 2933.61.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2024–28794 Filed 12–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[AFD–2200]

Notice of Intent To Grant a Joint Ownership Agreement With an Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant a joint ownership agreement with an Exclusive Patent License to The Board of Trustees of the University of Alabama, for and on behalf of The University of Alabama in Huntsville having a place of business at 301 Sparkman Drive NW, Huntsville, AL 35899.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to William Loux, AFRL/RWPB, 101 West Eglin Boulevard, Eglin AFB, FL 32542; Phone: (850) 882–3920; or Email: *afrl.rw.techtransfer@us.af.mil.* Include Docket No. AFD–2200 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: William Loux, AFRL/RWPB, 101 West Eglin Boulevard, Eglin AFB, FL 32542; phone: (850) 882–3920; or email: *afrl.rw.techtransfer@us.af.mil.*

SUPPLEMENTARY INFORMATION:

Abstract of patent application(s): An image processing system receives a digital image and analyzes the digital image to determine a resolution limit, referred to herein as ''feature resolution,'' for measuring a metric for features of the image within an acceptable margin of error. Specifically, the system segments a digital image and calculates the error associated with the segmented data when features within a certain range a measured metric (*e.g.,* size range) are removed from the segmented data. This analysis can be repeatedly performed with different cutoff values for the metric until at least a threshold amount of error is reached, thereby indicating a resolution limit at the boundary of an acceptable amount of error.

Intellectual property: U.S. Application No. 17/671,527, filed on February 14, 2022, and entitled ''*Systems and Methods for Determining Feature Resolution of Image Data.*''

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Authority: 35 U.S.C. 209; 37 CFR part 404.

Tommy W. Lee,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2024–28824 Filed 12–6–24; 8:45 am]

BILLING CODE 3911–44–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2411–030]

Eagle Creek Schoolfield, LLC, City of Danville; Notice of Intent To Prepare an Environmental Assessment

On July 29, 2022, Eagle Creek Schoolfield and the City of Danville filed a relicense application for the 4.5-megawatt Schoolfield Hydroelectric Project No. 2411. The project is located on the Dan River in Pittsylvania County near the City of Danville, Virginia.

In accordance with the Commission's regulations, on September 19, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to relicense the project.[1]

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

The application will be processed according to the following schedule. The EA will be issued for a 30-day comment period. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	December 2, 2025.

Any questions regarding this notice may be directed to Claire Rozdilski at (202) 502–8259 or *claire.rozdilski@ferc.gov.*

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28839 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

[1] In accordance with the Council on Environmental Quality's regulations, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1733139578. 40 CFR 1501.5(c)(4) (2024).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–49–000.
Applicants: Escape Solar LLC.
Description: Escape Solar LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.
Filed Date: 12/3/24.
Accession Number: 20241203–5084.
Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: EG25–50–000.
Applicants: Long Beach Generation LLC.
Description: Long Beach Generation LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.
Filed Date: 12/3/24.
Accession Number: 20241203–5158.
Comment Date: 5 p.m. ET 12/24/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–1848–001.
Applicants: Portland General Electric Company.
Description: Compliance filing: PGE Order Nos.2023_2023A_Amendment_Compliance_Filing to be effective 12/23/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5209.
Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: ER24–2804–000; ER18–1639–000; ER18–1639–014.
Applicants: Constellation Mystic Power, LLC, Constellation Mystic Power, LLC.
Description: Constellation Mystic Power, LLC submit a compliance filing to the November 1, 2024, Commission's order.
Filed Date: 11/27/24.
Accession Number: 20241127–5356.
Comment Date: 5 p.m. ET 12/18/24.

Docket Numbers: ER24–2896–002.
Applicants: ALLETE, Inc.
Description: Tariff Amendment: ALLETE CMA End Deferral Filing to be effective 8/29/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5121.
Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: ER25–85–000.
Applicants: Westside Canal 2A, LLC.
Description: Supplement to 10/11/2024 Westside Canal 2A, LLC tariff filing.
Filed Date: 11/27/24.
Accession Number: 20241127–5330.
Comment Date: 5 p.m. ET 12/9/24.

Docket Numbers: ER25–585–000.
Applicants: Pacific Gas and Electric Company.
Description: TO SA 489: Metcalf Energy Center Unexecuted LGIA to be effective 11/29/2024.
Filed Date: 11/27/24.
Accession Number: 20241127–5190.
Comment Date: 5 p.m. ET 12/18/24.
Docket Numbers: ER25–612–000.
Applicants: PJM Interconnection L.L.C.
Description: PJM Interconnection, L.L.C. submits one-time prospective limited waiver request for an extension of time to complete its annual review of costs and benefits of one economic project as required by Amended and Restated Operating Agreement.
Filed Date: 11/26/24.
Accession Number: 20241126–5347.
Comment Date: 5 p.m. ET 12/10/24.
Docket Numbers: ER25–613–000.
Applicants: New York Independent System Operator, Inc.
Description: Tariff Amendment: Notice of Cancellation: EPCA for LIPA SDU (SA2776) to be effective 2/3/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5042.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–614–000.
Applicants: New England Power Company.
Description: Notice of Cancellation of Service Agreement for Firm Local Generation Delivery Service of New England Power Company.
Filed Date: 11/26/24.
Accession Number: 20241126–5349.
Comment Date: 5 p.m. ET 12/17/24.
Docket Numbers: ER25–615–000.
Applicants: Speedway Solar, LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5067.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–616–000.
Applicants: Rocking R Solar, LLC.
Description: § 205(d) Rate Filing: Revised Market-Based Rate Tariff Filing to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5068.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–617–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA & CSA, SA Nos. 6874 & 6875; Queue No. AD2–086/AE1–090 (amend) to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5075.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–618–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 5846; Queue No. AB2–133 to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5080.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–619–000.
Applicants: ALLETE, Inc.
Description: § 205(d) Rate Filing: ALLETE CMA End Deferral Filing to be effective 8/29/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5088.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–620–000.
Applicants: LRE Interconnection Manager, LLC.
Description: § 205(d) Rate Filing: Shared Facilities Agreement and Request for Waivers and Blanket Authorization to be effective 12/4/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5092.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–621–000.
Applicants: Pacific Gas and Electric Company.
Description: Wholesale Distribution Tariff for Rate Year 2025 of Pacific Gas and Electric Company.
Filed Date: 12/2/24.
Accession Number: 20241202–5303.
Comment Date: 5 p.m. ET 12/23/24.
Docket Numbers: ER25–623–000.
Applicants: White Wing Ranch North, LLC.
Description: § 205(d) Rate Filing: Certificate of Concurrence to Shared Facilities Common Ownership Agreement to be effective 12/4/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5104.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–624–000.
Applicants: Pacific Gas and Electric Company.
Description: Informational Filing of 2025 Transmission Owner Tariff Formula Rate Annual Update of Pacific Gas and Electric Company.
Filed Date: 12/2/24.
Accession Number: 20241202–5304.
Comment Date: 5 p.m. ET 12/23/24.
Docket Numbers: ER25–625–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX–BT Cantwell 4th Amended Generation Interconnection Agreement to be effective 11/6/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5117.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–626–000.
Applicants: Blossburg Power, LLC, Brunot Island Power, LLC, Gilbert Power, LLC, Hamilton Power, LLC, Hunterstown Power, LLC, Mountain Power, LLC, New Castle Power, LLC, Orrtanna Power, LLC, Portland Power, LLC, Sayreville Power, LLC, Shawnee Power, LLC, Shawville Power, LLC, Titus Power, LLC, Tolna Power, LLC, Warren Generation, LLC.
Description: Joint Request for Limited Waiver of Blossburg Power, LLC, et. al.
Filed Date: 11/27/24.
Accession Number: 20241127–5358.
Comment Date: 5 p.m. ET 12/18/24.
Docket Numbers: ER25–627–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 6728; Queue No. AE2–001 to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5138.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–628–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original GIA Service Agreement No. 7424; Project Identifier No. AF2–417 to be effective 11/4/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5164.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–629–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original NSA, SA No. 7431; Queue No. AC1–010 to be effective 2/2/2025.
Filed Date: 12/3/24.
Accession Number: 20241203–5176.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–630–000.
Applicants: Emera Energy U.S. Subsidiary No. 1, Inc.
Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 12/31/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5180.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–631–000.
Applicants: Emera Energy U.S. Subsidiary No. 2, Inc.
Description: Tariff Amendment: Notice of Cancellation of Market-Based Rate Tariff to be effective 12/31/2024.
Filed Date: 12/3/24.
Accession Number: 20241203–5181.
Comment Date: 5 p.m. ET 12/24/24.
Docket Numbers: ER25–632–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2024–12–03_SA 3194 Wolf Run Solar-

Ameren Illinois 2nd Rev GIA (J641) to be effective 11/25/2024.

Filed Date: 12/3/24.

Accession Number: 20241203–5192.

Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: ER25–633–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: PGE Concurrence—Grassland IA to be effective 11/4/2024.

Filed Date: 12/3/24.

Accession Number: 20241203–5224.

Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: ER25–634–000.

Applicants: Manitowoc Public Utilities.

Description: § 205(d) Rate Filing: RS No. 5—Monthly System Support Resource Payment for Lakefront No. 9 to be effective 2/1/2025.

Filed Date: 12/3/24.

Accession Number: 20241203–5229.

Comment Date: 5 p.m. ET 12/24/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *https://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28835 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR25–21–000.

Applicants: Rocky Mountain Natural Gas LLC.

Description: § 284.123 Rate Filing: RMNG Revised SOC reflecting FLU Change to be effective 11/1/2024.

Filed Date: 12/3/24.

Accession Number: 20241203–5151.

Comment Date: 5 p.m. ET 12/24/24.

Docket Numbers: RP25–253–000.

Applicants: Rover Pipeline LLC.

Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements 12–2–2024 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5137.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–254–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Entergy LA 48769) to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5148.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–255–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rates—Northern to NRG Bus Mktg—eff 12–1–24 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5161.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–256–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Castleton 860576 and 860581 eff 12–1–24 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5173.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–257–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed 910950 Releases eff 12–1–24 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5177.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–258–000.

Applicants: Texas Gas Transmission, LLC.

Description: Compliance filing: Neg Rate Compliance Filing re CP21–467–000 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5182.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–259–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 12–1–24 to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5187.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–260–000.

Applicants: Eastern Shore Natural Gas Company.

Description: § 4(d) Rate Filing: Capital Cost Surcharge Eff. January 1, 2025, to be effective 1/1/2025.

Filed Date: 12/2/24.

Accession Number: 20241202–5190.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–261–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—Various Releases eff 12–1–2024a to be effective 12/1/2024.

Filed Date: 12/2/24.

Accession Number: 20241202–5242.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–262–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates—CNX 860004 eff 12–1–24 to be effective 12/1/2024.

Filed Date: 12/3/24.

Accession Number: 20241203–5000.

Comment Date: 5 p.m. ET 12/16/24.

Docket Numbers: RP25–263–000.

Applicants: Texas Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Flywheel to Gunvor) to be effective 12/1/2024.

Filed Date: 12/3/24.

Accession Number: 20241203–5118.

Comment Date: 5 p.m. ET 12/16/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28836 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL25–16–000]

Basin Electric Power Cooperative; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On December 2, 2024, the Commission issued an order in Docket No. EL25–16–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation to determine whether Basin Electric Power Cooperative's 2020 Rate Schedule A and Wholesale Power Contracts are considered unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Basin Electric Power Cooperative,* 189 FERC ¶ 61,162 (2024).

The refund effective date in Docket No. EL25–16–000 established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL25–16–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2024), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*https://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *https://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28838 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP25–19–000]

Southern Star Central Gas Pipeline, Inc.; Notice of Application and Establishing Intervention Deadline

Take notice that on November 18, 2024, Southern Star Central Gas Pipeline, Inc. (Southern Star), 4700 State Route 56, Owensboro, KY 42301, filed an application under section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization for its Cedar Vale Compressor Station Project (Project). The Project consists of constructing, installing, operating, and maintaining a new 6,091 horsepower (HP) [1] compressor station in Osage County, Oklahoma. The Project will add approximately 98,000 dekatherms per day (Dth/d) of incremental firm capacity for deliveries in Southern Star's Market Area and approximately 35,000 Dth/d of incremental firm capacity in its Production Area. Southern Star states that this added compression will assist shippers in moving gas to the growing markets in and around Springfield, Joplin, Kansas City, and Topeka in Missouri and Kansas. Southern Star estimates the total cost of the Project to be $48.4 million, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*https://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

[1] The 6,091 HP refers to nominal HP at International Organization for Standardization (ISO) conditions.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions regarding the proposed project should be directed to Will Wathen, Director, Rates, Regulatory and Strategic Planning, Southern Star Central Gas Pipeline, Inc., 4700 State Route 56, Owensboro, Kentucky 42301, by phone at (270) 925–1969, or by email at *will.wathen@southernstar.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify Federal and State agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 24, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[3] and 385.211[4] of the Commission's regulations under the NGA, any person[5] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[6] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before December 24, 2024.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP25–19–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP25–19–000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[7] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[8] and the regulations under the NGA[9] by the intervention deadline for the project, which is December 24, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more

[2] 18 CFR 157.9.

[3] 18 CFR 157.10(a)(4).

[4] 18 CFR 385.211.

[5] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[6] 18 CFR 385.2001.

[7] 18 CFR 385.102(d).

[8] 18 CFR 385.214.

[9] 18 CFR 157.10.

information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP25–19–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf.;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP25–19–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail at: Will Wathen, Director, Rates, Regulatory and Strategic Planning, Southern Star Central Gas Pipeline, Inc., 4700 State Route 56, Owensboro, Kentucky 42301 or by email (with a link to the document) at *will.wathen@southernstar.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [10] motions to intervene are automatically granted by operation of Rule 214(c)(1).[11] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[12] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on December 24, 2024.

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28837 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed on the Commission's website at *https://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

[10] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[11] 18 CFR 385.214(c)(1).

[12] 18 CFR 385.214(b)(3) and (d).

Docket Nos.	File date	Presenter or requester
Prohibited:		
None.		
Exempt:		
1. P–2639–028	11–21–2024	U.S. Environmental Protection Agency.
2. P–15332–000	11–26–2024	York County Board of Commissioners.

Dated: December 3, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–28840 Filed 12–6–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R05–SFUND–2024–0559; FRL–12429–01–R5]

Proposed Prospective Purchaser Agreement for the Brandon Road Interbasin Project Site in Joliet, Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Prospective Purchaser Agreement, notice is hereby given of a proposed administrative settlement concerning the property to be used in the Brandon Road Interbasin Project with the following Settling Party: Illinois Department of Natural Resources. The Settling Party intends to acquire title to an approximately 2.32-acre portion of the property at 1800 Channahon Road, Joliet, Illinois, which is adjacent to the Joliet 29 Generating Station and borders the Brandon Road Lock and Dam.

DATES: Comments must be submitted on or before January 8, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R05–SFUND–2024–0559, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, ATTN: David Duckett, Assistant Regional Counsel, Office of Regional Counsel (C–14J), 77 W Jackson Blvd., Chicago, Illinois 60604.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Duckett, Office of Regional Counsel, Environmental Protection Agency, telephone number: (312) 886–0140; email address: *duckett.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–R05–SFUND–2024–0559, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

For thirty (30) days following the date of publication of this notice, the EPA will receive written comments relating to the proposed settlement. The EPA will consider all comments received and may modify or withdraw its consent to the proposed settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The proposed settlement is available for public inspection at *https://www.regulations.gov.* The EPA's response to any comments received will be available for public inspection at the EPA, Region 5, Records Center, 77 W Jackson Blvd., 7th Fl., Chicago, Illinois 60604. Commenters may request an opportunity for a public hearing in the affected area, in accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The settlement requires the Settling Party to enroll the property in the Illinois Site Remediation Program (''Illinois SRP'') within thirty days of acquiring the property and conduct a comprehensive site investigation including geotechnical and environmental investigations to determine the nature and extent of any soil or groundwater contamination. Based on the results of the site investigation, Purchaser will conduct a remedial action that generally includes addressing the presence of any contaminants of concern requiring remediation under the Illinois SRP, constructing a barrier to facilitate excavation of the Waste Material, excavating all Waste Material (as defined in the settlement) and properly disposing of it, relocating and extending a storm sewer system, and backfilling the excavated areas with clean fill. The Settling Party will complete all activities required by the Illinois SRP and obtain a No Further Remediation Letter for the Property from the Illinois Environmental Protection Agency. The settlement includes a covenant not to sue by the United States pursuant to sections 106 and 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act and section 7003 of the Resource Conservation and Recovery Act for Existing Contamination and the Work. Existing Contamination is defined as any hazardous substances, pollutants, or contaminants or Waste Material present or existing on or under the Property as of the Effective Date of the settlement; any hazardous substances, pollutants, or contaminants or Waste Material that migrated from the property prior to the Effective Date; and any hazardous substances, pollutants, or contaminants or Waste Material presently at the site at 1800 Channahon Rd. in Joliet, Illinois, that migrate onto, under, or

from the Property after the Effective Date.

Thomas Short,

Deputy Director, Superfund & Emergency Management Division, Region 5.

[FR Doc. 2024–28615 Filed 12–6–24; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Board of Directors Meeting

SUMMARY: Notice of the forthcoming regular meeting of the Board of Directors of the Farm Credit System Insurance Corporation (FCSIC), is hereby given in accordance with the provisions of the Bylaws of the FCSIC.

DATES: 10 a.m., Wednesday, December 11, 2024.

ADDRESSES: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to virtually attend, at least 24 hours in advance, visit *FCSIC.gov,* select ''News & Events,'' then select ''Board Meetings.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

FOR FURTHER INFORMATION CONTACT: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public. The following matters will be considered:

Portions Open to the Public

- Approval of Minutes for October 9, 2024
- Quarterly FCSIC Financial Reports
- Quarterly Report on Insured Obligations
- Quarterly Report on Annual Performance Plan
- Policy Statement Addressing Dual Board Governance Structure
- Policy Statement Addressing FCSIC Examination Authorities

Portions Closed to the Public

- Quarterly Report on Insurance Risk
- Audit Plan for the Year Ended December 31, 2024
- Executive Session of the Audit Committee with Auditor

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2024–28774 Filed 12–6–24; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of 2025 Federal Accounting Standards Advisory Board Meetings

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) will hold its meetings on the following dates throughout 2025, unless otherwise noted.

DATES:

February 25–26, 2025
April 22–23, 2025
June 17–18, 2025
August 19–20, 2025
October 21–22, 2025
December 9–10, 2025

ADDRESSES: Agendas, briefing materials, and virtual meeting information will be available at *https://www.fasab.gov/briefing-materials/* approximately one week before each meeting.

Any interested person may attend the meetings as an observer. Board discussion and reviews are open to the public. GAO building security requires advance notice of your attendance for in-person meetings. If you wish to attend a FASAB meeting that is being held in-person, please register on our website at *https://www.fasab.gov/pre-registration/* no later than 5 p.m. the Thursday before the meeting to be observed.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

SUPPLEMENTARY INFORMATION: The purpose of the meetings is to discuss issues related to the following topics:

Accounting and Reporting of Government Land
Climate-Related Financial Reporting Commitments
Direct Loans and Loan Guarantees
Federal GAAP Hierarchy
Intangible Assets
Leases
Omnibus Amendments
Public-Private Partnerships
Reexamination of Existing Standards
Omnibus Concepts Amendments
Management's Discussion and Analysis Revenue
Software Technology
Appointments Panel
Any other topics as needed

Notice is hereby given that a portion of each scheduled meeting may be closed to the public. The Appointments Panel, a chartered subcommittee of FASAB that makes recommendations regarding appointments for non-Federal member positions, is expected to meet during each meeting. A portion of each Appointments Panel meeting will be closed to the public. The reason for the closures is that matters covered by 5 U.S.C. 552b(c)(2) and (6) will be discussed. Any such discussions will involve matters that relate solely to internal personnel rules and practices of the sponsor agencies and the disclosure of information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. Such discussions will be segregated into separate discussions so that a portion of each meeting will be open to the public.

Pursuant to section 10(d) of the Federal Advisory Committee Act (FACA), 5 U.S.C. 1009(d), portions of advisory committee meetings may be closed to the public where the head of the agency to which the advisory committee reports determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. The determination shall be in writing and shall contain the reasons for the determination. A determination has been made in writing by the U.S. Government Accountability Office, the U.S. Department of the Treasury, and the Office of Management and Budget, as required by section 10(d) of FACA, that such portions of the meetings may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code.

Unless otherwise noted, FASAB meetings begin at 9 a.m. and conclude before 5 p.m. Meetings are either in-person at the U.S. Government Accountability Office (GAO) building at 441 G St. NW or virtual. Unless otherwise noted, the February and June meetings are virtual, and the April, August, October, and December meetings are in-person. Regardless of whether the Board meeting is virtual or in-person, you may observe the meeting virtually.

Authority: 31 U.S.C. 3511(d); Federal Advisory Committee Act, 5 U.S.C. 1001–1014.

Dated: December 4, 2024.

Monica R. Valentine,

Executive Director.

[FR Doc. 2024–28863 Filed 12–6–24; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Appointments Panel Meeting

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Appointments Panel, a subcommittee of the Federal Accounting Standards Advisory Board (FASAB), will hold a meeting on January 30, 2025 and February 19, 2025. The Appointments Panel makes recommendations regarding appointments for non-Federal member positions.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

SUPPLEMENTARY INFORMATION: The meetings are closed to the public. The reason for the closure is that matters covered by 5 U.S.C. 552b(c)(2) and (6) will be discussed. Any such discussions will involve matters that relate solely to internal personnel rules and practices of the sponsor agencies and the disclosure of information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Pursuant to section 10(d) of the Federal Advisory Committee Act (FACA), 5 U.S.C. 1009(d), portions of advisory committee meetings may be closed to the public where the head of the agency to which the advisory committee reports determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. The determination shall be in writing and shall contain the reasons for the determination. A determination has been made in writing by the U.S. Government Accountability Office, the U.S. Department of the Treasury, and the Office of Management and Budget, as required by section 10(d) of FACA, that such portions of the meetings may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code.

Authority: 31 U.S.C. 3511(d); Federal Advisory Committee Act, 5 U.S.C. 1001–1014).

Dated: December 4, 2024.

Monica R. Valentine,

Executive Director.

[FR Doc. 2024–28862 Filed 12–6–24; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0207; FR ID 266100]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before February 7, 2025. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–0207.

Title: Part 11—Emergency Alert System (EAS), Order, FCC 21–77.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local, or Tribal Government.

Number of Respondents and Responses: 63,084 respondents; 3,588,845 responses.

Estimated Time per Response: 0.017 hours–112 hours.

Frequency of Response: On occasion and annual reporting requirements.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. 154(i) and 606 of the Communications Act of 1934, as amended.

Total Annual Burden: 141,414 hours.

Total Annual Cost: No Cost.

Needs and Uses: Part 11 contains rules and regulations addressing the nation's Emergency Alert System (EAS). The EAS provides the President with the capability to provide immediate communications and information to the general public during periods of national emergency over broadcast television and radio, cable, direct broadcast radio and other EAS Participants, as defined in section 11.11(a) of the Commission's rules The EAS also provides State and local governments and the National Weather Service with the capability to provide immediate communications and information to the public concerning emergency situations posing a threat to life and property. Part 11 includes testing requirements to ensure proper and efficient operation of the EAS. State and local use of the EAS, alert processing requirements, and monitoring assignments covering the distribution of EAS alerts within the State, among other things, are required to be described in State EAS Plans that are administered by State Emergency Communications Committees (SECC) and submitted to the FCC annually for approval.

The Order, PS Docket Nos. 15–91 and 15–94, FCC 21–77, pursuant to the directions set forth in Section 9201 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283, 134 Stat. 3388, sec. 9201 (NDAA21), among other things, (i) requires the Public Safety and Homeland Security Bureau (Bureau) to establish a State EAS Plan Content Checklist composed of the content set forth in section 11.21 of the Commission's rules, (47 CFR 11.21), post the checklist on the FCC's website, and incorporate it as an appendix in ARS user manual; (ii) amend the State EAS Plan requirements in section 11.21

of the Commission's rules to ensure plans are updated annually, require a certification by the SECC Chairperson or Vice-Chairperson that the SECC met (in person, via teleconference, or via other methods of conducting virtual meetings) at least once in the twelve months prior to submitting the annual updated plan, and require that the Bureau approve or reject State EAS Plans submitted for approval within 60 days of receipt; and (iii) require the Bureau to list the approval dates of State EAS Plans submitted on ARS on the Commission's website, and in the event a final decision is made to deny a plan, directly notify the chief executive of the State to which the plan applies of that determination and the reasons for such denial within 30 days of such decision. The Order also amends section 11.45 of the Part 11 rules to enable voluntary reporting to the Commission by the FEMA Administrator and Tribal, State, local or territorial governments of false EAS alerts.

The Commission seeks OMB approval of these rule amendments as an extension of a previously approved information collection. Congress has determined that EAS rule changes are necessary to increase oversight over the distribution of State and local EAS alerts within States, and increase false alert reporting capabilities to help ameliorate confusion or other harmful effects that might result from false EAS alerts. The internal State EAS Plan processing requirements and rule changes adopted in the Order will improve State EAS Plan processing and administration, improving the capabilities and efficacy of EAS as a national system for distributing vital alert information to all Americans, and will do so in a cost-effective manner.

The following information collections contained in Part 11 may be impacted by the rule amendments described herein.

State EAS Plans (47 CFR 11.21)

The establishment of a State EAS Plan Content Checklist for SECCs should have no impact or lessen SECC burdens, and posting it on the FCC's website, and incorporating it as an appendix in the ARS user manual, are routine Bureau activities. The requirement to ensure State EAS Plans are updated annually already was contained in section 11.21, and thus does not represent a new burden.

The amendment to include as a required element in the State EAS Plan, a certification (which will be incorporated into the ARS) by the SECC Chairperson or Vice-Chairperson that the SECC met (in person, via teleconference, or via other methods of conducting virtual meetings) at least once in the twelve months prior to submitting the annual updated plan to review and update their State EAS Plan should promote added diligence in SECC administration of State EAS Plans. The Commission estimates the burden to SECC members in complying with this requirement to be two hours per member.

The rule amendment requiring the Bureau approve or reject State EAS Plans submitted for approval within 60 days of receipt does not impose new burdens on any entity. The Bureau already is charged with reviewing State EAS Plans. The internal requirement that the Bureau list the approval dates of State EAS Plans submitted on ARS on the Commission's website, and in the event a final decision is made to deny a plan, directly notify the chief executive of the State to which the plan applies of that determination and the reasons for such denial within 30 days, does not impose new burdens on any entity. The Bureau already maintains a web page on the Commission's website dedicated to SECC and State EAS Plan information.

False EAS Alert Reporting (47 CFR 11.45)

The amendment enabling the FEMA Administrator and Tribal, State, local or territorial governments to file reports of false EAS alerts provides another mechanism for the Commission to receive information concerning false EAS alerts, does not impose burdens on any entity. Should any permitted government entity voluntarily elect to file a false EAS alert report, the burden associated with this provision amounts to composing an email, which the Commission estimates will take an hour or less to prepare, and falls within the routine activities of government employees. False alert reports help the Commission to identify, investigate, correct and prevent false EAS activations, which enhances the EAS's efficacy and the public trust in the EAS.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–28783 Filed 12–6–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0121; –0135]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (OMB Control No. 3064–0121 and –0135).

DATES: Comments must be submitted on or before February 7, 2025.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7 a.m. and 5 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collections of information:

1. *Title:* Certification of Compliance with Mandatory Bars to Employment.

OMB Number: 3064–0121.

Form Number: 2120/16.

Affected Public: Individuals seeking employment from the FDIC.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

[OMB No. 3064–0121]

Information collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Form 2120/16, (Mandatory)	Reporting (Annual)	866	1	00:10	144
Total Annual Burden (Hours)					144

Source: FDIC.

General Description of Collection: This information collection arises from the reporting requirements contained in 12 CFR part 336, subpart B, of the FDIC Rules and Regulations entitled ''Minimum Standards of Fitness for Employment with the Federal Deposit Insurance Corporation.'' This rule implements section 19 of the Resolution Trust Corporation Completion Act, Public Law 103–204, by (among other things) prescribing a certification, with attachments in some cases, relating to job applicants' fitness and integrity. More specifically, the statute provides that the FDIC shall issue regulations implementing provisions that prohibit any person from becoming employed by the FDIC who has been convicted of any felony; has been removed from, or prohibited from participating in the affairs of, any insured depository institution pursuant to any final enforcement action by any appropriate Federal banking agency; has demonstrated a pattern or practice of defalcation regarding obligations to insured depository institutions; or has caused a substantial loss to Federal deposit insurance funds. This collection of information implements these mandatory bars to employment through a certification, signed by job applicants prior to an offer of employment using Form 2120/16. There is no change in the methodology or substance of this information collection. The increase in total estimated annual burden from 88 hours in 2022 to 144 hours currently is due to an increase in the estimated number of respondents.

2. *Title:* Purchaser Eligibility Certification.

OMB Number: 3064–0135.

Form Number: 7300/06.

Affected Public: Individuals and entities wishing to purchase receivership assets from the FDIC.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

[OMB No. 3064–0135]

Information collection (IC) (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Purchaser Eligibility Certification, 12 CFR 340 (Required to obtain or retain benefits).	Reporting (On Occasion)	140	1	00:30	70
Total Annual Burden (Hours)					70

Source: FDIC.

General Description of Collection: The FDIC is statutorily prohibited from selling assets held by insured depository institutions that have been placed under the conservatorship or receivership of the FDIC to individuals or entities that profited or engaged in wrongdoing at the expense of those failed institutions, or seriously mismanaged those failed institutions. This statutory prohibition is implemented by regulation. The FDIC uses Form No. 7300–06: Purchaser Eligibility Certification (PEC) to determine an entity or person's eligibility to purchase assets. This information collection (IC) pertains to the voluntary submission of the PEC by persons seeking to certify their eligibility to be able to purchase receivership assets. Potential respondents to this IC include any entity or individual that wishes to bid on or purchase assets held by insured depository institutions that have been placed under the conservatorship or receivership of the FDIC. There is no change in the substance of this IC. The decrease in total estimated annual burden from 190 hours in 2022 to 70 hours currently is due a decrease in the estimated number of annual respondents for cash sales, ORE sales, and securities sales as compared to the 2022 IC, reflecting the decrease in forecasted sales. This decrease is attenuated by the inclusion of joint venture transactions in the calculation of the estimated number of respondents, which were not included in the 2022 IC.

Request for Comment

Comments are invited on (a) whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, December 4, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–28842 Filed 12–6–24; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

[NOTICE 2024–27]

Filing Dates for the Florida Special Election in the 1st Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Florida has scheduled special elections to fill the U.S. House of Representatives seat in the 1st Congressional District vacated by Representative Matt Gaetz.

DATES: There are two possible special elections, but only one may be necessary.

- *Special Primary Election:* January 28, 2025.
- *Possible Special General Election:* January 28, 2025. In the event that all partisan nominations are uncontested and the Special Primary Election is not necessary, the Special General Election will instead be held on January 28, 2025.
- *Special General Election:* April 1, 2025. However, if a Special Primary Election is not necessary, the Special General Election will be held on January 28, 2025.

ADDRESSES: 1050 First Street NE, Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, (202) 694–1100 or (800) 424–9530, *info@fec.gov.*

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

Special Primary Only

All principal campaign committees of candidates only participating in the Florida Special Primary shall file a consolidated Pre-Primary and Year-End Report on January 16, 2025. (See charts below for the closing date for the report.)

Special Primary and Special General Elections

If two elections are held, all principal campaign committees of candidates who participate in the Florida Special Primary and Special General Election shall file a consolidated Pre-Primary and Year-End Report on January 16, 2025; a Pre-General Report on March 20, 2025, and a Post-General Report on May 1, 2025. (See charts below for the closing date for each report.)

Special General Election

If only one election is held, all principal campaign committees of candidates who participate in the Florida Special General Election shall file a consolidated Pre-General and Year-End Report on January 16, 2025, and a Post-General Report on February 27, 2025. (See charts below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See charts below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees not filing monthly are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Florida Special Primary or Special General Election by the close of books for the applicable report(s). (See charts below for the closing date for each report.)

Since disclosing financial activity from two different calendar years on one report would conflict with the calendar year aggregation requirements stated in the Commission's disclosure rules, unauthorized committees that trigger the filing of the consolidated Pre-Primary and Year-End Report (if two elections are held) or the consolidated Pre-General and Year-End Report (if one election is held) will be required to file this report on two separate forms: One form to cover 2024 activity, labeled as the Year-End Report; and the other form to cover only 2025 activity, labeled as the Pre-Primary or Pre-General Report, as applicable. Both forms must be filed by January 16, 2025.

Committees filing monthly that make contributions or expenditures in connection with the Florida Special Primary or Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information for the Florida special elections may be found on the FEC website at *https://www.fec.gov/help-candidates-and-committees/dates-and-deadlines/.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the lobbyist bundling threshold during the special election reporting periods. (See charts below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b), 110.17(e)(2), (f).

The lobbyist bundling disclosure threshold for calendar year 2024 is $22,700. This threshold amount may change in 2025 based upon the annual cost of living adjustment (COLA). As soon as the adjusted threshold amount is available, the Commission will publish it in the **Federal Register** and post it on its website. 11 CFR 104.22(g) and 110.17(e)(2).

CALENDAR OF REPORTING DATES FOR FLORIDA SPECIAL ELECTIONS

Report	Close of books [1]	Reg./cert. & overnight mailing deadline	Filing deadline
If Two Elections Are Held, Candidate Committees Involved in Only the Special Primary (01/28/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Only the Special Primary (01/28/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If Two Elections Are Held, Candidate Committees Involved in Both the Special Primary (01/28/2025) and Special General (04/01/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025

CALENDAR OF REPORTING DATES FOR FLORIDA SPECIAL ELECTIONS—Continued

Report	Close of books [1]	Reg./cert. & overnight mailing deadline	Filing deadline
Pre-General	03/12/2025	03/17/2025	03/20/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
July Quarterly	06/30/2025	07/15/2025	07/15/2025
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Both the Special Primary (01/28/2025) and Special General (04/01/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
Pre-General	03/12/2025	03/17/2025	03/20/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If Two Elections Are Held, Candidate Committees Involved in Only the Special General (04/01/2025) Must File:			
Pre-General	03/12/2025	03/17/2025	03/20/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
July Quarterly	06/30/2025	07/15/2025	07/15/2025
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Only the Special General (04/01/2025) Must File:			
Pre-General	03/12/2025	03/17/2025	03/20/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If One Election Is Held, Candidate Committees Involved in the Special General (01/28/2025) Must File:			
Pre-General & Year-End [3]	01/08/2025	01/13/2025	01/16/2025
Post-General	02/17/2025	02/27/2025	02/27/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
If One Election Is Held, PACs and Party Committees Not Filing Monthly Involved in the Special General (01/28/2025) Must File:			
Pre-General & Year-End [3]	01/08/2025	01/13/2025	01/16/2025
Post-General	02/17/2025	02/27/2025	02/27/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.
[2] Committees should file a consolidated Pre-Primary & Year-End Report by the filing deadline of the Pre-Primary Report.
[3] Committees should file a consolidated Pre-General & Year-End Report by the filing deadline of the Pre-General Report (if primary not held).

Dated: December 3, 2024.

On behalf of the Commission,

Sean J. Cooksey,

Chairman, Federal Election Commission.

[FR Doc. 2024–28770 Filed 12–6–24; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

[NOTICE 2024–28]

Filing Dates for the Florida Special Election in the 6th Congressional District

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for special election.

SUMMARY: Florida has scheduled special elections to fill the U.S. House of Representatives seat in the 6th Congressional District being vacated by Representative Michael Waltz.

DATES: There are two possible special elections, but only one may be necessary.

- *Special Primary Election:* January 28, 2025.
- *Possible Special General Election:* January 28, 2025. In the event that all partisan nominations are uncontested and the Special Primary Election is not necessary, the Special General Election will instead be held on January 28, 2025.
- *Special General Election:* April 1, 2025. However, if a Special Primary Election is not necessary, the Special General Election will be held on January 28, 2025.

ADDRESSES: 1050 First Street NE, Washington, DC 20463.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth S. Kurland, Information Division, (202) 694–1100 or (800) 424–9530, *info@fec.gov.*

SUPPLEMENTARY INFORMATION:

Principal Campaign Committees

Special Primary Only

All principal campaign committees of candidates *only* participating in the Florida Special Primary shall file a consolidated Pre-Primary and Year-End Report on January 16, 2025. (See charts below for the closing date for the report.)

Special Primary and Special General Elections

If two elections are held, all principal campaign committees of candidates who participate in the Florida Special Primary and Special General Election shall file a consolidated Pre-Primary and Year-End Report on January 16, 2025; a Pre-General Report on March 20, 2025, and a Post-General Report on May 1, 2025. (See charts below for the closing date for each report.)

Special General Election

If only one election is held, all principal campaign committees of candidates who participate in the Florida Special General Election shall file a consolidated Pre-General and Year-End Report on January 16, 2025, and a Post-General Report on February 27, 2025. (See charts below for the closing date for each report.)

Note that these reports are in addition to the campaign committee's regular quarterly filings. (See charts below for the closing date for each report).

Unauthorized Committees (PACs and Party Committees)

Political committees not filing monthly are subject to special election reporting if they make previously undisclosed contributions or expenditures in connection with the Florida Special Primary or Special General Election by the close of books for the applicable report(s). (See charts below for the closing date for each report.)

Since disclosing financial activity from two different calendar years on one report would conflict with the calendar year aggregation requirements stated in the Commission's disclosure rules, unauthorized committees that trigger the filing of the consolidated Pre-Primary and Year-End Report (if two elections are held) or the consolidated Pre-General and Year-End Report (if one election is held) will be required to file this report on two separate forms: One form to cover 2024 activity, labeled as the Year-End Report; and the other form to cover only 2025 activity, labeled as the Pre-Primary or Pre-General Report, as applicable. Both forms must be filed by January 16, 2025.

Committees filing monthly that make contributions or expenditures in connection with the Florida Special Primary or Special General Election will continue to file according to the monthly reporting schedule.

Additional disclosure information for the Florida special elections may be found on the FEC website at *https://www.fec.gov/help-candidates-and-committees/dates-and-deadlines/.*

Disclosure of Lobbyist Bundling Activity

Principal campaign committees, party committees and leadership PACs that are otherwise required to file reports in connection with the special elections must simultaneously file FEC Form 3L if they receive two or more bundled contributions from lobbyists/registrants or lobbyist/registrant PACs that aggregate in excess of the lobbyist bundling threshold during the special election reporting periods. (See charts below for closing date of each period.) 11 CFR 104.22(a)(5)(v), (b), 110.17(e)(2), (f).

The lobbyist bundling disclosure threshold for calendar year 2024 is $22,700. This threshold amount may change in 2025 based upon the annual cost of living adjustment (COLA). As soon as the adjusted threshold amount is available, the Commission will publish it in the **Federal Register** and post it on its website. 11 CFR 104.22(g) and 110.17(e)(2).

CALENDAR OF REPORTING DATES FOR FLORIDA SPECIAL ELECTIONS

Report	Close of books [1]	Reg./Cert. & overnight mailing deadline	Filing deadline
If Two Elections Are Held, Candidate Committees Involved in Only the Special Primary (01/28/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Only the Special Primary (01/28/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If Two Elections Are Held, Candidate Committees Involved in Both the Special Primary (01/28/2025) and Special General (04/01/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
Pre-General	03/12/2025	03/17/2025	03/20/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
July Quarterly	06/30/2025	07/15/2025	07/15/2025
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Both the Special Primary (01/28/2025) and Special General (04/01/2025) Must File:			
Pre-Primary & Year-End [2]	01/08/2025	01/13/2025	01/16/2025
Pre-General	03/12/2025	03/17/2025	03/20/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If Two Elections Are Held, Candidate Committees Involved in Only the Special General (04/01/2025) Must File:			
Pre-General	03/12/2025	03/17/2025	03/20/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
July Quarterly	06/30/2025	07/15/2025	07/15/2025

CALENDAR OF REPORTING DATES FOR FLORIDA SPECIAL ELECTIONS—Continued

Report	Close of books [1]	Reg./Cert. & overnight mailing deadline	Filing deadline
If Two Elections Are Held, PACs and Party Committees Not Filing Monthly Involved in Only the Special General (04/01/2025) Must File:			
Pre-General	03/12/2025	03/17/2025	03/20/2025
Post-General	04/21/2025	05/01/2025	05/01/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025
If One Election Is Held, Candidate Committees Involved in the Special General (01/28/2025) Must File:			
Pre-General & Year-End [3]	01/08/2025	01/13/2025	01/16/2025
Post-General	02/17/2025	02/27/2025	02/27/2025
April Quarterly	03/31/2025	04/15/2025	04/15/2025
If One Election Is Held, PACs and Party Committees Not Filing Monthly Involved in the Special General (01/28/2025) Must File:			
Pre-General & Year-End [3]	01/08/2025	01/13/2025	01/16/2025
Post-General	02/17/2025	02/27/2025	02/27/2025
Mid-Year	06/30/2025	07/31/2025	07/31/2025

[1] The reporting period always begins the day after the closing date of the last report filed. If the committee is new and has not previously filed a report, the first report must cover all activity that occurred before the committee registered as a political committee up through the close of books for the first report due.
[2] Committees should file a consolidated Pre-Primary & Year-End Report by the filing deadline of the Pre-Primary Report.
[3] Committees should file a consolidated Pre-General & Year-End Report by the filing deadline of the Pre-General Report (if primary not held).

Dated: December 3, 2024.

On behalf of the Commission.

Sean J. Cooksey,

Chairman, Federal Election Commission.

[FR Doc. 2024–28771 Filed 12–6–24; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, December 12, 2024, 10:00 a.m.

PLACE: Hybrid meeting: 1050 First Street NE, Washington, DC (12TH Floor) and virtual.

Note: If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public. To access the meeting virtually, go to the Commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Draft Advisory Opinion 2024–15: Unified Libertarians of Massachusetts
MUR 1604 (Brady Campaign to Prevent Gun Violence, et al): Recommendation to Relieve the Brady Campaign from a Remedial Measure in a Conciliation Agreement
REG 2024–06 (Request to Modify or Redact Contributor Info)—Draft Notice of Proposed Rulemaking
Draft Legislative Recommendations 2024
Sample LLC Donor Form
Recommendation That the Office of General Counsel Conduct a Review of the Agency's Regulations
Proposed Revisions to Directives 10 (Rules of Procedure of the Federal Election Commission Pursuant to 2 U.S.C. 437(c)(e)) and 17 (Circulation Authority; Agenda Deadline Procedures)
Election of Officers for 2025
Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040 or *secretary@fec.gov,* at least 72 hours prior to the meeting date.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2024–28995 Filed 12–5–24; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

Succession Plan for the Federal Mediation and Conciliation Service

AGENCY: Federal Mediation and Conciliation Service (FMCS).

ACTION: Notice of succession plan for the FMCS.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) is issuing this notice to inform the public of the succession plan for the Federal Mediation and Conciliation Service (FMCS) provided by the Director of FMCS. This notice supersedes all prior succession plans issued by the agency for officials performing the functions and duties of the Director of FMCS.

DATES: This succession plan for the FMCS is effective December 9, 2024.

FOR FURTHER INFORMATION CONTACT: For specific questions related to this notice, please contact Greg Goldstein, 202–606–8111, *ggoldstein@fmcs.gov.*

SUPPLEMENTARY INFORMATION: By the authority vested in the Director of the Federal Mediation and Conciliation Service (FMCS) by 29 U.S.C. 172, and to provide for the continuity of essential operations of the FMCS in all circumstances this Notice provides the succession plan of officials authorized to perform the functions and duties of the Director of the Federal Mediation and Conciliation Service. The following is the succession plan of officials hereby ordered:

Order of Succession

During any period in which the Director has died, resigned, or otherwise become unable to perform the functions and duties of the office of the Director, and there is no Acting Director serving under the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345–3349d, the following officers of the FMCS, in the order listed, are hereby delegated the authority to perform the functions and duties of the Director, to the extent permitted by law:

1. Principal Deputy, Chief Operating Officer;
2. Deputy Director, Field Operations;
3. Deputy Director for Labor Policy and Communications;
4. Director, Procurement and Operational Support;
5. General Counsel;
6. Associate Deputy Director for Field Operations, National;
7. Associate Deputy Director for Field Operations, Regional;
8. Director, Human Resources; and
9. Director, Budget.

No individual who is serving in an office listed in this order in an acting capacity, by virtue of so serving, shall be delegated the functions and duties of the Director.

Dated: December 4, 2024.

Gregory Goldstein,

Chief Operating Officer Performing the Duties of the Director.

[FR Doc. 2024–28847 Filed 12–6–24; 8:45 am]

BILLING CODE 6732–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Medical Care for Adults With Down Syndrome

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Medical Care for Adults with Down Syndrome,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 8, 2025.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, telephone: 301–427–1656 or email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Medical Care for Adults with Down Syndrome.* AHRQ is conducting this review pursuant to section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Medical Care for Adults with Down Syndrome.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/care-adults-down-syndrome/protocol.*

This is to notify the public that the EPC Program would find the following information on *Medical Care for Adults with Down Syndrome* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

1. What are the benefits, harms, and considerations of screening and diagnostic interventions, for co-occurring medical and behavioral health conditions in adults with Down syndrome?

2. What are the benefits and harms, and considerations of interventions to treat co-occurring medical and behavioral health conditions specifically in adults with Down syndrome?

Contextual Questions (CQ)

1. What conditions occur at an increased or decreased prevalence in adults with Down syndrome compared to the general adult population. How does prevalence vary by age/decade of age, gender, setting (rural), and race/ethnicity?

2. How do clinical symptoms and the presentation of common co-occurring behavioral/mental health conditions (*e.g.,* anxiety and depression) differ among adults with Down syndrome compared to their presentation in the general adult population?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

PICOTS	KQ1	KQ2
Population	Adults 18+ years of age with Down syndrome. *Subgroups:* demographics (age, race, ethnicity, gender), geography (rural and urban), socioeconomic status.	Adults 18+ years of age with Down syndrome *Subgroups:* demographics (age, race, ethnicity, gender), geography (rural and urban), socioeconomic status.
Intervention	Screening/diagnostic tests for co-occurring medical conditions in adults with Down syndrome.	Treatment interventions for co-occurring medical conditions in adults with Down syndrome.
Comparator	Alternative test for screening/diagnosis or no screening.	For all conditions, compared with usual care or alternative intervention for treatment.
Outcome	*Benefits:* accurate diagnosis, time to diagnosis or intervention/treatment. Health and quality of life outcomes. *Harms:* adverse events related to screening/diagnosis (mortality, medical trauma, unnecessary testing, etc.).	*Intermediate outcomes:* Treatment adherence. Lab values. Healthcare utilization. *Final outcomes:* Change in standardized symptom measures. Morbidity/mortality. Quality of life. Functional outcomes (*e.g.,* activities of daily living, assisted living/nursing home status). Caregiver or family outcomes (including caregiver health and quality of life). *Harm outcomes:* Adverse treatment effects.
Timing	All duration and follow up.	All duration and follow up.
Setting	US and non-US settings. All healthcare settings (*e.g.*, primary care, specialty care, specialized clinics, etc.)	US and non-US settings. All healthcare settings (*e.g.*, primary care, specialty care, specialized clinics, etc.).

Abbreviations: KQ = key question.

Dated: December 3, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–28830 Filed 12–6–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–319, CMS–2088–17, CMS–224–14 and CMS–R–297/CMS–L564]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 8, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Use:* Title XIX and title XXI State agencies are required to submit the MEQC pilot planning document in accordance with § 431.814(b), and the MEQC case level and CAP reports based on pilot findings in accordance with §§ 431.816 and 431.820, respectively.

The primary users of this information are State Medicaid (and where applicable CHIP) agencies and CMS. State agencies are expected to use the information collected for continuous quality improvement purposes. They will identify patterns of error in their eligibility processing operations and systems and take corrective actions to address issues and improve the eligibility determination process. CMS will use the data collected to identify and help those States that are most in need of technical assistance. CMS will also use the data set to identify potential weaknesses in Federal regulations. It will propose regulatory modifications designed to ensure that there are more effective quality controls in the eligibility determination process.; *Form Number:* CMS–319 (OMB control number: 0938–0147); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Number of Responses:* 647; *Total Annual Hours:* 9,840. (For policy questions regarding this collection contact Camiel Rowe at 410–786–0069.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Community Mental Health Center Cost Report *Use:* CMS requires the Form CMS–2088–17 to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. In addition, CMHCs may receive reimbursement through the cost report for Medicare reimbursable bad debts. CMS uses the Form CMS–2088–17 for rate setting; payment refinement activities, including market basket analysis; Medicare Trust Fund projections; and to support program operations. The primary function of the cost report is to determine provider reimbursement for services rendered to Medicare beneficiaries. Each CMHC submits the cost report to its contractor for reimbursement determination. Section 1874A of the Act describes the functions of the contractor. CMHCs must follow the principles of cost reimbursement, which require they maintain sufficient financial records and statistical data for proper determination of costs. The S series of worksheets collects the provider's location, CBSA, date of certification, operations, and unduplicated census days. The A series of worksheets collects the provider's trial balance of expenses for overhead costs, direct patient care services, and non-revenue generating cost centers. The B series of worksheets allocates the overhead costs to the direct patient care and non-revenue generating cost centers using functional statistical bases. The Worksheet C computes the apportionment of costs between Medicare beneficiaries and other patients. The D series of worksheets are Medicare specific and calculate the reimbursement settlement for services rendered to Medicare beneficiaries. The Worksheet F collects the provider's revenues and expenses data from the provider's income statement. *Form Number:* CMS–2088–17 (OMB control number: 0938–0378); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 191; *Total Annual Responses:* 191; *Total Annual Hours:* 17,190. (For policy questions regarding this collection contact Jill Keplinger at 410–786–4550.)

3. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* The Form CMS–224–14 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and to calculate the FQHC settlement amount. These providers, paid under the FQHC prospective payment system (PPS), may receive reimbursement outside of the PPS for Medicare reimbursable bad debts, pneumococcal, influenza, and COVID–19 vaccines, and monoclonal antibody products. CMS uses the Form CMS–224–14 for rate setting; payment refinement activities, including developing a FQHC market basket; Medicare Trust Fund projections; and to support program operations. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the FQHC Medicare cost report data to calculate Medicare margins; to formulate recommendations to Congress regarding the FQHC PPS; and to conduct additional analysis of the FQHC PPS. *Form Number:* CMS–224–14 (OMB control number: 0938–1298); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 2,967; *Total Annual Responses:* 2,967; *Total Annual Hours:* 172,086. (For policy questions regarding this collection contact LuAnn Piccione at 410–786–5423.)

4. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Medicare Request for Employment Information; *Use:* Section 1837(i) of the Social Security Act (the Act) provides for a SEP for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. Disabled individuals with Medicare may also delay enrollment because they have large group health plan coverage based on their own or a family member's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. Form CMS L564 provides this proof so that SSA can determine eligibility for the SEP. Individuals eligible for the SEP can enroll in Part B without incurring a late enrollment penalty (LEP). Individuals may also use this form to prove that their group health plan coverage is based on current employment status and to have the assessed Medicare LEP reduced. *Form Number:* CMS–R–297/CMS–L564 (OMB control number: 0938–0787); *Frequency:* Annually; *Affected Public:* Individuals or households, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 594,998; *Total Annual Responses:* 594,998; *Total Annual Hours:* 243,949. (For policy questions regarding this collection contact Candace Carter at 410–786–8466 or *Candace.Carter@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–28857 Filed 12–6–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget for Review and Approval; ''State SNAP Agency NDNH Matching Program Performance Report'' (Office of Management Budget #: 0970–0464)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: OCSS is requesting the Office of Management and Budget (OMB) to approve the ''State SNAP Agency NDNH Matching Program Performance Report,''

with minor revisions, for an additional three years. State agencies administering their Supplemental Nutrition Assistance Program (SNAP) provide the annual performance report to OCSS in accordance with the computer matching agreement between state SNAP agencies and OCSS. The current OMB approval expires on February 28, 2025.

DATES: Comments due January 8, 2025. The Office of Management and Budget (OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: State agencies administering SNAP are mandated to participate in a computer matching program with OCSS. The matching program compares SNAP applicant and recipient information with employment and wage information maintained in the National Directory of New Hires (NDNH). The outcomes of the compared information help State SNAP agencies verify an individual's identity and determine a benefit eligibility. To receive NDNH information, state agencies enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSS with annual performance outcomes attributable to the use of NDNH information. To fulfill OMB requirements, OCSS periodically reports performance measurements demonstrating how the use of information in the NDNH supports the OCSS strategic mission, goals, and objectives. These periodic reports include information derived from state SNAP agency annual NDNH performance reports. OCSS provides states with required performance report template and instructions, which OCSS revised to update the submission contacts and formatting, improve grammar, and to change ''Office of Child Support Enforcement (OCSE)'' to ''Office of Child Support Services (OCSS).''

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Total annual burden hours
SNAP Agency Performance Reporting Tool and Instructions	53	1	0.83	43.99

Authority: 42 U.S.C. 653(j)(10); 5 U.S.C. 552a; and Pub. L. 111–352.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28760 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Electronic Document Exchange (Office of Management and Budget #: 0970–0435)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF), is requesting the Office of Management and Budget (OMB) to approve the Electronic Document Exchange (EDE), with minor revisions, for an additional three years. State child support agencies (CSAs) use the EDE to improve case processing. The current OMB approval expires on June 30, 2025.

DATES: Comments due February 7, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The EDE provides a centralized, secure system for authorized users in state CSAs to electronically exchange child support and spousal support case information with other state CSAs. EDE benefits state CSAs by reducing delays, costs, and barriers associated with interstate case processing. It increases state collections, improves document security, standardizes data sharing, increases state participation, and improves case processing, resulting in better overall child and spousal support outcomes. OCSS made minor updates to the Portal screens to enhance functionality and changed ''Office of Child Support Enforcement (OCSE)'' to ''Office of Child Support Services (OCSS).''

Respondents: State CSAs

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
EDE Screens	49	7,383	0.017	6,150

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652(a)(7); 42 U.S.C. 666(c)(1); and 45 CFR 303.7(a)(5).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28766 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Request for Certification of Adult Victims of Human Trafficking

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP) is requesting a 3-year extension of the form: Request for Certification of Adult Victims of Human Trafficking (RFC) form (Office of Management and Budget (OMB) #: 0970–0454, expiration April 30, 2025).

DATES: Comments due February 7, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The U.S. Department of Health and Human Services (HHS) provides letters of certification to victims of severe forms of trafficking in persons under the authority of the Trafficking Victims Protection Act of 2000 (TVPA), as amended 22 U.S.C. 7105(b)(1)(C) and (E). HHS delegated this authority to OTIP. Certification is required for foreign national adult victims of human trafficking in the U.S. to apply for federally funded benefits and services.

OTIP developed the RFC form for potential victims and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives to provide the required information for certification to HHS in accordance with the TVPA of 2000, as amended.

Since the RFC form originally received clearance, OTIP modernized its request process and launched Shepherd, an online case management system, to process requests for certification and assistance. The PDF version of the form should only be used in exceptional circumstances when the online case management system is inaccessible. If a requester encounters issues submitting a request through Shepherd, they may submit the RFC form to OTIP as a password protected PDF to *Trafficking@acf.hhs.gov.*

The form asks the requester for their identifying information, identifying information for the individual who experienced trafficking victimization in the event the form is submitted by a case manager, and information describing the victim's case management service needs.

Respondents: Potential victims of a severe form of trafficking in persons and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives.

Annual Burden Estimates

The fluctuation in certification letters issued by HHS primarily reflects changing patterns in law enforcement investigations and the number of T visas and Continued Presence status issued by the Department of Homeland Security (DHS). In April 2024, DHS U.S. Citizenship and Immigration Services (USCIS) issued a (89 FR 34864*)* updating regulations that govern the requirements and procedures for foreign nationals who have experienced human trafficking seeking a T visa and eligible family members seeking derivative T–2 nonimmigrant status (T visa derivative). The Final Rule established a process for USCIS to conduct bona fide determinations (BFDs). Principal applicants who have submitted a complete bona fide T visa application will receive a BFD and are eligible for case management services and for benefits and services to the same extent as refugees through HHS Certification while their application is pending. OTIP anticipates that the USCIS Final Rule will significantly increase the number of requests for certification received. Since the Final Rule went into effect, OTIP has received approximately 100 RFCs per week, whereas historically, OTIP received approximately 8 to 12 RFCs per week. Burden estimates for this collection have been revised, accordingly.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Request for Certification of Adult Victims of Human Trafficking	15,600	1	1	15,600	5,200

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 22 U.S.C. 7105.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28819 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Child Support Portal Registration (Office of Management and Budget #: 0970–0370)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) approve the ''Child Support Portal Registration,'' with minor revisions, for an additional three years. The OCSS Child Support Portal (''Portal'') contains applications to help state child support agencies administer their programs. Authorized Portal users must register with OCSS to access Portal applications and provide OCSS with certain Portal application preferences. The current OMB approval expires on February 28, 2025.

DATES: Comments due January 8, 2025. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCSS maintains the Portal, which contains various applications through which authorized users may view, update, upload, or download information for child support purposes. Authorized users must register to access the Portal. The OCSS Portal authenticates registrants and then creates secure profiles for authorized users for employers, insurers, and financial institutions based on information provided in the Employer Services Profile and Insurance Match Debt Inquiry Portal Agreement and Profile forms. Information provided in the electronic National Medical Support Notice (e-NMSN), the electronic Incoming Withholding Order (e-IWO), and the Federally Assisted State Transmitted (FAST) Levy Financial Institution Profile forms gives OCSS the necessary information to set up the respective program user's process and capture preferences. State child support agencies manage and authenticate authorization for individual users via the state proxy server; therefore, a Portal Registration form is not required. State users must, however, provide OCSS with their respective Portal preferences. The information OCSS collects for the Portal registration and profiles remains the same but they underwent minor clarification revisions and edits to update ''Office of Child Support Enforcement (OCSE)'' to ''Office of Child Support Services (OCSS).'' OCSS revised the ''Registration Screen'' burden after the 60-day notice published to correctly reflect the current number of respondents and removed ''agreement'' from the Employer Services Profile form. OCSS also removed the e-NMSN Plan Administrator form because there are no respondents.

Respondents: Employers, Financial Institutions, Insurers, and State Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual estimated number of respondents	Total annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Portal Registration Screens	16,268	1	0.15	2,440.20
Employer Services Profile	20,040	1	0.08	1,603.20
e-NMSN: Employer Profile	20	1	0.22	4.40
e-NMSN: State Profile	4	1	0.22	0.88
e-IWO Employer/Payroll Provider Profile	117	1	0.08	9.36
Insurance Match Debt Inquiry Agreement and Profile	6	1	0.08	0.48
FAST Levy Financial Institution Profile	2	1	0.08	0.16

Estimated Total Annual Burden Hours: 4,058.68.

Authority: 42 U.S.C. 653(m)(2) and 44 U.S.C. 3554.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–28761 Filed 12–6–24; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0481]

Standardized Format for Electronic Submission of Marketing Application Content for the Planning of Bioresearch Monitoring Inspections for Center for Drug Evaluation and Research Submissions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.'' This guidance describes the electronic submission of certain data and information in standardized formats. This information is used by the Center for Drug Evaluation and Research (CDER) in the planning of, and by FDA's Office of Inspections and Investigations (OII) in the conduct of, BIMO inspections.

DATES: The announcement of the guidance is published in the **Federal Register** on December 9, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–0481 for ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as ''confidential.'' Any information marked ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box, and follow the prompts; and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time ((see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0980.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions.'' This guidance describes the electronic submission of certain data and information in standardized formats. CDER uses the data and information described in the guidance to plan BIMO inspections. The guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in new drug applications (NDAs), biologic license applications (BLAs) regulated by CDER, as well as supplements containing new clinical study reports.

To meet its review performance goals in accordance with CDER good review management principles and practices for products covered by the Prescription Drug User Fee Act, CDER generally initiates inspection planning early in the application review process (*i.e.,* during the filing determination and review planning phase). CDER's inspection planning includes the selection of clinical investigator sites and other regulated entities for on-site inspections, and the preparation of assignment memos and background packages that CDER provides to OII investigators, who perform FDA's BIMO inspections. CDER uses the data and information described in this guidance to plan BIMO inspections, including: (1) to facilitate the timely identification of sites for inspection and (2) to ensure the availability of information needed to conduct BIMO inspections by OII investigators.

This guidance finalizes the draft guidance entitled ''Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions'' issued on February 16, 2018 (83 FR 7043). The draft guidance superseded the previously issued draft guidance for industry ''Providing Submissions in Electronic Format—Summary Level Clinical Site Data for CDER's Inspection Planning'' issued on December 19, 2012 (77 FR 75174).

We reviewed all comments received on the draft guidance issued on February 16, 2018, and revised several sections of the guidance. The updates include:

- Clarified, throughout the guidance, which NDA and BLA supplements the requirements in the guidance apply to.
- Clarified that clinical sites that screened, consented, or enrolled trial participants are to be included in the table listing all clinical sites that participated in clinical studies.
- Clarified that the request for a list of all entities that the sponsor has used to conduct clinical trial related activities includes both entities the sponsor has contracted without a transfer of regulatory obligations and those to whom the sponsor has transferred regulatory obligations.
- Deleted specific directions related to eCTD formatting and optional submission of a BIMO Reviewer's Guide and clarified that specifications for these items are now included in the technical specifications document.
- Additional comments received, which were related to the technical specifications document ''Bioresearch Monitoring Technical Conformance Guide,'' have been addressed separately in prior revisions to that document.

In section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)), Congress granted explicit authorization to FDA to specify, in guidance, the electronic format for submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)). Accordingly, to the extent that this guidance provides such requirements, as indicated by the use of the words *must* or *required,* this guidance will not be subject to the usual restrictions in FDA's good guidance practices regulations (GGPs), such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act'' issued on December 18, 2014 (79 FR 75570)).

To comply with GGPs and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance document because it is not an accurate description of this guidance. Insofar as this guidance specifies the format for electronic submissions pursuant to section 745A(a) of the FD&C Act, 24 months after the issuance of this guidance, electronic submission of certain data and information in the standardized formats described in the guidance will be required.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information contained in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 2, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28807 Filed 12–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5331]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Extended-Release/Long-Acting Opioid Analgesic Postmarketing Requirement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (the Committees). The general function of the Committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 5, 2025, from 8 a.m. to 5 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–5331. The docket will close on February 4, 2025. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before January 22, 2025, will be provided to the Committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–5331 for ''Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Extended-Release/Long-Acting (ER/LA) Opioid Analgesic (OA) Postmarketing Requirement (PMR).'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *DSaRM@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committees will discuss the findings of the completed ER/LA OA PMRs 3033–1 and 3033–2 (link to Release and Reissue letter: *https://www.fda.gov/media/95546/download*).

These PMRs are prospective (3033–1) and retrospective (3033–2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online

teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The online presentation of materials will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committees. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before January 22, 2025, will be provided to the Committees. Oral presentations from the public will be scheduled between approximately between 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before January 13, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by January 14, 2025. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: December 2, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28811 Filed 12–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 8, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments,'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program Part F Regional AIDS Education and Training Center Program Activities, OMB No. 0906–xxxx—New.

Abstract: The Ryan White HIV/AIDS Program's (RWHAP) AIDS Education and Training Center (AETC) Program, authorized under title XXVI of the Public Health Service Act, supports a network of regional centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating people with HIV. The RWHAP Regional AETC Program's purpose is to increase the number of health care providers who are effectively educated and equipped to counsel, diagnose, treat, and medically manage people with HIV. The RWHAP Regional AETC Program recipients are required to report data on the training activities and trainees to HRSA once a year. HRSA is requesting the approval of new AETC data collection forms to accurately capture data relating to Regional AETC activities, participants, and site information for both Practice Transformation (PT) and Interprofessional Education (IPE) sites as well as involvement in the HIV care and treatment workforce (1-year post-participation), knowledge gained through participating in an activity, and satisfaction with the activity. The RWHAP Regional AETC Program recipients will gather data on the training activities they conduct using six data collection instruments. The Individual Participant Record is completed at least once every reporting period by participants actively engaging in Regional AETC activities. This form includes Regional AETC participant demographic, workplace, and clients-served data for the participant's

respective provider sites. The Regional AETC recipient completes the Training Activity Record form at the end of each Regional AETC activity that takes place during the reporting period. This form describes the activity in hours, modality, and topic(s). The PT Site Characteristics/Outcomes form collects site characteristics information for PT recipient sites only, such as clinic activities and procedures and aggregate counts of clients. PT sites provide clinical services and differ from IPE sites that support students, thus necessitating a different form. The IPE Site Characteristics/Outcomes form collects site characteristics information for IPE recipient sites only. The Participant Post-Activity Immediate Survey collects information from participants immediately after an activity, specifically, their satisfaction and potential increased knowledge due to participating in said activity. The IPE Long-Term form collects 1-year post-participation information from participant students who engaged in an IPE program to assess involvement in the field of HIV care and treatment.

A 60-day notice published in the **Federal Register** on July 19, 2024, 89 FR 58744–45. The 60-day FRN publication elicited 15 public comments, including feedback from eight currently funded AETC regional recipients. The public comments offered input to clarify the definitions of the terminology used on the forms; requested additions and revisions to response options and categories; provided feedback to update demographic questions; requested more review to identify which professions should be included or removed from the forms; asked for clarity on the training track and the process for selecting a track; and suggested that there be a balance of questions on both HIV treatment and prevention.

HRSA's HIV/AIDS Bureau conducted a thorough review of all the feedback provided by the public during the 60-day publication period. HRSA will incorporate much of the public feedback into the new forms, including through the addition of new proposed questions, removal of current incompatible questions, correcting spelling and grammar, providing definitions and instructions for clarity, incorporating skip logic to streamline question response options/categories, updating the form format, and the change of the form title from Interprofessional Education Site Characteristics/Outcomes Form to the Interprofessional Education Health Profession Program Characteristics/Outcomes Form. Other suggestions may be further reviewed in future OMB packages or non-substantive change memos.

Need and Proposed Use of the Information: HRSA uses the data collected when conducting RWHAP AETC programmatic assessments to determine future program needs. These data allow HRSA to identify where gaps exist in training HIV professionals as well as to measure whether training activities are meeting the goals of the National HIV/AIDS Strategy and the RWHAP statute.

Likely Respondents: RWHAP Regional AETC participants complete the Individual Participant Record at least once a reporting period. Regional AETC recipients complete a Training Activity Record for each training activity they conduct during the reporting period. All Regional AETC participants will take the Participant Post-Activity Survey immediately after any attended activity. The IPE Long-Term form will only be completed by participants who engaged in an IPE program, 1-year post-participation in the program. Finally, PT recipients will complete the PT Site Characteristics/Outcomes form at least once per reporting period, and IPE recipients will complete the IPE Site Characteristics/Outcomes form at least once per reporting period.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Individual Participant Record	59,576	1	59,576	0.27	16,085.52
Training Activity Record	12,226	1	12,226	0.21	2,567.46
PT, Site Characteristics and Outcomes	128	1	128	0.31	39.68
IPE, Site Characteristics and Outcomes	86	1	86	0.09	7.74
Participant Post-Activity Immediate Survey	59,576	3	178,728	0.06	10,723.68
IPE, Long-Term	4,403	1	4,403	0.07	308.21
Combined Data Set	8	1	8	64.00	512.00
Total	136,003	.....	255,155	.....	30,244.29

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–28803 Filed 12–6–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Health Center Program Scope Policy Manual Guidance

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: HRSA requests public comments on the Draft Health Center Program Scope of Project Manual (draft Scope Policy Manual). The draft Scope Policy Manual provides updated policy guidance on what constitutes the Health Center Program scope of project under the Public Health Service Act (PHS Act).

DATES: Submit comments no later than February 7, 2025.

ADDRESSES: Electronic comments should be submitted through the HRSA Bureau of Primary Health Care Contact Form (*https://hrsa.my.site.com/support/s/*), by selecting ''Comment on Draft Policy'' under the ''Policy'' section.

FOR FURTHER INFORMATION CONTACT: Jennifer Joseph, Office of Policy and Program Development Director, Bureau of Primary Health Care, HRSA, at *jjoseph@hrsa.gov* and 301–594–4300.

SUPPLEMENTARY INFORMATION: The draft Scope Policy Manual (*https://bphc.hrsa.gov/sites/default/files/bphc/compliance/draft-health-center-program-scope-project-manual*) updates Health Center Program scope of project policy guidance for all health centers that apply for and receive federal award (*https://bphc.hrsa.gov/compliance/compliance-manual/glossary#federal-award*) funds under the Health Center Program subrecipient organization (sections 1861(aa)(4)(A)(ii) and 1905(l)(2)(B)(ii) of the Social Security Act; *https://bphc.hrsa.gov/compliance/compliance-manual/glossary#subrecipient*), and Health Center Program look-alikes (sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act; (*https://bphc.hrsa.gov/compliance/compliance-manual/glossary#look-alike*).

The draft Scope Policy Manual proposes new policy and clarifies existing policy in key areas. Through the draft Scope Policy Manual, HRSA updates the Health Center Program scope of project policy to consolidate scope of project-related policy into a single policy document to assist health centers in understanding scope of project, statutory language and the Health Center Program Compliance Manual (*https://bphc.hrsa.gov/compliance/compliance-manual*).

The draft Scope Policy Manual does not include scope of project process-related instructions. Instructions for documenting and updating scope of project will continue to be available on the Health Center Program Scope of Project web page (*https://bphc.hrsa.gov/compliance/scope-project*).

HRSA proposes that the final Scope Policy Manual supersede the following previously issued scope of project Policy Information Notices (PINs):

- *PIN 2007–09:* Service Area Overlap: Policy and Process
- *PIN 2008–01:* Defining Scope of Project and Policy for Requesting Changes
- *PIN 2009–02:* Specialty Services and Health Centers' Scope of Project
- *PIN 2009–05:* Policy for Special Populations-Only Grantees Requesting a Change in Scope to Add a New Target Population

HRSA provides grants to eligible applicants under section 330 of the PHS Act (42 U.S.C. 254b) to support the delivery of preventive and primary care services to the nation's underserved individuals and families. HRSA also designates eligible applicants as Health Center Program look-alikes. Look-alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Nearly 1,400 Health Center Program-funded health centers and more than 100 Health Center Program look-alike organizations operate more than 15,000 service delivery sites that provide care to more than 30.5 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of this document, the term ''health center'' refers to entities that receive a federal award under section 330 of the PHS Act, as well as subrecipients and organizations designated as look-alikes, unless otherwise stated.

Carole Johnson,

Administrator.

[FR Doc. 2024–28748 Filed 12–6–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a webcast on January 7, 2025. This virtual meeting will be open to the public.

DATES: The virtual ACMH meeting will be held on January 7, 2025, from 2 p.m. to 3 p.m. EST. If the Committee completes its work before 3 p.m. EST, the meeting will adjourn early.

Any individual who wishes to participate in the virtual meeting should register using the Zoom registration link provided below by 5 p.m. EST on January 3, 2025.

ADDRESSES: The meeting will be held virtually and will be accessible by webcast. Instructions regarding webcast access and providing written public comments will be given after meeting registration occurs.

Registration is required for the public to attend the meeting, provide comment, and/or distribute material(s) to ACMH members. Instructions regarding participating in the call and providing written or verbal public comments will be provided after meeting registration occurs. Information about the meeting will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov*. Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups*.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6816; email: *OMH-ACMH@hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties.

The topic to be discussed during the virtual meeting will be finalizing recommendations on the

implementation of the updated Office of Management and Budget (OMB) Federal race and ethnicity data collection standards (SPD 15) that is focused on opportunities for engagement with racial, ethnic, and Tribal community level organizations to support increased awareness of OMB SPD 15 and their intended goals within their communities. The final recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to engagement with racial, ethnic, and tribal community level organizations to support increased awareness of OMB SPD 15 and their intended goals within their communities.

Any individual who wishes to attend the meeting must register via the Zoom registration link, *https://www.zoomgov.com/webinar/register/WN_Lvv-t5RdTNi0Hfqz6basPQ,* by 5 p.m. EST on January 3, 2025. Each registrant should provide their name, affiliation, phone number, email address, if they plan to provide either written or verbal comment, and whether they have requests for special accommodations, including sign language interpretation. After registering, registrants will receive an automated email response with the meeting connection link. The meeting connection link is unique to each registrant and should not be shared.

Members of the public will have an opportunity to provide comments at the meeting. Individuals should indicate during registration whether they intend to provide written or verbal comment. Public comments will be limited to two minutes per speaker during the time allotted. Individuals of the public may also submit and distribute electronic or printed statements or material(s) related to this meeting's topic. Written statements or material(s) should be double-spaced with one-inch margins and not exceed two pages in length. Any content beyond the two-page limit will not be presented to the Committee. Registered members of the public who plan to submit electronic and distribute electronic or printed public statements or material(s) related to the meeting's topic should email the material to *OMH-ACMH@hhs.gov* at least two (2) business days prior to the meeting.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2024–28823 Filed 12–6–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurobiology of Pain and Itch.

Date: January 6, 2025.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Anne-Sophie Marie Lucie Wattiez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (301) 594–4642, *anne-sophie.wattiez@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 3, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28808 Filed 12–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Eye Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: January 16–17, 2025.

Time: January 16, 2025, 8:50 a.m. to 5:30 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: National Eye Institute, Claude D. Pepper Building, Rooms F/G, 31 Center Drive, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Time: January 17, 2025, 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: National Eye Institute, Claude D. Pepper Building, Rooms F/G, 31 Center Drive, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Contact Person: David M. Schneeweis, Ph.D., Acting Scientific Director, National Eye Institute, National Institutes of Health, Building 31, Room 6A22, Bethesda, MD 20892, 301–451–6763, *David.schneeweis@nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.nei.nih.gov/about/advisory-committees,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 4, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28865 Filed 12–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2023–1 Phase II: Artificial Intelligence to Improve Clinical Microscopy for Diagnosis of Infectious Diseases (Topic 121).

Date: January 7, 2025.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A Rockville, MD 20892 (Virtual Meeting).

Contact Person: Shilpakala Ketha, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A, Rockville, MD 20892, (301) 761–6821, *shilpa.ketha@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 4, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28844 Filed 12–6–24; 8:45 am]

BILLING CODE 4140–01–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Program Comment on Stewardship and Management of National Park Service Mission 66-Era Facilities (1945–1972)

AGENCY: Advisory Council on Historic Preservation

ACTION: Notice of approval of program comment.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) has approved a program comment to facilitate continued use and preservation of Mission 66-era historic properties.

DATES: The program comment went into effect on November 4, 2024.

FOR FURTHER INFORMATION CONTACT: Kirsten Kulis, (202) 517–0217, *kkulis@achp.gov.*

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act, 54 U.S.C. 306108 (Section 106 and NHPA), requires Federal agencies to consider the effects of projects they carry out, license/permit/approve, or assist (undertakings) on historic properties, and provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under section 800.14(e) of those regulations, agencies can request the ACHP to provide a ''Program Comment'' on a particular category of undertakings in lieu of conducting individual reviews of each individual undertaking under such category, as set forth in 36 CFR 800.4 through 800.7. An agency can meet its Section 106 responsibilities with regard to the effects of those undertakings by taking into account an applicable Program Comment and following the steps set forth in that comment.

The U.S. Department of the Interior, National Park Service (NPS) sought a Program Comment to facilitate continued use and preservation of Mission 66-era historic properties. On November 4, 2024, the ACHP issued such a Program Comment, the text of which is reproduced at the end of this notice, with various typographical errors corrected.

I. Background

''Mission 66'' refers to the massive building campaign that occurred between 1945 and 1972 that improved, standardized, and democratized the public's national park experience with new facilities including comfort stations, picnic shelters, campgrounds, visitor centers, park staff housing, maintenance buildings, warehouses, roads, and other infrastructure. This period of feverish construction was called ''Mission 66'' because it was supposed to have been completed by 1966, in time for the fiftieth anniversary of the founding of the NPS.

The NPS requested a Program Comment (PC) to facilitate continued use and preservation of Mission 66-era historic properties by providing parks with an optional tool that would reduce or eliminate external reviews for certain straightforward Mission 66-era focused undertakings. It would also allow superintendents to consider Mission 66-era facilities as eligible for listing in the National Register of Historic Places (National Register) when they reference the Mission 66-Era Multiple Property Determination Form (MPDF), thereby addressing NPS's identification backlog. Recent laws provided NPS with funding and charged them with improving the visitor experience and addressing accessibility requirements. NPS plans to meet these mandates using these facilities and reinvesting in the historic properties from this era.

II. Program Comment Summary

The PC is intended to be an optional compliance tool and park superintendents will not be required to use it. Moreover, the PC cannot be used in a variety of circumstances including:

—when there's potential to affect National Historic Landmarks, historic battlefields, burial sites, human remains, and/or funerary objects, or if an undertaking is proposed to occur on or affect historic properties located on Tribal lands (as defined in the NHPA), or there's potential to affect properties of religious and cultural significance to Indian Tribes or Native Hawaiian Organizations, or to the Native Hawaiian Community;

—when there may be adverse effects to historic properties that are significant for reasons other than Mission 66 (*e.g.,* not primarily National Register -eligible or -listed due any association with the Mission 66-era as it is described in the MPDF); or

—when there's potential for adverse effects to Mission 66-era historic properties such that they would become ineligible for National Register listing or candidates for de-listing.

The PC will not amend or change the existing Programmatic Agreement among the National Park Service (U.S. Department of the Interior), the Advisory Council on Historic Preservation, and the National Conference of State Historic Preservation Officers for Compliance with Section 106 of the National Historic Preservation Act (2008 PA), nor any other valid Section 106 agreements.

The implementation of the PC will include regional and national oversight and reporting, as well as regular training, to ensure accountability. The PC will facilitate nationwide implementation of the aforementioned MPDF, so that NPS may achieve a broader perspective in managing these properties and they may be understood within their national context. The NPS

believes that the PC will encourage reuse of Mission 66 era resources.

III. NPS Consultation Summary

The PC is the product of more than a year of early coordination as well as formal NPS consultation which was initiated last Fall and closed this past Summer. NPS determined the development of this request required government-to-government consultation with Tribes. NPS held six virtual formal consultation meetings that were attended by sixty-two (62) external participants. This included two government-to-government consultation meetings with Tribes. The other four formal meetings were attended by State Historic Preservation Officers (SHPO) from twenty (20) separate states and other stakeholders. In addition to the comments from Tribes described immediately below, NPS received a total of sixteen (16) correspondences including from eight SHPOs, three members of the public, and the National Trust for Historic Preservation.

NPS received one verbal comment about identification from one Tribal representative who participated in one of the meetings and NPS responded via email. Over the course of the NPS comment period, NPS received four written comment letters from Tribes. One had specific questions about a park and their comments are confidential; one was not concerned because the proposed PC would not be used as a method of Section 106 compliance for undertakings with potential to affect Tribal lands and/or properties of religious or cultural significance to Tribes; and two others declined to participate but wanted to be made aware if there was an unanticipated discovery. NPS responded to each of these directly.

Some of the comments from the SHPOs emphasized that qualified NPS staff must be involved in all aspects of project planning and execution, especially given the nuanced approach to adverse effects in the PC. Other SHPOs noted that the proposed fifteen (15) calendar day review period was too short for ''meaningful'' comments, and that NPS should use proprietary (*e.g.,* State) databases to enter project information instead of providing information on Planning, Environment, and Public Comment (PEPC) and emailing stakeholders. Comments from SHPOs, the National Trust for Historic Preservation, and members of the public also indicated concern that mitigation should be commensurate with the adverse effects associated with the specific undertakings, and inquired about how the mitigation will benefit the public.

NPS considered all comments received in consultation and responded directly to written comments. NPS changed certain aspects of the PC to address the comments, adding or clarifying language in the PC regarding qualified personnel, park suspension, use on Tribal lands (it will not be so used), consultation responsibilities and confidentiality. At that time, NPS did not adjust the proposed fifteen (15) calendar day review period. However, NPS responded that the accelerated timeframe will better allow Parks to focus on other more complex projects using the standard Section 106 process. Also, NPS clarified that Park Superintendents will notify the relevant SHPO and/or THPO and potentially interested Indian Tribe, Native Hawaiian Organization or others in the Native Hawaiian Community or Alaska Natives via email, hard-copy letter via mail or mail service (or an alternative method arranged in advance in writing) when external review process (ERP) packages are available for review and comment.

Finally, NPS clarified that NPS will provide mitigation for collective adverse effects to Mission 66-era historic properties at the national level, rather than park-/undertaking-specific approaches. However, ERP packages must identify mitigation measures, and the Federal Preservation Officer must track mitigation progress annually. NPS also added a requirement for NPS to develop a brief web-based on-demand training for use by internal and external partners. NPS provided drafts of PC to the ACHP and made various changes to address ACHP staff comments.

In summary, NPS addressed consulting party comments on the PC conceptual overview and outline/plan and made substantive changes in preparation of the PC based on that consultation. NPS subsequently prepared the PC draft, in coordination with ACHP through several iterations of review and comment. NPS addressed all ACHP staff comments and submitted the resulting final PC for ACHP action.

IV. ACHP Consultation Summary

ACHP initiated consultation on August 26, 2024, and held two virtual consultation meetings; one was with SHPOs, and one was government-to-government consultation with Indian Tribes. The meetings were attended by thirty-five (35) external participants, including representatives from seventeen (17) SHPOs, and four THPOs as well as staff from the National Conference of State Historic Preservation Officers and the National Association of Tribal Historic Preservation Officers (NATHPO). ACHP also posted a dedicated website and accepted public comments through October 18, 2024. ACHP members discussed the PC at a Regulations and Governance Committee meeting on October 7, 2024. ACHP received twelve (12) correspondences from SHPOs and one from NATHPO, totaling eighty (80) comments. ACHP responded directly to all written correspondences.

About thirty (30) of the comments were addressed with minor edits or clarifications. The remaining comments focused on the topics below and were addressed with substantive changes listed in order of magnitude:

—External Review Process: The steps in this clause were clarified and the review period was extended to fifteen (15) business days with an optional additional five (5) business day review and consultation period for handling objections. The requirements for objections were specified, and it was made clear that objections are made by the relevant SHPO/THPO, Indian Tribe, or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives.

—Special External Review Process for Certain Findings of No Historic Properties: Additional language in this clause clarifies that a special external review must occur when a Park Superintendent makes a finding that a Mission 66-era facility is no longer historic because it lacks integrity. It also explains that the main purpose of the review is to confirm that there are no properties of religious and cultural significance to an Indian Tribe or to Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives.

—Discoveries: This clause was expanded to provide step-by-step instructions for Park Superintendents, to reference the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001 *et seq.*), and to state, ''When applicable, the Park Superintendent will consider the principles within the ACHP's Policy Statement on Burial Sites, Human Remains, and Funerary Objects, dated March 1, 2023.'' The clause also states that the NPS will fulfill its Tribal and Native Hawaiian consultation obligations ''consistent with all relevant Executive Orders, Secretary's Orders, the Department of the Interior Departmental Manual, and NPS Director's Orders and Related Guidance. NPS recognizes and considers Indigenous Knowledge in

the Section 106 review process in accordance with the November 30, 2022 Guidance for Federal Departments and Agencies on Indigenous Knowledge issued by the White House Office of Science and Technology Policy and Council on Environmental Quality and the Departmental Manual (301 DM 7, Departmental Responsibilities for Consideration and Inclusion of Indigenous Knowledge in Departmental Actions and Scientific Research).''

—Mitigation: This clause commits NPS to developing and publishing an Administrative History of NPS Housing which will be completed as part of a partnership with the NPS History Program and a public university and made publicly available by the spring of 2027. It also commits NPS to publishing an MPDF reference guide for internal and external partners within about six (6) months. In addition, the agency will develop a brief web-based on-demand training for use by internal and external partners within one (1) year of the publication of the PC in the **Federal Register**.

—Park Suspension: New language in this clause specifies that the respective SHPO/THPO, Indian Tribes and Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives may also offer comments on park suspension.

—Design Guidelines: This clause allows for the development of various types of design guidelines. It also explains that if design guidelines are being developed for a specific park, comments from the respective SHPO must be reasonably incorporated.

Finally, ACHP staff provided a final review and NPS duly addressed its requests for minor edits and clarifications. ACHP staff concluded that the PC request met the requirements in 36 CFR 800.14(e)(1) and the changes made in the document reasonably addressed the comments and concerns offered during consultation, the ACHP's Regulations and Governance Committee meeting, and ACHP's staff review.

V. Text of the Program Comment

The full text of the issued program comment, with various typographical errors corrected, is reproduced below. Please note that the text of the issued program comment includes hyperlinks. The footnotes below show the web addresses that were hyperlinked:

Program Comment on Stewardship and Management of National Park Service Mission 66-Era Facilities (1945–1972) for Compliance With Section 106 of the National Historic Preservation Act

This Program Comment (Program Comment) provides the U.S. Department of Interior, National Park Service (NPS) with an alternative way to comply with their responsibilities under Section 106 of the National Historic Preservation Act (54 U.S.C. 306108, and 36 CFR part 800 (Section 106)) regarding certain stewardship and management undertakings at NPS facilities built between 1945 and 1972 (Mission 66-era). This document was developed in consultation by the NPS, as part of a larger agency request, and submitted for consideration by the Advisory Council on Historic Preservation (ACHP) pursuant to 36 CFR 800.14(e) in August 2024. It was consulted upon by the ACHP between August and October 2024, and edits were duly incorporated.

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For purposes of this Program Comment, definitions listed in 54 U.S.C. 300309 (*i.e.,* Tribe, Tribal lands), 54 U.S.C. 300214 (*i.e.,* Native Hawaiian organization), and in the regulations at 36 CFR part 800 broadly and in 36 CFR 800.16 are incorporated by reference. Other definitions appear within the document in parenthesis (*e.g.,* ERP, IRP, 2008 PA, Qualifying Undertaking, etc.). Native Hawaiian Community is defined in 43 CFR part 50.4. The NPS has requested that Native Hawaiian Communities and Alaska Natives be specifically included in the scope, consultation, and other review points in the Program Comment. The NPS consults with the Native Hawaiian Community and Alaska Natives in accordance with U.S. Department of Interior Departmental Manual 512 (2022) Chapters 4–7 and Departmental Manual 513 Chapters 1–2. More information about the Program Comment can be found on the NPS Section 106 Compliance web page (ParkPlanning—Mission 66 Program Comment (*nps.gov*) [1]).

I. Introduction

A. *Background.* In 2020, the U.S. Congress provided NPS with $1.5 billion in funding via the Great American Outdoors Act (Pub. L. 116–152), and other legislation and funding followed. Funds from these laws must be obligated by NPS within the next few years or they will no longer be available for NPS use. The laws called out the agency's deferred maintenance backlog generally, but also the need for the agency to ensure people with disabilities have equal opportunity to benefit from park facilities, programs, services, and activities.

There are approximately 20,000 Mission 66-era facilities in NPS parks, many of them serving visitors and staff, located across the country and

[1] *https://parkplanning.nps.gov/projectHome.cfm?projectID=116344.*

concentrated in the Pacific West and Intermountain Regions. According to NPS data, while almost 50% of Mission 66-era facilities are in ''good'' or ''fair'' condition, 35% are in ''poor'' condition and 16% are in ''serious'' condition and contribute to the NPS deferred maintenance and repair backlog. This backlog totals $23.3 billion as of the end of fiscal year 2023.

Many NPS visitor centers still lack accessible restrooms, water fountains, and entrances. Also, paths between parking lots, sidewalks, buildings, and interpretive programs are often not accessible. Many facilities in staff areas (*e.g.,* housing and maintenance facilities) are also in need of accessibility improvements, as detailed in NPS reports and testimony before the U.S. Congress (ALL IN! Accessibility in the National Park Service 2015–2020).

Further, the lack of suitable affordable NPS staff housing in parks has been identified by the current NPS director as a ''critical issue,'' and widely reported.

B. *Significance.* The massive NPS ''Mission 66'' building campaign that occurred between 1945 and 1972 improved, standardized, and democratized the public's national park experience with new facilities including comfort stations, picnic shelters, campgrounds, visitor centers, park staff housing, maintenance buildings, warehouses, roads, and other infrastructure. This period of feverish construction was called ''Mission 66'' because it was supposed to have been completed by 1966, in time for the fiftieth anniversary of the founding of the NPS.

Based on NPS nationwide data, the Intermountain Region and Pacific West have the greatest number of NPS Mission 66-era facilities, followed by the Southeast and Northeast, Midwest, National Capital, and the Alaska Regions. The states with 500 or more Mission 66-era facilities are: California (2,450), Wyoming (1,500), Washington (1,200), Virginia (1,150), North Carolina (900), Utah (900), Arizona (900), Colorado (800), Tennessee (700), New York (650), Montana (650), Mississippi (600), Maryland (500), and Texas (500), for a total of about 12,950 facilities (approximately). Other States have less than 500 each. (All figures are approximate and nationwide data has not been verified at the regional, State, or park levels.)

While some of the Mission 66-era facilities, especially visitor centers, were designed by renowned architects, many others were built using standard plans such as those developed for comfort stations, staff housing, administrative and maintenance/utility buildings, ranger kiosks, and similar. During the Mission 66-era, some adjustments were made to the standard plans to address changing park needs as well as both the suitability and availability of construction materials in different regions.

NPS staff typically utilizes the National Register of Historic Places Multiple Property Documentation Form (MPDF, NRIS #64501248, 2015, *https://npgallery.nps.gov/AssetDetail/84789671-6031-4916-8bf1-18fbe8c80511/*) to provide a framework for identification of Mission 66-era historic properties. The MPDF established the period of significance as 1945 to 1972. It mentions certain properties as early or exemplary embodiments of the period, lists the ninety-five (95) parks that were established as part of Mission 66, sets eligibility evaluation criteria for individual listings and park-wide districts, and focuses on consideration of small area use-specific districts.

A monograph on the subject, ''Mission 66: Modernism and the National Park Dilemma'' (Ethan Carr, LALH, 2007, Review of Mission 66: Modernism and the National Park Dilemma (*nps.gov*)[2]), and an NPS-published book, ''MISSION 66 VISITOR CENTERS: The History of a Building Type'' (Sarah Allaback, Ph.D., NPS, 2000, National Park Service: Mission 66 Visitor Centers (*nps.gov*)[3]), provide additional context. In 2022, NPS also published process guidelines for determinations of eligibility for Mission 66 Campgrounds (Mission 66 Campgrounds Determination of Eligibility Process Guidelines (*npshistory.com*)[4]).

C. *Current Compliance Efforts.* The Programmatic Agreement among the National Park Service (U.S. Department of Interior), the Advisory Council on Historic Preservation, and the National Conference of State Historic Preservation Officers for Compliance with Section 106 of the National Historic Preservation Act (2008) (2008 PA, What We Do—Section 106 Compliance Program (U.S. National Park Service) (*nps.gov*)[5]), governs implementation of regular management activities at the NPS. Such management activities may include work done on Mission 66-era facilities; however, as described below, the 2008 PA has limited applicability in regard to many undertakings on Mission 66-era facilities.

The 2008 PA requires Park Superintendents to develop an inventory of historic properties, properties that are listed in or eligible for listing in the National Register. When an undertaking is proposed, the 2008 PA's streamlined process requires that ''identification and evaluation of all types of historic properties within the project area of potential effects (APE) must have been previously undertaken, sufficient to assess effects on those resources'' either via 36 CFR part 800 or section 110 (54 U.S.C. 306102) (The identification effort would have occurred sometime before the undertaking was planned.).

These processes can be time consuming and according to NPS nationwide data, approximately 75% of Mission 66 facilities have not been evaluated for listing in the National Register.

Furthermore, the 2008 PA focuses on regular management activities. As many Mission 66-era facilities are in poor or serious condition and hundreds are underutilized or unutilized (defined in the Federal Real Property Profile Data Dictionary, FRPC Guidance Library | GSA[6]), scopes of work may address more than regular management. Also, the streamlined review process described in the 2008 PA can only be used by Park Superintendents when there is a determination of ''no historic properties affected'' or ''no adverse effects'' (36 CFR part 800). Some proposed scopes of work go beyond regular management and may pose adverse effects to Mission 66-era historic properties, rendering the 2008 PA inapplicable. Finally, the 2008 PA's streamlined review process cannot be used when there is a lease that includes a change of use or where projects cumulatively result in the complete rehabilitation of a historic property.

While it is standard for NPS to make reasonable efforts to avoid and minimize adverse effects (*e.g.,* so activities are completed in accordance with various NPS Preservation Briefs Preservation Briefs—Technical Preservation Services (U.S. National Park Service) (*nps.gov*)[7]), again, there may be cases in which projects cannot achieve mission goals while completely avoiding or minimizing adverse effects to Mission 66-era historic properties

[2] Book review—*https://www.nps.gov/crps/CRMJournal/Winter2010/reviewbook3.html.*

[3] *https://www.nps.gov/parkhistory/online_books/allaback/index.htm.*

[4] *https://www.npshistory.com/publications/mission66/campground-doe-process-guidelines-2022.pdf.*

[5] *https://www.nps.gov/orgs/1966/whatwedo.htm.*

[6] *https://www.gsa.gov/policy-regulations/policy/real-property-policy-division-overview/asset-management/federal-real-property-council/frpc-guidance-library.*

[7] *https://www.nps.gov/orgs/1739/preservation-briefs.htm.*

(*e.g.,* such as making accessibility improvements to comfort stations by changing their layouts, upgrading staff housing kitchens and baths, applying certain preventive seal treatments to vehicular areas, switching out building yard plantings to address the changing climate, and improving utilities at campgrounds, etc.). There may also be temporary adverse effects to Mission 66-era historic properties and other historic properties during construction and reasonably associated with construction activities, that may not be entirely avoidable or minimizable, but will cease once construction is complete.

In these cases, compliance for Mission 66-era facilities has often occurred in conjunction with other larger park initiatives, for which a memorandum of agreement or a programmatic agreement has been executed, or when a park-wide programmatic agreement is already in place.

D. *Goals.* The Program Comment will support specific NPS efforts to use Mission 66-era historic properties to meet mission needs, by expediting Section 106 reviews. It will help NPS fulfill legislated mandates to improve the visitor experience and accessibility, enhance conditions for staff, address longstanding deferred maintenance, and advance ongoing stewardship efforts. NPS plans to accomplish the following with the Program Comment:

1. implement the MPDF on a national level, to address the NPS identification backlog and alleviate workloads;

2. utilize the existing NPS compliance staffing and teams with Qualified Personnel and/or Cultural Resource Management (CRM) Team engagement;

3. encourage preservation and predictability in project planning by requiring internal reviews by Qualified Personnel and/or a CRM Team for certain undertakings that either pose no adverse effects to historic properties or when the only condition for such a finding, by a Park Superintendent, is that the undertaking will follow the Secretary of the Interior's Standards for the Treatment of Historic Properties, (Secretary's Standards, The Secretary of the Interior's Standards for the Treatment of Historic Properties—Technical Preservation Services (U.S. National Park Service) (*nps.gov*) [8]) and applicable guidelines;

4. provide for accountability by listing requirements for the Consultation Record and ensuring the NPS Federal Preservation Officer (FPO) and deputies have access to it for oversight and regular reporting, and may reference it as needed;

5. complete mitigation for adverse effects associated with undertakings subject to the Program Comment with measures including development of additional National Register documentation of Mission 66-era historic properties, development and publication of an Administrative History of NPS Housing available by spring 2027, and either advancing conservation of Mission 66-era materials via materials research and analysis or developing a nationwide interpretive plan, as funds allow; and

6. facilitate a smooth transition to consistent use of the 2008 PA, for regular routine management activities, at the end of the Program Comment's ten-year duration.

E. *Existing Compliance Structure.* NPS will utilize the existing NPS compliance staffing and teams (described in the 2008 PA and this Program Comment) at the national, regional, and park levels, with Qualified Personnel and/or Cultural Resource Management Team engagement, to implement this Program Comment as described below.

1. In the entire Federal Government, NPS has one of the largest concentrations of qualified cultural resource personnel. In this Program Comment, the term Qualified Personnel (Qualified Personnel) refers to those in NPS employ that meet the Secretary of the Interior's Professional Qualification Standards or the OPM Personnel Qualification Standards, which codify the minimum requirements that must be met for professional work concerning historic properties.

2. The term Cultural Resources Management Team or CRM Team is explained in the 2008 PA and in NPS's PA Guidance as follows: A team of subject matter experts appropriate to the resource types found in the park. The number of individuals on the CRM Team may vary from park to park as needed to represent all disciplines appropriate to the park's resources. For example, an undertaking being planned that involves a historic building must have a historical architect on the CRM Team. Typical CRM Teams often include a historical architect, a historical landscape architect, an archeologist, a cultural anthropologist, a historian, and a museum curator. Members may include park staff or staff of other parks, NPS Regional Offices, NPS Centers, federally recognized Indian Tribes or Native Hawaiian organizations, or others from the public or private sector. Agency personnel or contractors who participate on the Park's CRM Team must meet either the qualification standards established in Appendix E to NPS–28, which references the Office of Personnel Management (OPM) Personnel Qualifications Standards, or the Professional Qualification Standards in the Secretary of the Interior's Standards and Guidelines for Archeology and Historic Preservation. These qualification standards define minimum education and experience required to perform identification, evaluation, registration, and treatment activities. In some cases, additional areas or levels of expertise may be needed, depending on the complexity of the task and the nature of the historic properties involved (NPS Nationwide Programmatic Agreement National Guidance Document, 2022, NPS Nationwide Programmatic Agreement National Guidance Document [9]). A CRM Team may be brought in by a Park Superintendent to support the review process set forth in the Program Comment as needed.

II. Scope

A. *Mission 66-Era Historic Properties.* Within this Program Comment, the term Mission 66-era Historic Property refers to a type of historic property (see 36 CFR 800.16(l)) that was built between 1945–1972, during a massive NPS ''Mission 66'' building campaign that was called ''Mission 66'' because it was supposed to have been completed by 1966, in time for the fiftieth anniversary of the founding of the NPS. This term includes Operations Outdoors historic properties that were built for the U.S. Forest Service, or any other historic properties from the Mission 66-era that are now in the custody and control of the NPS as described in the relevant section in this document. Any facility built between 1945–1972 may be covered by this Program Comment; the facility does not need to have been built as part of the Mission 66 program. (May be referred to in singular as a Mission 66-era Historic Property, and both historic and non-historic Mission 66-era properties are referred to as Mission 66-era facilities.)

B. *Overall Effect.* This Program Comment will provide an alternative way for NPS to fulfill their Section 106 responsibilities to take into account the effects on historic properties of their covered undertakings at Mission 66-era facilities. The Program Comment also provides the ACHP a reasonable opportunity to comment regarding

[8] *https://www.nps.gov/orgs/1739/secretary-standards-treatment-historic-properties.htm.*

[9] *https://www.nps.gov/orgs/1966/upload/2022-06-06-PA_Guidance_508_2022-0606-3.pdf.*

covered undertakings at Mission 66-era facilities.

C. *Effect on Other Applicable Laws or Existing Agreements.* The Program Comment is an optional tool, and will not replace, amend, or otherwise change the 2008 PA, nor any other park- or project-specific Section 106 agreements.

Under NPS policy, each Park Superintendent serves as the responsible agency official for the purposes of Section 106 compliance for their park and makes all findings and determinations in the Section 106 process.

If standard Section 106 review, the 2008 PA, a park- or project-specific agreement, or some other applicable program alternative is better suited for NPS to fulfill their Section 106 responsibilities for a given undertaking, there is no requirement for this Program Comment to be used by the Park Superintendent. Again, use of this Program Comment is optional.

D. *Effect on Tribal Lands.* This Program Comment cannot be used on Tribal lands (as defined in the NHPA). In addition, this Program Comment cannot be used when any portion of an undertaking is proposed to occur on or affect historic properties located on Tribal lands or when the undertaking includes activities that may affect historic properties located on Tribal lands (section II.F.2.).

E. *Category of Undertakings.* A Park Superintendent will determine whether it is appropriate to use this Program Comment for a given undertaking as described immediately below and referencing both the park inventory of historic properties described in I.C, above and the park's most recent annual report, such as a report associated with the 2008 PA or some other park-wide agreement, and going forward as described in section X.

This Program Comment may be selected by a Park Superintendent as the appropriate Section 106 compliance method when one of the following management undertakings is planned to take place: (a) at a single Mission 66-era facility or (b) at one or more NPS facilities where the majority of facilities (or resources) within the APE are from the Mission 66-era (1945 to 1972), as determined by the Park Superintendent (in consultation with Qualified Personnel and/or the CRM Team with such consultation documented in the Consultation Record).

The following lists the qualified undertakings (Qualified Undertaking(s) or Qualifying Undertaking(s)) covered by this Program Comment:

1. Regular repetitive management activities (as listed in the 2008 PA Stipulation III.C, and referred to in this Program Comment as Regular Management Activities.) and associated work (*e.g.,* site, site signage, and utilities) and

2. Other management activities (Other Management Activities) and associated work (*e.g.,* site, site signage, and utilities) listed below:

i. Complete rehabilitation in accordance with the Secretary's Standards, specifically the Secretary's Standards for Rehabilitation, and applicable guidelines; and/or

ii. section II.E.2.i. when associated with leasing; and/or

iii. Alteration, accessibility improvements, HazMat abatement, stabilization and mothballing, demolition of non-historic properties, new construction in accordance with the Secretary's Standards and applicable guidelines or with Design Guidelines (section II.H.), and construction of additions.

F. *Non-Qualifying Undertakings.* However, an otherwise Qualifying Undertaking may not utilize the Program Comment when the Park Superintendent (in consultation with Qualified Personnel and/or the CRM Team and documented in the Consultation Record), determines that any of the conditions below (also referred to as Kick-Outs) are present, as it would then be considered non-qualified or non-qualifying (Non-Qualified Undertaking(s) or Non-Qualifying Undertaking(s)):

1. potential to affect National Historic Landmarks (NHLs) (including those from the Mission 66-era), historic battlefields, burial sites, human remains, and/or funerary objects;

2. any portion is proposed to occur on or affect historic properties located on Tribal lands, or there is the potential to affect properties of religious and cultural significance to an Indian Tribe or to Native Hawaiian organizations or others in the Native Hawaiian Community, or to Alaska Natives;

3. potential to affect a historic property that is significant for reasons other than Mission 66 (*e.g.,* National Register-eligible or -listed historic properties that are not primarily-eligible or -listed due to any association with the Mission 66-era as it is described in the MPDF, such as a Colonial-period archaeological site, a Queen Anne Style farmhouse complex district, a CCC-era structure or linear district, a historic landscape site or district, etc.); and/or

4. potential to affect a Mission 66-era historic property or properties such that it/they would be ineligible for National Register listing or a candidate(s) for de-listing.

To clarify, the majority of facilities (or resources) within the APE must have been built within the Mission 66-era (1945 to 1972), as determined by the Park Superintendent (in consultation with Qualified Personnel and/or the CRM Team with such consultation documented in the Consultation Record), section II.E., or the undertaking is Non-Qualifying.

G. *Temporary Effects.* Use of this Program Comment may still occur if there may be potential temporary adverse effects to a historic property or properties during construction which may be reasonably associated with construction activities for the Qualifying Undertaking. Such temporary adverse effects are the type that will cease once construction is complete (Temporary Effects) (*e.g.,* temporary effects associated with safety signage or apparatus, construction lay-down or staging areas, or for temporary provision or cessation of utilities or channeled drainage). These effects must be minimized with assistance from Qualified Personnel and/or the CRM Team, as documented in the Qualifying Undertaking's Consultation Record.

If a Qualified Undertaking would not otherwise trigger an External Review Process (defined below), but may cause Temporary Effects, the External Review Process will not be triggered due to the Temporary Effects.

H. *Design Guidelines.* Guidelines for new construction, construction of additions, or other actions (II.E.2.) at Mission 66-era facilities that may be developed on a park-by-park basis or on a facility type basis (*e.g.,* Design and Maintenance Guidelines: Mission 66 Comfort Stations, National Capital Region, Washington, DC) and utilized in conjunction with this Program Comment to avoid and minimize adverse effects when comments by ACHP, the National Conference of State Historic Preservation Officers (NCSHPO), and the respective state State Historic Preservation Officers (SHPOs) for park-by-park guidelines have been reasonably incorporated and the final document is promulgated by the Federal Preservation Officer (FPO) to ACHP, NCSHPO, and the respective state SHPO(s) online, and in regular reporting (Design Guidelines).

III. Identification of Historic Properties

A. *Reasonable and Good Faith Effort.* After determining that it is appropriate to use the Program Comment for the proposed Qualifying Undertaking as described above, the Park Superintendent will identify historic properties within its APE. Qualified Personnel and/or a CRM Team will

support Park Superintendents to help them make informed determinations. The Park Superintendent will make a reasonable and good-faith effort to identify historic properties through one of the options described below, or a combination thereof, and must also reference their park's most recent annual report, such as a report associated with the 2008 PA or some other parkwide agreement and going forward as described in section X.

1. Rely on the records from previous identification efforts including but not limited to those completed pursuant to 36 CFR 800.4(c) for another undertaking within the APE, or identification efforts done in implementation of the agency's responsibilities under section 110 of the NHPA (54 U.S.C. 306102). In consultation with the Qualified Personnel and/or CRM Team, the Park Superintendent would determine if those previous efforts are sufficient to identify historic properties within the APE for the proposed undertaking.

2. Alternatively and in lieu of conducting individual determinations of eligibility in accordance with 36 CFR 800.4, the Park Superintendent may consider unevaluated Mission 66-era facilities (or those for which evaluations were incomplete or insufficient) as eligible for the National Register for the purposes of compliance with Section 106 via the Program Comment, with assistance from Qualified Personnel and/or a CRM Team primarily by applying the criteria set forth in the MPDF, and the National Register criteria, and any associated guidance so that the historic property's character-defining features are identified and documented as described immediately below.

Identification efforts and consultation (*e.g.,* among the Park Superintendent, Qualified Personnel and/or a CRM Team), including any disagreements and their resolution, must be documented in the Qualifying Undertaking's Consultation Record. The Consultation Record must also summarize the applicability of the MPDF and the National Register criteria, and any associated guidance, the summary being prepared by Qualified Personnel and/or the CRM Team, so that the historic property's character-defining features are identified. The following resources, ''Mission 66: Modernism and the National Park Dilemma'' (Ethan Carr, LALH, 2007) and ''MISSION 66 VISITOR CENTERS: The History of a Building Type'' (Sarah Allaback, Ph.D., NPS, 2000), and other NPS publications may provide additional context, if necessary.

B. *Re-evaluation of Previously Evaluated Non-Mission 66-Era Historic Properties.* Analysis and formal correspondence may be necessary to determine whether properties that are not from the Mission 66-era are historic. This may require re-evaluation of previously evaluated properties (*e.g.,* in accordance with 36 CFR 800.4), and would preclude use of the Program Comment until such evaluation is complete.

C. *Properties Built Between 1990 and the Present Day.* The Park Superintendent would not carry out any identification or evaluation efforts on properties within the APE that were built between 1990 and the present day unless previous review or consultation identified that property as National Register-eligible under Criteria Consideration G. Excepting previously determined eligible properties, the Park Superintendent would have no further review responsibility to consider effects for Qualifying Undertakings on post-1990 properties under the Program Comment.

D. *Mission 66-Era Utilities.* The Mission 66 program provided funds to introduce potable water, sewer systems, and electricity to new comfort stations and other buildings and structures within a park, as well as certain roads or trails. While construction of this infrastructure addressed Mission 66 goals to modernize parks and visitor services, utility infrastructure, such as water, sewer, telephone (communication), and electric lines (above and below ground), the utilities seldom in and of themselves have architectural or historical significance. Utility resources that are buried, either wholly or in part, should be described as a part of the overall setting, but need not be further evaluated or assessed to consider potential effects to them. They should be considered and described within the context of a related historic district, as applicable. As such, there are two (2) types of Mission 66-era facilities for which no further review is required under the Program Comment:

i. Effects to those Mission 66-era facilities already formally determined as ineligible, when those determinations indicated that the MPDF was taken into consideration and did not call for further evaluation of the subject facilities; and

ii. Effects to below-grade utilities and above or below-grade utility covers, lines, poles, and pipes (*e.g.,* water, sewer, telephone and communication, and electric) unless it is/they are an example of distinctive design or engineering.

However, there may be components of Mission 66-era utility systems that are visible and if, based on a determination of the Park Superintendent with input from Qualified Personnel and/or the CRM Team, they constitute examples of distinctive design or engineering compatible with other Mission 66 facilities and retain integrity, they should be evaluated for eligibility and included with the Park Superintendent's assessment of effects under the Program Comment (sections IV. and V.).

E. *Identification Findings and Next Steps.* After completing the effort described above, the Park Superintendent will make one of the following determinations (with input from Qualified Personnel and/or the CRM Team and made part of the Consultation Record):

1. A finding of no historic properties within the APE including no Mission 66-era historic properties, or

2. A finding that properties identified within the APE consist of:

i. only Mission 66-era historic properties, or

ii. Mission 66-era facilities (a combination of Mission 66-era historic properties and Mission 66-era facilities that are not historic), or

iii. a combination of Mission 66-era historic properties and other non-historic facilities (or resources) from outside of the Mission 66-era (but with the latter not representing a majority of the properties, per the Kick-Outs); or

iv. Mission 66-era facilities that are not historic and other facilities (or resources) from outside of the Mission 66-era that are historic (section II.E.).

Once one of these determinations has been made by the Park Superintendent, they will proceed to the next steps in the process, sections IV. and V., below.

The Park Superintendent must also record the identification finding(s), for the purposes of the annual report (section X.).

F. *Identification Findings for the Program Comment.* The Park Superintendent would only make National Register determinations of eligibility as described above for Mission 66-era facilities when considering a Qualified Undertaking(s) under the Program Comment. If for any reason Section 106 compliance must be accomplished via another means (*e.g.,* standard Section 106 review, a park-specific programmatic agreement, or an undertaking-specific memorandum of agreement is needed because an undertaking is no longer a Qualified Undertaking), additional analysis and reviews may be necessary.

IV. Review Process Overview and Assessing Effects

A. *Two Review Processes.* Under this Program Comment, there are two review processes. Some Qualifying Undertakings may require an External Review Process (ERP) and others may require only an Internal Review Process (IRP). The ERP package and IRP package will include relevant documentation so as to meet the requirements set forth in 36 CFR 800.11, as described below, and will be part of the Consultation Record.

Qualified Personnel and/or a CRM Team will support Park Superintendents to help them make informed determinations, to avoid or minimize adverse effects, and to take cumulative effects into consideration. It is standard for Park Superintendents to make reasonable efforts to avoid and minimize adverse effects to historic properties. The Consultation Record must indicate that such consideration occurred and support the Park Superintendent's findings. Any disagreements about the ERP or IRP between Park Superintendents, Qualified Personnel, and/or a CRM Team, and their resolution, must also be part of the Consultation Record.

B. *Special External Review Process for Certain Findings of No Historic Properties.* When no historic properties are identified within the APE, including findings that there are no Mission 66-era historic properties (section III.E.1.) or some Mission 66-era facilities that are not historic because they lack integrity (section III.E.2.ii. and iv.), a special ERP is required. This review is independent of the ERP but follows the same process (section V.A.) and has the same ERP Package Content requirements (section IV.A.). It requires a special review with Indian Tribes or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives and the main purpose is to confirm that there are no properties of religious and cultural significance to an Indian Tribe or to Native Hawaiian organizations or others in the Native Hawaiian Community or to Alaska Natives in the APE.

If an ERP is occurring, the Special ERP may be accomplished in conjunction with the ERP. If an ERP is not occurring, the Special ERP must be completed separately.

C. *Internal Review Process for Certain No Adverse Effects Findings.* For all findings in section III.E.2., when there is a determination that there are no adverse effects to historic properties in the APE because the Secretary's Standards and applicable guidelines will be applied (confirmed with input from Qualified Personnel and/or the CRM Team and as shown in in the Consultation Record), and there are no other conditions (Conditions such as but not limited to archaeological monitoring, movement monitoring, and similar, but not those for Temporary Effects), the Park Superintendent is required to do an IRP.

D. *External Review Process for Certain No Adverse Effects Findings.* For all findings in section III.E.2., when there is also a determination that there are no adverse effects to historic properties in the APE because the Secretary's Standards and applicable guidelines will be applied, and other conditions will also be applied (aside from those for Temporary Effects), the Park Superintendent is required to do an ERP. (Conditions such as but not limited to archaeological monitoring, movement monitoring, and similar.)

E. *External Review Process for Adverse Effects Findings.* For findings in section III.E.2.i–iii., if there is a determination that there may be adverse effects to Mission 66-era historic properties, the Park Superintendent is required to do an ERP.

(For findings in section III.E.2.iv., if there is a determination that there may be adverse effects to non-Mission 66 era historic properties (*i.e.,* II.F.3.), excepting Temporary Effects, the Park Superintendent must follow the standard Section 106 review process or another applicable program alternative, because such adverse effects would render the undertaking Non-Qualifying.)

V. The External and Internal Review Processes

A. *The External Review Process.* The ERP will occur in the situations described above, sections IV. B. and D–E. The Park Superintendent will develop the ERP package as set forth in section VI. and post it on a public-facing PEPC (or other publicly accessible) website for Notified Parties (hereinafter defined) and consulting parties.

The Park Superintendent will notify the relevant SHPO and/or Tribal Historic Preservation Officer (THPO) and potentially interested Indian Tribes, or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives (Notified Parties) (*i.e.,* via email, hard-copy letter via mail or mail service, or an alternative method arranged in advance in writing) that the ERP package has been posted.

Upon the Notified Parties' receipt of the notification, a fifteen (15) business day review period commences. The public-facing PEPC (or other publicly accessible) website and the first page of the ERP will clearly indicate the last day of the review period.

Consulting parties and the Notified Parties may provide any comments in writing via the public-facing PEPC (or other publicly accessible) website or email to the Park Superintendent within the review period, and the Park Superintendent will take them into account.

If no written objection or no response from the Notified Parties is received by the Park Superintendent within the review period, the Section 106 review as documented in the ERP is complete and no further review or consultation on the Qualifying Undertaking is required.

A Notified Party may object to the ERP package by providing a written notice to the Park Superintendent within the review period with a substantive, fact-based, and project-specific objection, and including a reasonable level of detail. Upon receipt, the Park Superintendent will either follow the standard Section 106 review process in 36 CFR part 800 or another applicable program alternative, or attempt to resolve the objection with the objecting Notified Party.

If the Park Superintendent attempts to resolve the objection, they may reach out to the objecting Notified Party and/or other Notified Parties to consult. If additional materials are necessary, they must be posted on the public-facing PEPC (or other publicly accessible) website for an additional five (5) business day review and consultation period. The Notified Parties will be notified of the availability of the additional information in the same way they received the initial ERP notification, and the first page of the public-facing PEPC (or other publicly accessible) website and the first page of the additional ERP information will clearly indicate the last day of the additional review and consultation period.

If the Park Superintendent is able to resolve the objection by the end of the additional review and consultation period, a summary of the resolution will be posted on the public-facing PEPC (or other publicly accessible) website promptly, and the Notified Parties will be notified of the resolution in the same way they received the initial ERP notification.

If the Park Superintendent is unable to resolve the Notified Party's objection by the end of the additional review and consultation period, the Program Comment cannot be used for the proposed undertaking and the Park Superintendent will follow the standard Section 106 review process in 36 CFR

part 800 or another applicable program alternative.

All ERP package materials, comments, and objections will become part of the Consultation Record.

B. *The Internal Review Process.* The IRP will occur in the situations described in section IV.C. Park Superintendents, Qualified Personnel, and/or a CRM Team will develop the IRP package in accordance with the requirements in section VI., reasonable time periods will be provided for internal review and discussion, and the Consultation Record must reflect all findings and determinations. Any disagreements between Park Superintendents, Qualified Personnel, and/or a CRM Team, and their resolution must also be documented in the Consultation Record.

C. *Implementation as Documented and Reporting.* Implementation of a Qualifying Undertaking in accordance with the finding(s) as documented in the ERP or IRP, including with any documented resolution summary described in section V.A., fulfills the agency's responsibilities under Section 106 for the Qualifying Undertaking.

The status of any ERP or IRP will be included in annual reporting, described in section X. If the Qualified Undertaking is not being reasonably executed as documented in the ERP or IRP package (*e.g.,* due to substantive differences between the preliminary design documents from the ERP or IRP package and later final design or construction documents that introduce Kick-Outs or new adverse effects, intensification of adverse effects, etc., or for another reason), then NPS will consult with Qualified Personnel and/or the CRM Team to determine whether the matter can be resolved, the initial effect findings maintained, and documented appropriately (*i.e.,* in the Consultation Record). If it cannot, Section 106 compliance must be reopened and accomplished via the Program Comment (*i.e.,* a new or updated IRP or a new ERP) or another means (*i.e.,* standard Section 106 review, a park-specific programmatic agreement, or an undertaking-specific memorandum of agreement). If this occurs, additional analysis and reviews may be necessary.

VI. ERP and IRP Package Contents

A. *ERP Package Contents.* The ERP package for the proposed Qualifying Undertaking must include:

1. a description of the Qualifying Undertaking;

2. analysis confirming no Kick-Outs are present;

3. a relevant excerpt of current preliminary design documents that clearly depict and delineate the Qualifying Undertaking (*i.e.,* plans, elevations, and specifications);

4. a description and map of the APE;

5. ground-disturbance information and surveys as appropriate and consistent with confidentiality provisions in 36 CFR 800.11(c);

6. a finding by the Park Superintendent as noted in section III.E.;

7. a finding by the Park Superintendent as noted in section IV. B., D. (*e.g.,* conditions), or E.;

8. the Park Superintendent's name and the name(s) of Qualified Personnel and/or the CRM Team; and,

9. the Park Superintendent's signature on the ERP package to confirm: the proposed project is a Qualifying Undertaking; that reasonable efforts were made to avoid and minimize adverse effects; the finding and determinations; that the park will execute the Qualifying Undertaking as documented; and,

10. the following statement, to account for various situations such as where there may be substantive differences between the preliminary design documents from the ERP package and later final design or construction documents that introduce Kick-Outs or new adverse effects, or intensify adverse effects, ''If the Qualifying Undertaking is not substantively executed as documented in the ERP, including any resolution summary if applicable, NPS will consult with Qualified Personnel and/or the CRM Team to determine whether the matter can be resolved and documented appropriately (*i.e.,* in the Consultation Record). If the matter cannot be resolved, and the initial effect findings would change, the Park Superintendent will reopen Section 106 and accomplish compliance for the proposed project via the Program Comment (*i.e.,* a new or updated ERP or IRP) or another means (*i.e.,* standard Section 106 review, a park-specific programmatic agreement, or an undertaking-specific memorandum of agreement).''

With regard to section VI.A.7., when adverse effects to Mission 66-era historic properties may result from the proposed undertaking, the Park Superintendent will reference the commensurate and relevant Mitigation Menu measure in section VIII., which will not be subject to further consultation, nor available for objection in the ERP.

The status of the ERP for the Qualifying Undertaking will be posted on a public-facing PEPC (or other publicly accessible) website for the duration of construction.

B. *IRP Package Contents.* The IRP package for the proposed Qualifying Undertaking must include the same elements listed for the ERP package to the extent applicable to the proposed undertaking, but will be posted on an internal-facing PEPC site, and all references to ERP above will be substituted with the term IRP.

VII. The Consultation Record

A. A complete Consultation Record that follows the documentation standards in 36 CFR 800.11, will be available and accessible to NPS staff at the park-, regional-, and national-levels for NPS reporting purposes, and includes:

—a summary of the Qualifying Undertaking;
—the APE;
—information on Kick-Outs, and their applicability;
—a summary of the applicability of the MPDF and National Register criteria and any associated guidance;
—a summary of any Temporary Effects and how they were minimized;
—the ERP package or IRP package including the finding of effects, comments and objections, and resolution summaries, as applicable;
—any other relevant internal or external comments or objections and their resolution or next steps planned or taken.
—in cases when the undertaking is not substantively executed as documented in the ERP or the IRP, and consultation must occur with Qualified Personnel and/or the CRM Team to determine whether the matter can be resolved and documented in the Consultation Record, such documentation or information on how the matter was addressed;
—the date the PEPC file was closed.

VIII. Mitigation

A. *Collective Mitigation.* NPS will provide mitigation for collective adverse effects to Mission 66-era historic properties at the national level, rather than park-/undertaking-specific approaches. The list below is a Mitigation Menu which consists of measures which may be employed alone or combined, and may be accomplished at the park-, regional-, or national-level(s), or some combination thereof. The Park Superintendent will identify the selected measure to resolve adverse effects to Mission 66-era historic properties that may occur when Qualified Undertakings are completed in accordance with the Program Comment:

—resource stewardship training;
—national-level inventory management;
—national-, park-, district-, and individual property-level National Register documentation;
—development and publication of an Administrative History of NPS Housing which will be completed as part of a partnership with the NPS History Program and a public university, and which will be publicly available by the spring of 2027;
—publication of an MPDF reference guide for internal and external partners, to facilitate standardized use of the MPDF, within six months of publication of the Program Comment in the **Federal Register**, and
—formal study of materials analysis and/or materials conservation or development of a national-level Mission 66-focused interpretive plan (as funds allow).

(The above list will be referred to as the Mitigation Menu and the individual measures will be referred to as Mitigation Measure(s).)

In addition, utilizing materials generated from regular reporting and Mitigation Measures, NPS national-level staff may endeavor to conduct data (statistics) collection and perform associated analysis, which may be described in the agency annual report (defined below).

For Qualifying Undertakings that pose adverse effects to historic properties, the associated ERP package will reference associated Mitigation Measure(s). The Park Superintendent will specify whether the Mitigation Measure will be completed at the park-, regional-, or national-level and who will be responsible for reporting on its status.

Mitigation Measures will be tracked by the FPO and deputy associate directors at the national level. National-, regional- and park-level progress must be detailed in the annual meeting and report, the regional annual report, and the agency annual report and meeting (defined below), segments of which must be posted on a public-facing PEPC (or other publicly accessible) website as described in the section X.

Within one (1) year of publication of the Program Comment in the **Federal Register**, NPS will also develop a brief web-based on-demand training for use by internal and external partners.

B. *Changes to Mitigation Measures.* Any change or modification to the mitigation menu would require an amendment to this Program Comment.

IX. Park Suspension

A. *Park Suspension Process.* Park suspension from use of the Program Comment, for a reasonable period of time, may occur if there are repeated or egregious instances where the Qualified Undertaking was not reasonably executed as documented in the IRP package or ERP package, or for similar concerns as may be raised by Notified Parties, the ACHP, NCSHPO, individual SHPOs, or Tribes or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives, as noted below and as determined by the FPO in consultation with regional leadership, and with input from the respective Park Superintendent and the Qualified Personnel and/or the CRM Team(s). It may also occur if a park has a pattern of not complying with the terms of the Program Comment when it was the selected Section 106 compliance method, with such pattern documented in the Consultation Records or annual reporting, also as determined by the FPO as described in this section.

The respective SHPO/THPO, Indian Tribes and Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives may also offer comments in this regard to the Park Superintendent and/or FPO at any time in writing.

B. *Notification of Park Suspension.* The ACHP, NCSHPO, and the respective SHPO/THPO, Indian Tribes and Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives, will be promptly notified, in writing, if a park has been suspended from using the Program Comment and informed of the terms of such suspension. Those parks suspended from use of the Program Comment will be listed in the annual meeting and report (*e.g.,* to close out the year for that park), the regional annual report, and the agency annual report and meeting. (Segments of certain reports must be posted on a public-facing PEPC or other publicly accessible website, as described in the next section.)

X. Reporting and Meetings

A. *Park Annual Report and Annual Meeting.* For parks using or planning to use the Program Comment, the Park Superintendent will develop a park annual report and hold an annual meeting with consulting parties each year, initially occurring at least within eight (8) months of the issuance of the Program Comment or in conjunction with biannual meetings already occurring to meet requirements of other program alternatives (*e.g.,* the 2008 PA), whichever is earlier, either virtually, in-person, or via telephone.

Primary invitees include the SHPO, THPO, Indian Tribes and Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives, and a reasonable effort will be made, by the Park Superintendent, to accommodate their schedules. Other invitees may include other consulting parties, lessees, historic societies, gateway communities, Qualified Personnel and/or CRM Teams. Other stakeholders may also be invited.

The Park Superintendent will provide the park annual report to invitees concurrently with the annual meeting invitation via email, hard-copy letter through mail or other shipping service, or an alternative method arranged in advance and agreed to in writing by the sending and receiving parties. The annual reports will include:

—updates to inventories of Mission 66-era historic properties and non-historic properties, including new determinations of National Register eligibility;
—a summary of undertakings that were completed which utilized the Program Comment (if applicable);
—information about undertakings that are ongoing or are planned and the status of any relevant objections on an ERP package;
—park-level mitigation status;
—problems with implementation of the Program Comment;
—training administered;
—relevant NPS contact information; and
—any park suspension status.

The park will hold the annual meeting no less than thirty (30) days after the park has transmitted the invitation and park annual report.

Meeting minutes will be distributed by the park to all attendees, the Regional Director and Regional Section 106 Coordinator, and the Park 106 Coordinator, within thirty (30) days after the meeting. The park will also provide a summary on public-facing PEPC (or other publicly-accessible website) including meeting highlights, within that same period.

If a THPO, Indian Tribe and/or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives has informed a Park Superintendent of an area of interest or concern due to the location of a property of religious and cultural significance to them, and a Mission 66-era facility has any geographic overlap with that area of interest or concern, the Park Superintendent will individually write to the respective THPO, Indian Tribe and/or Native Hawaiian organizations or others in the Native Hawaiian Community or Alaska Natives, (*i.e.,* via email, hard-copy letter through mail or other shipping service, or an alternative method arranged in

advance and agreed to in writing by the sending and receiving parties) in parallel with the park annual reporting, to inform them of the inventory and any updates. Park Superintendents will comply with all confidentiality requirements as applicable.

B. *Regional, Agency, and Wrap-Up Reports.* For regions that include parks using or planning to use the Program Comment, a regional annual report must be provided to the FPO within one (1) month before the end of the fiscal year and include a summary and compilation of:

—PEPC data;
—inventories of Mission 66-era historic properties and non-historic properties including new determinations of National Register eligibility;
—a summary of undertakings that were completed which utilized the Program Comment (if applicable);
—undertakings that are ongoing or are planned;
—park- and regional-level mitigation status;
—problems with implementation of the Program Comment including any park suspension(s) or overarching objections to multiple ERP packages;
—training administered; and
—NPS contact information.

Any disagreements between Park Superintendents, Qualified Personnel, and/or a CRM Team, and their resolution, must also be listed in summary fashion.

The FPO's summary and compilation of all the regional annual reports, as well as a summary of national-level mitigation status will comprise the agency annual report. It will include an executive summary that will be posted by the FPO on a public-facing PEPC (or other publicly accessible) website by the end of the fiscal year. The ACHP and NCSHPO will be notified of the posting in writing.

At the written request of the ACHP and/or NCSHPO, an annual meeting may occur to review implementation of the terms of the Program Comment and determine whether an amendment is needed. In the event that a meeting on the agency annual report is held by NPS, ACHP and NCSHPO will both be invited and it will occur no less than thirty (30) days after the agency annual report was posted on a PEPC (or other publicly accessible) website.

Three (3) years before the end of the duration of the Program Comment, the FPO will send a report to the ACHP and NCSHPO detailing progress made with the Program Comment, Mitigation Measures completed, National Register nomination status, challenges encountered, and the NPS's plans for the final two and a half (2.5) years of the Program Comment's duration. This will be known as the Program Comment wrap-up report.

In the final six (6) months of the ninth year of Program Comment's duration, regardless of the status of an amendment (if pursued), the FPO will submit an agency report to ACHP and NCSHPO detailing progress made and providing links to completed mitigation. NPS will also promptly post a summary of the agency report for public review on a public-facing PEPC (or other publicly accessible) website.

XI. Administrative Clauses and Discoveries

A. *Duration and Amendment.* The Program Comment will remain in effect until November 4, 2034 unless, prior to that time, the ACHP withdraws the Program Comment in accordance with 36 CFR 800.14(e)(6). Following such expiration or withdrawal, NPS will be required to comply with Section 106 through the process in 36 CFR part 800, or an applicable program alternative under 36 CFR 800.14.

During the first six (6) months of the ninth year of the issuance of the Program Comment, and at the time the wrap-up report is supposed to be issued, NPS and the ACHP will meet to determine whether the ACHP should consider an extension to its term via an amendment.

The Program Comment may be amended by the ACHP's Executive Director when the NPS, NCSHPO, or the ACHP's Executive Director proposes an amendment in writing to the other parties. In deciding whether to amend the Program Comment, the ACHP's Executive Director will consult with NPS and NCSHPO, and other parties as appropriate. The ACHP will publish notice in the **Federal Register** within thirty (30) days after the Executive Director's decision to amend the Program Comment, and also provide written notification to NPS, NCSHPO, and other parties as appropriate.

B. *Discoveries.* In the event that previously undocumented historic properties are encountered during an undertaking for which review has been completed under this Program Comment, the Park Superintendent will stop work and notify the SHPO/THPO, Indian Tribe(s), and/or Native Hawaiian organizations and the Native Hawaiian Community, as appropriate, within 48 hours, or as soon as reasonably possible. The Park Superintendent in consultation with Qualified Personnel and/or the CRM Team, will notify the parties of the park's proposed eligibility assessment for the property(ies) and any proposed measures to avoid, minimize, or mitigate adverse effects to historic property(ies), if present. The SHPO/THPO, Tribes, NHOs and Native Hawaiian Community will have 48 hours from receipt of the notice to provide the Superintendent with any comments on the proposal. The Superintendent will take into account any timely comments, in consultation with Qualified Personnel and/or the CRM Team, in implementing the proposal and proceed with the undertaking.

In the event the discovery includes human remains, funerary objects, sacred objects, or objects of cultural patrimony, the Park Superintendent will comply with the Native American Graves Protection and Repatriation Act (NAGPRA, 25 U.S.C. 3001 *et seq.*). Pursuant to an applicable NAGPRA Plan of Action or as otherwise required, the Park Superintendent will ensure that any human remains are left in situ, are not exposed, and remain protected while the park complies with relevant provisions of applicable Federal, State, and/or local laws.

When applicable, the Park Superintendent will consider the principles within the ACHP's Policy Statement on Burial Sites, Human Remains, and Funerary Objects, dated March 1, 2023. In implementing the Program Comment the NPS will fulfill its obligation to consult with Tribes and Native Hawaiian organizations and the Native Hawaiian Community consistent with all relevant Executive Orders, Secretary's Orders, the Department of the Interior Departmental Manual, and NPS Director's Orders and Related Guidance. NPS recognizes and considers Indigenous Knowledge in the Section 106 review process in accordance with the November 30, 2022 Guidance for Federal Departments and Agencies on Indigenous Knowledge issued by the White House Office of Science and Technology Policy and Council on Environmental Quality and the Departmental Manual (301 DM 7, Departmental Responsibilities for Consideration and Inclusion of Indigenous Knowledge in Departmental Actions and Scientific Research).

C. *Emergencies.* Emergency situations will be addressed via 36 CFR 800.12.

D. *Section 106 Review for a Single Undertaking.* Each proposed undertaking to be subject to the Program Comment should be reviewed in its entirety. Different program alternatives may not be used to fulfill Section 106 review responsibility for a single undertaking. To clarify, a Park Superintendent may not use more than

one program alternative to fulfill that park's Section 106 compliance for a single undertaking.

E. *Document Website.* This document will initially be available at *www.achp.gov* and Park 106 Compliance—Section 106 Compliance Program (U.S. National Park Service) (*nps.gov*) [10] and will continue to be made available online by NPS as referenced in agency annual reports. (END OF DOCUMENT)

Authority: 36 CFR 800.14(e).

Dated: December 2, 2024.

Javier Marqués,

General Counsel.

[FR Doc. 2024–28519 Filed 12–6–24; 8:45 am]

BILLING CODE 4310–K6–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0733]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0128

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0128, Prospect Questionnaire, Chat Now Questionnaire, and the Officer Program Application; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before January 8, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2024–0733]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email *hqs-dg-m-cg-61-pii@uscg.mil* for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0733, and must be received by January 8, 2025.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0128

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 71915, September 4, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Prospect Questionnaire, Chat Now Questionnaire, and the Officer Program Application.

OMB Control Number: 1625–0128.

Summary: This collection contains the recruiting website gocoastguard.com Prospect Questionnaire (CGRC–1130), Chat Now Questionnaire (CGRC–1132), and the Officer Program Application (CGRC–1131) that are used to screen active duty and reserve enlisted and officer applicants.

Need: The information is needed to initiate the recruiting and commissioning of active duty and reserve, enlisted and officer members.

[10] *https://www.nps.gov/orgs/1966/park-106-compliance.htm.*

14 U.S.C. 468 authorizes the United States Coast Guard to recruit personnel for military service. The information requested on the gocoastguard.com website is collected in accordance with 10 U.S.C. 503 and may be used to identify and process individuals interested in applying for enlistment or commission into the United States Coast Guard or Coast Guard Reserve.

Forms: Online Application plus hard copy of the Prospect Questionnaire (CGRC–1130), and/or the Officer Program Application (CGRC–1131) if a prospect does not use gocoastguard.com but contacts a recruiter directly.

Respondents: Approximately 50,000 applicants apply annually to initiate the screening process.

Frequency: Applicants may apply more than once, by initially completing the Chat Now Questionnaire (CGRC–1132) to answer questions on eligibility and may apply for both enlisted and officer programs through the Prospect Questionnaire (CGRC–1130) and/or Officer Program Application (CGRC–1131).

Hour Burden Estimate: The estimated burden remains 11,625 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: November 19, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–28809 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0734]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0089

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0089, National Recreational Boating Safety Survey; reinstatement with change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before January 8, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2024–0734]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email *hqs-dg-m-cg-61-pii@uscg.mil* for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0734, and must be received by January 8, 2025.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0089.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 71917, September 4, 2024) required by 44 U.S.C. 3506(c)(2). That notice received six supportive comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: National Recreational Boating Safety Survey.

OMB Control Number: 1625–0089.

Summary: The National Recreational Boating Safety Survey collects data on recreational boating participation and exposure. Specifically, the survey focuses on the types of boats used, the demographics of boaters, the types of safety equipment on recreational boats, and the amount of time boaters spend on the water. Boating hours calculated from this survey play an integral part in calculating risk ratios associated with recreational boating. In light of the USCG's safety-oriented mission, we are proposing a name change of this survey to the National Recreational Boating Safety Survey from the National Recreational Boating Survey.

Need: The Federal Boat Safety Act of 1971 determines the framework of the Coast Guard recreational boating safety program. This program as set forth in 46 U.S.C., Chapter 131, requires the Coast Guard to ''encourage greater State participation and uniformity in boating safety efforts, and particularly to permit the States to assume a greater share of boating safety education, assistance, and enforcement activities.'' See 46 U.S.C. 13102. The Coast Guard Office of Auxiliary & Boating Safety, Boating Safety Division achieves these goals by providing timely and relevant information on boating activities that occur in each respective jurisdiction. The boating information provided by the Coast Guard enables each State agency to tailor and implement safety initiatives addressing specific needs of boaters in local jurisdictions. The primary objective of this collection is to provide the Coast Guard with the required information in a format suitable to effectively manage the program.

Forms: None.

Respondents: Recreational boaters and recreational boat owners living in the 50 states and the District of Columbia.

Frequency: The survey takes place every five to eight years and the last survey was conducted in 2018.

Hour Burden Estimate: The survey will take approximately 125,863 respondents a total estimate burden of 15,151 hours.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: November 19, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–28810 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0736]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0081

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0081, Alternate Compliance Program; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before January 8, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2024–0736]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave SE, Stop 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email *hqs-dg-m-cg-61-pii@uscg.mil* for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0736, and must be received by January 8, 2025.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate

comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0081

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 71380, September 3, 2024) required by 44 U.S.C. 3506(c)(2). That notice received one supportive comment. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Alternate Compliance Program.

OMB Control Number: 1625–0081.

Summary: This information is used by the Coast Guard to assess vessels participating in the voluntary Alternate Compliance Program (ACP) before issuance of a Certificate of Inspection.

Need: Sections 3306 and 3316 of 46 U.S.C. authorize the Coast Guard to establish vessel inspection regulations and inspection alternatives. Part 8 of 46 CFR contains the Coast Guard regulations for recognizing classification societies and enrollment of U.S.-flag vessels in ACP.

Forms: None.

Respondents: Owners and operators of U.S.-flag inspected vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 198 hours to 178 hours a year, due to a decrease in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: November 19, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–28812 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0739]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0113

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0113, Crewmember Identification Documents; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before January 8, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2024–0739]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email *hqs-dg-m-cg-61-pii@uscg.mil* for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0739, and must be received by January 8, 2025.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0113.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 71914, September 4, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Crewmember Identification Documents.

OMB Control Number: 1625–0113.

Summary: This information collection covers the requirement that crewmembers on vessels calling at U.S. ports must carry and present on demand an identification that allows the identity of crewmembers to be authoritatively validated.

Need: 46 U.S.C.70111 mandated that the Coast Guard establish regulation about crewmember identification. The regulations are in 33 CFR part 160 Subpart D.

Forms: None.

Respondents: Crewmembers, and operators of certain vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 32,955 hours to 35,724 hours a year, due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: November 19, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–28813 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0738]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0084

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0084, Audit Reports under the International Safety Management Code; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before January 8, 2025.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2024–0738]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email *hqs-dg-m-cg-61-pii@uscg.mil* for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.,* chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0738, and must be received by January 8, 2025.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. We review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0084

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 71379, September 3, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Audit Reports under the International Safety Management Code.

OMB Control Number: 1625–0084.

Summary: This information helps to determine whether U.S. vessels, subject to SOLAS 74, engaged in international trade, are in compliance with that treaty. Organizations recognized by the Coast Guard conduct ongoing audits of vessels' and companies' safety management systems.

Need: 46 U.S.C. 3203 authorizes the Coast Guard to prescribe regulations regarding safety management systems. 33 CFR part 96 contains the rules for those systems and hence the safe operation of vessels.

Forms: None.

Respondents: Owners and operators of vessels, and organizations authorized to issue ISM Code certificates for the United States.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 15,512 hours to 16,814 hours a year, due to an increase in the estimated annual number of responses.

Authority:

The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.,* chapter 35, as amended.

Dated: November 19, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–28814 Filed 12–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0107]

Agency Information Collection Activities; Revision of a Currently Approved Collection: H–2 Petitioner's Employment Related or Fee Related Notification

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments. The changes to this information collection are related to the ongoing rulemaking, Modernizing H–2 Program Requirements, Oversight, and Worker Protections, proposed rule, and are contingent on its successful conclusion.

DATES: Comments are encouraged and will be accepted until January 8, 2025.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0015. All submissions received must include the OMB Control Number 1615–0107 in the body of the letter, the agency name and Docket ID USCIS–2009–0015.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on October 3, 2024, at 89 FR 80589, allowing for a 60-day public comment period. USCIS received three comments in connection with the 60-day notice.

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2009–0015 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.* Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* H–2 Petitioner's Employment-Related or Fee-Related Notification.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129N; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. The notification requirement is necessary to ensure that alien workers maintain their nonimmigrant status and will help prevent H–2 workers from engaging in unauthorized employment.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection H–2 Petitioner's Employment Related Notification (email) is 8,893 and the estimated burden per response is 0.4167 hours and the H–2 Petitioner's Employment Related Notification (mail) is 371 and the estimated burden per response is 0.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 3,891 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $1,852.80.

DHS is proposing changes to this information collection to align with the regulatory changes proposed in *Modernizing H–2 Program Requirements, Oversight, and Worker Protections,* proposed rule, 88 FR 65040 (Sep. 20, 2023) and are contingent on the successful completion of that rulemaking.

Dated: December 3, 2024.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2024–28784 Filed 12–5–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7082–N–12]

60-Day Notice of Proposed Information Collection: Self-Help Homeownership Opportunity Program (SHOP); OMB Control No.: 2506–0157

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comment Due Date:* February 7, 2025.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Holly A. Kelly, Office of Rural Housing and Economic Development, Department of Housing and Urban Development, 451 Seventh Street SW, Room 7132, Washington, DC 20410–4500; email *Holly.A.Kelly@hud.gov;* telephone 202–402–6324. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Kelly.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Self-Help Homeownership Opportunity Program (SHOP).

OMB Approval Number: 2506–0157.

Type of Request: Extension of currently approved collection.

Form Number: SF–424; SF–424B; HUD 424 CB; HUD 424 CBW; SF–424D; HUD 425; HUD 425.1; HUD 2880; HUD 50153; SF–LLL/OMB 0348–00; SF–LLL/OMB 4040–0013; and Grant Reporting (Disaster Recover Grant Reporting/DRGR System).

Description of the need for the information and proposed use: This is a proposed information collection for submission requirements under the SHOP Notice of Funding Availability (NOFO) and post-award reporting requirements. HUD requires information to ensure the eligibility of SHOP applicants and the compliance of SHOP proposals, to rate and rank SHOP applications, and to select applicants for grant awards. Information is collected on an annual basis from each applicant that responds to the SHOP NOFO. The SHOP NOFO requires applicants to submit specific forms and narrative responses. HUD also requires semi-annual grant reporting post-award in order to ensure the SHOP grantees are complying with the terms of the Executed Grant Agreement.

Respondents: National and regional non-profit self-help housing organizations (including consortia) that apply for funds in response to the SHOP NOFO.

Frequency of Submission: Annually in response to the issuance of a SHOP NOFO. Semi-annually in response to post-award grant reporting.

Estimation of the Total Number of Hours Needed To Prepare the Information Collection Including Number of Respondents, Hours per Response, Frequency of Response, and Total Hours of Response for All Respondents

The estimates of the average hours needed to prepare the information collection are based on information provided by previous applicants and grantees. Actual hours will vary depending on the proposed scope of the applicant's/grantee's program, the applicant's/grantee's geographic service area and the number of affiliate organizations. The information burden is generally greater for national organizations with numerous affiliates.

Information collection	Number of respondents	Frequency of response	Responses per annual	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Application for Federal Assistance SF–424 ..	10.00	1.00	10.00	1.00	10.00	$82.38	$823.80
Assurances for Non-Construction Program SF–424B	10.00	1.00	10.00	0.50	5.00	82.38	411.90
Assurances for Construction Programs SF–424D	10.00	1.00	10.00	0.50	5.00	82.38	411.90
Certification Regarding Lobbying SF–LLL/ OMB 0348–0046	10.00	1.00	10.00	0.50	5.00	82.38	411.90
Disclosure of Lobbying Activities SF–LLL/ OMB 4040–0013	10.00	1.00	10.00	0.50	5.00	82.38	411.90
Grant Application Detailed Budget HUD–424CB	10.00	1.00	10.00	1.00	10.00	82.38	823.80
Grant Application Detailed Budget Worksheet HUD–424CBW	10.00	1.00	10.00	1.00	10.00	82.38	823.80
Rural Equity Preference Points HUD–425	10.00	1.00	0	0	0	82.38	0
Rural Partners Network Certification Instructions HUD–425.1	10.00	1.00	0	0	0	82.38	0
Applicant Recipient Disclosure Update Report HUD–2880	10.00	1.00	10.00	.50	5.00	82.38	411.90
Promise Zone Certification HUD 50153	10.00	1.00	10.00	.50	5.00	82.38	411.90
Applicant Eligibility	10.00	1.00	10.00	2.00	20.00	82.38	1,647.60
SHOP Program Design and Scope of Work	10.00	1.00	10.00	30.00	300.00	82.38	24,714.00
Rating Factor1	10.00	1.00	10.00	25.00	250.00	82.38	20,595.00
Rating Factor 2	10.00	1.00	10.00	30.00	300.00	82.38	24,714.00
Rating Factor 3	10.00	1.00	10.00	55.00	550.00	82.38	45,309.00
Rating Factor 4	10.00	1.00	10.00	30.00	300.00	82.38	24,714.00
Rating Factor 5	10.00	1.00	10.00	25.00	250.00	82.38	20,595.00
Grant Reporting (DRGR)	4.00	2.00	4.00	100.00	400.00	82.38	32,952.00
Total Annual Hour Burden				303	2,430.00		200,183.40

Note: Hourly cost per response was updated from the FY2021 rate of $70.45 to the FY2024 hourly cost per response rate of $82.38.

B. Solicitation of Public Comments

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Marion M. McFadden,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2024–28853 Filed 12–6–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7082–N–13]

60-Day Notice of Proposed Information Collection: Continuum of Care (CoC) Program Registration; OMB Control No: 2506–0182

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 7, 2025.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone (202) 402–3400. (this is not a toll-free number) or email at *Colette.Pollard@hud.gov,* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Robert Waters, Senior Program Specialist, Office of Special Needs Assistance Programs, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Robert.P.Waters@hud.gov,* telephone (202) 402–4494. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Mr. Waters or Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Continuum of Care (CoC) Program Registration.

OMB Approval Number: 2506–0182.

Type of Request: Extension of currently approved collection.

Description of the need for the information and proposed use: This submission is to request an extension of an existing collection in use with OMB Control Number 2506–0182, for the Recordkeeping for HUD's Continuum of Care Homeless Assistance Grant Application—Continuum of Care Registration. CoC Program Collaborative Applicants complete forms registering CoCs prior to the annual CoC Program Competition, which collects each CoCs number and name (designated by HUD), the geographic codes selected by CoCs to designate the areas each CoC covers to provide housing and services to individuals and families experiencing homelessness. The information collected during the registration process is used by HUD to determine the CoCs that will submit a CoC Consolidated Application when the Competition process opens.

During CoC Program Registration, Collaborative Applicants may also request Unified Funding Agency (UFA) or High Performing Community (HPC) designation. If requesting UFA or HPC designation, additional forms and attachments created by the Collaborative Applicant or CoC are submitted for HUD's review to determine eligibility. The statutory and regulatory requirements related to the CoC Program and applicable supplementary documents are located on the CoC Program page on HUD's website.

Respondents (i.e., affected public): Nonprofit organizations, states, local governments, and instrumentalities of state and local governments, Indian Tribes, Tribally Designated Housing Entities (TDHEs) (as defined in section 4 of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103)), and Public Housing Agencies (PHAs), as such term is defined in 24 CFR 5.100.

Information Collection/Form Number: Information is collected via the electronic e-snaps application system.

Estimated Number of Respondents: 405.

Estimated Number of Responses: 405.

Frequency of Response: Annually.

Responses per Annum: 835.

Average Hours per Response: See chart.

Total Estimated Burdens: See chart; however, the information included in the chart below is subject to change due to: 1) increase or decrease, based on the number of CoCs due to CoC mergers, splits, or creation of new CoCs; and 2) submission of UFA and HPC registration forms due to the number of Collaborative Applicants requesting UFA designation and the number of CoCs requesting HPC designation.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
CoC Registration—Basic	405	1	405	1	405	$43.55	$17,637.75
CoC Registration—UFA designation request	20	1	20	15	300	43.55	13,065.00
CoC Registration—HPC designation request	5	1	5	10	50	43.55	2,177.50
Grant Inventory Worksheet	405	1	405	4	1,620	43.55	70,551.00
Total	405	1	835	5	3,995		103,431.25

*Responses to UFA and HPC designations are subsets of the total 405 basic registration numbers as the basic CoC Registration is completed by all Collaborative Applicants to register the CoCs. On average there are 20 requests for UFA designation and to date no requests for HPC designation. The total number of respondents is subject to change annually due to CoCs merging or splitting and with newly created CoCs due to authorizing language expanding eligibility (*e.g.,* FY 2021 appropriations language authorizing the Indian Tribes and TDHEs eligibility to form CoCs, submit CoC Consolidated applications, and project applications).

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Marion M. McFadden,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2024–28854 Filed 12–6–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[256A2100DD/AAKC001030/A0A501010.999900; OMB Control Number 1076–0169]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Probate of Indian Estates, Except for Members of the Osage Nation and Five Civilized Tribes

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 8, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection request (ICR) should be sent within 30 days of publication of this notice to the Office of Information and Regulatory Affairs (OIRA) through *https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202405-1076-013* or by visiting *https://www.reginfo.gov/public/do/PRAMain* and selecting ''Currently under Review—Open for Public Comments'' and then scrolling down to the ''Department of the Interior.''

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; *comments@bia.gov;* (202) 924–2650.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. You may also view the ICR at *https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=1076-0169.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on June 21, 2024 (89 FR 52076). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Secretary of the Interior probates the estates of individual Indians owning trust or restricted property in accordance with 25 U.S.C. 372–373. In order to compile the probate file, the BIA must obtain the family heirship data regarding the deceased from individuals and the tribe. This section contains the procedures that the Secretary of the Interior follows to initiate the probate of the trust estate for a deceased person who owns an interest in trust or restricted property. The Secretary must perform the necessary research of family heirship data collection requests in this part to obtain the information necessary to compile an accurate and complete probate file. This file will be forwarded to the Office of Hearing and Appeals (OHA) for disposition. Responses to these information collection requests are required to create a probate file for the decedent's estate so that OHA can determine the heirs of the decedent and order distribution of the trust assets in the decedent's estate.

Title of Collection: Probate of Indian Estates, Except for Members of the Osage Nation and Five Civilized Tribes.

OMB Control Number: 1076–0169.

Form Number: OHA–7 form.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Indians, businesses, and tribal authorities.

Total Estimated Number of Annual Respondents: 36,906 per year.

Total Estimated Number of Annual Responses: 41,139 per year.

Estimated Completion Time per Response: Varies from 0.5 hours to 45 hours.

Total Estimated Number of Annual Burden Hours: 617,486 per year.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Once per respondent per year.

Total Estimated Annual Nonhour Burden Cost: $0.

Authority

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Steven Mullen,

Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2024–28856 Filed 12–6–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_CA_FRN_MO4500183243]

Filing of Plats of Survey: California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), California State Office, Sacramento, California, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the U.S. Forest Service, U.S. Fish and Wildlife Service, and Bureau of Land Management, are necessary for the management of these lands.

DATES: Unless there are protests to this action, the plats described in this notice will be filed on January 8, 2025.

ADDRESSES: You may submit written protests to the BLM California State Office, Cadastral Survey, 2800 Cottage Way, W–1623, Sacramento, CA 95825. A copy of the plats may be obtained from the BLM California State Office, Public Room, 2800 Cottage Way, W–1623, Sacramento, California 95825, upon required payment.

FOR FURTHER INFORMATION CONTACT: Joan Honda, Chief, Branch of Cadastral Survey, Bureau of Land Management, California State Office, 2800 Cottage Way, W–1623, Sacramento, California 95825; 1–916–978–4316; *jhonda@blm.gov.*

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Honda. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Mount Diablo Meridian, California

T. 15 S., R. 35 E., dependent resurvey and

subdivision, for Group No. 1813, accepted May 31, 2024.

T. 18 N., R. 9 W., dependent resurvey and metes-and-bounds survey of tracts 37 through 49, for Group No. 1740, accepted September 5, 2024

T. 6 N., R. 13 E., dependent resurvey, for Group No. 1819, accepted September 30, 2024.

T. 23 S., R. 24 E., dependent resurvey, subdivision, metes-and-bounds survey and corrective dependent resurvey, for Group No. 1804, accepted October 3, 2024.

San Bernardino Meridian, California

T. 2 N., R. 6 W., dependent resurvey, subdivision and metes-and-bounds survey, for Group No. 1798, accepted September 27, 2024.

A person or party who wishes to protest one or more plats of survey must file a written notice of protest within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. Any notice of protest received after the due date will be untimely and will not be considered. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed at the same address within 30 calendar days after the notice of protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved.

Before including your address, phone number, email address, or other personal identifying information in your notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available at any time. While you can ask the BLM to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. chapter 3.

Joan H. Honda,

Chief Cadastral Surveyor.

[FR Doc. 2024–28792 Filed 12–6–24; 8:45 am]

BILLING CODE 4331–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLHQ220000 L63000000 PH0000 25X; OMB Control No. 1004–0058]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Reporting Provision for Timber Export Determination and Log Scale Disposition

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 8, 2025.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Chris Schumacher by email at *c1schuma@blm.gov,* or by telephone at (202) 577–6745. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data are provided in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on March 24, 2024 (89 FR 20999).

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comment addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BLM collects the information from respondents to determine if they are qualified by statute to purchase Federal timber resources originating from public lands managed by the BLM. This OMB control number is currently scheduled to expire December 31, 2024. This request is for OMB to renew this OMB control number for an additional three (3) years.

Title of Collection: Reporting Provision for Timber Export Determination and Log Scale Disposition (43 CFR parts 5424 and 5462).

OMB Control Number: 1004–0058.

Form Numbers: 5450–17 and 5460–15.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Purchasers of Federal timber and their affiliates.

Total Estimated Number of Annual Respondents: 200.

Total Estimated Number of Annual Responses: 200.

Estimated Completion Time per Response: 1 hour.

Total Estimated Number of Annual Burden Hours: 200.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2024–28868 Filed 12–6–24; 8:45 am]

BILLING CODE 4310–84–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–606 and 731–TA–1416 (Review)]

Quartz Surface Products From China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty and countervailing duty orders on quartz surface products From China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: September 6, 2024.

FOR FURTHER INFORMATION CONTACT: (Julie Duffy (202) 708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On September 6, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 47614, June 3, 2024) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on December 18, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before December 26, 2024 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by December 26, 2024. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: December 3, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–28772 Filed 12–6–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1425]

Certain TOPcon Solar Cells, Modules, Panels, Components Thereof, and Products Containing Same (II); Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 23, 2024, under section 337 of the Tariff Act of 1930, as amended, on

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the responses submitted on behalf of Cambria Company LLC, Dal-Tile LLC, and Guidoni USA to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

behalf of Trina Solar (U.S.), Inc. of Fremont, California; Trina Solar US Manufacturing Module 1, LLC of Wilmer, Texas; and Trina Solar Co., Ltd. of China. Supplements to the complaint were filed on November 8, 2024, and November 15, 2024. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain TOPCon solar cells, modules, panels, components thereof, and products containing same by reason of the infringement of certain claims of U.S. Patent No. 9,722,104 (''the '104 patent'') and U.S. Patent No. 10,230,009 (''the '009 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2024).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 3, 2024, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–11 of the '104 patent and claims 1–17 of the '009 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''Tunnel Oxide Passivated Contact ('TOPCon') solar cells that include an isolation portion in an edge portion of a silicon semiconductor substrate and that prevents contact between two opposite type conductive semiconductor regions and solar modules and panels that include such solar cells'';

(3) Pursuant to Commission Rule 210.50(b)(l), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. l337(d)(l), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Trina Solar (U.S.), Inc., 7100 Stevenson Blvd., Fremont, CA 94538

Trina Solar US Manufacturing Module 1, LLC, Tradepoint 45 West, 1200 Sunrise Road, Wilmer, TX 75172

Trina Solar Co., Ltd., No. 2 Tianhe Road, Trina PV Industrial Park, Xinbei District, Jiangsu Province, China, 213031

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

CSI Solar Co., Ltd., 199 Lushan Road, Suzhou National & Hi-Tech Industrial Development Zone, Suzhou, Jiangsu Province, China, 215129

Canadian Solar Inc., 545 Speedvale Avenue, West Guelph, Ontario, N1K 1E6

Canadian Solar (USA) Inc., 1350 Treat Blvd. Ste 500, Walnut Creek, CA 94597

Canadian Solar Manufacturing (Thailand) Co., Ltd., 168, Bo Win, Si Racha District, Chon Buri 20230, Thailand

Canadian Solar US Module Manufacturing Corporation, 3000 Skyline Drive, Mesquite, TX 75149

Recurrent Energy Development Holdings, LLC, 98 San Jacinto Boulevard, Suite 750, Austin, TX 78701

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge, and the Chief Administrative Law Judge is authorized to consider whether to consolidate Inv. No. 337–TA–1425 with Inv. No. 337–TA–1422, and to consolidate them if he deems it appropriate.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 4, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–28832 Filed 12–6–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0036]

Agency Information Collection Activities; Proposed eCollection eComments Requested; FFL Out of Business Records Request—ATF Form 5300.3A

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until January 8, 2025.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Matthew S. Grim, NTCD/TORM, by email at *matthew.grim@atf.gov,* or telephone at 304–260–3683.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register**, 89 FR 81552, on Tuesday, October 8, 2024, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1140–0036. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *Title of the Form/Collection:* FFL Out of Business Records Request.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* ATF Form 5300.3A.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected Public: Private Sector-for or not for profit institutions.

Abstract: Information Collection (IC) OMB 1140–0036 (FFL Out of Business Records Request—ATF Form 5300.3A) is used by ATF to notify licensees who go out of business and fail to submit their records in the prescribed time frame. The questions are simple and a return physical or email address is provided. The format is easy for the user to list the required information ATF needs to perform its function regarding laws and regulations. Upon receipt of this form, licensees are to submit their records to the ATF Out-of-Business Records or transfer them to an active FFL successor. Information collection (IC) OMB #1140–0036 is being revised to reflect minor changes in narrative text to articulate more clearly what out out-of-business records are required to be submitted, where they are to be submitted, and how they are to be submitted to the ATF OOBRC by OOB FFLs.

5. *Obligation to Respond:* The obligation to respond is mandatory per, 18 U.S.C. 923(g)(4), as implemented by 27 CFR 478.127.

6. *Total Estimated Number of Respondents:* 3,030 respondents.

7. *Estimated Time per Respondent:* 10 hours.

8. *Frequency:* Once annually.

9. *Total Estimated Annual Time Burden:* 30,300 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: December 4, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–28816 Filed 12–6–24; 8:45 am]

BILLING CODE 4410–FY–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 9, 16, 23, 30, 2024 and January 6, 13, 2025. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on

requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of December 9, 2024

There are no meetings scheduled for the week of December 9, 2024.

Week of December 16, 2024—Tentative

There are no meetings scheduled for the week of December 16, 2024.

Week of December 23, 2024—Tentative

There are no meetings scheduled for the week of December 23, 2024.

Week of December 30, 2024—Tentative

There are no meetings scheduled for the week of December 30, 2024.

Week of January 6, 2025—Tentative

There are no meetings scheduled for the week of January 6, 2025.

Week of January 13, 2025—Tentative

Tuesday, January 14, 2025

9:00 a.m. Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Nuclear Materials Users Business Lines (Public Meeting) (Contact: Araceli Billoch Colon: 301–415–3302)

Additional Information: The meeting will be held in the Commissioners' Hearing Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 4, 2024.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2024–28927 Filed 12–5–24; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 63–001–HLW; ASLBP No. 09–892–HLW–CAB04]

United States Department of Energy (Yucca Mountain Nevada High-Level Waste Geologic Repository); Notice of Atomic Safety and Licensing Board Reconstitution

Pursuant to 10 CFR 2.313(c) and 2.321(b), the Atomic Safety and Licensing Board in the above-captioned ASLBP No. 09–892–HLW–CAB04 proceeding is hereby reconstituted by designating Administrative Judge G. Paul Bollwerk, III to serve as Presiding Officer in place of Administrative Judge Paul S. Ryerson, who retired from Federal service on November 30, 2024.[1]

All correspondence, documents, and other materials shall continue to be filed in accordance with the NRC E-filing rule. *See* 10 CFR 2.302.

Rockville, Maryland

Dated: December 3, 2024.

Edward R. Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 2024–28773 Filed 12–6–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2025–525 and K2025–523; MC2025–536 and K2025–534; MC2025–537 and K2025–535; MC2025–555 and K2025–553; MC2025–556 and K2025–554; MC2025–557 and K2025–555; MC2025–558 and K2025–556; MC2025–559 and K2025–557; MC2025–560 and K2025–558; MC2025–561 and K2025–559; MC2025–562 and K2025–560; MC2025–563 and K2025–561; MC2025–564 and K2025–562; MC2025–565 and K2025–563; MC2025–566 and K2025–564; MC2025–567 and K2025–565; MC2025–568 and K2025–566; MC2025–569 and K2025–567; MC2025–570 and K2025–568]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 10, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR

[1] Judge Ryerson was appointed as an Administrative Judge on the Atomic Safety and Licensing Board Panel in 2008. Since 2012, he has served as the Panel's Associate Chief Administrative Judge. In all his adjudicatory and leadership roles, Judge Ryerson served with surpassing distinction.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* MC2025–525 and K2025–523; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 817 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 10, 2024.

2. *Docket No(s).:* MC2025–536 and K2025–534; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 828 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 10, 2024.

3. *Docket No(s).:* MC2025–537 and K2025–535; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 829 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 10, 2024.

4. *Docket No(s).:* MC2025–555 and K2025–553; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 842 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 10, 2024.

5. *Docket No(s).:* MC2025–556 and K2025–554; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 843 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 10, 2024.

6. *Docket No(s).:* MC2025–557 and K2025–555; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 844 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* December 10, 2024.

7. *Docket No(s).:* MC2025–558 and K2025–556; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 845 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 10, 2024.

8. *Docket No(s).:* MC2025–559 and K2025–557; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 846 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 10, 2024.

9. *Docket No(s).:* MC2025–560 and K2025–558; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 847 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 10, 2024.

10. *Docket No(s).:* MC2025–561 and K2025–559; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 848 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 10, 2024.

11. *Docket No(s).:* MC2025–562 and K2025–560; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 849 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 10, 2024.

12. *Docket No(s).:* MC2025–563 and K2025–561; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 850 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 10, 2024.

13. *Docket No(s).:* MC2025–564 and K2025–562; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 851 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* December 10, 2024.

14. *Docket No(s).:* MC2025–565 and K2025–563; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 852 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 10, 2024.

15. *Docket No(s).:* MC2025–566 and K2025–564; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage 853 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public*

Representative: Almaroof Agoro; *Comments Due:* December 10, 2024.

16. *Docket No(s).:* MC2025–567 and K2025–565; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 854 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 10, 2024.

17. *Docket No(s).:* MC2025–568 and K2025–566; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 855 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 10, 2024.

18. *Docket No(s).:* MC2025–569 and K2025–567; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 856 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 10, 2024.

19. *Docket No(s).:* MC2025–570 and K2025–568; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 857 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* December 10, 2024.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–28747 Filed 12–6–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. K2025–577; MC2025–571 and K2025–569; MC2025–572 and K2025–570; MC2025–573 and K2025–571; MC2025–574 and K2025–572; MC2025–575 and K2025–573; MC2025–576 and K2025–574; MC2025–577 and K2025–575; MC2025–578 and K2025–576; MC2025–579 and K2025–578; MC2025–580 and K2025–579; MC2025–581 and K2025–580; MC2025–582 and K2025–581; MC2025–583 and K2025–582; MC2025–584 and K2025–583; MC2025–585 and K2025–584; MC2025–586 and K2025–585; MC2025–587 and K2025–586; MC2025–588 and K2025–587]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 10, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*https://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* K2025–577; *Filing Title:* Request of United States Postal Service Concerning Functionally Equivalent Inbound Competitive Multi-Service Agreement with Foreign Postal Operator—FY25–1; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 CFR 3035.105 and 39 CFR 3041.315; *Public Representative:* Katalin

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Clendenin; *Comments Due:* December 10, 2024.

2. *Docket No(s).:* MC2025–571 and K2025–569; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 858 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* December 10, 2024.

3. *Docket No(s).:* MC2025–572 and K2025–570; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 859 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* December 10, 2024.

4. *Docket No(s).:* MC2025–573 and K2025–571; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 860 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* December 10, 2024.

5. *Docket No(s).:* MC2025–574 and K2025–572; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 493 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* December 10, 2024.

6. *Docket No(s).:* MC2025–575 and K2025–573; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 494 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* December 10, 2024.

7. *Docket No(s).:* MC2025–576 and K2025–574; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 495 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* December 10, 2024.

8. *Docket No(s).:* MC2025–577 and K2025–575; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 496 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* December 10, 2024.

9. *Docket No(s).:* MC2025–578 and K2025–576; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 497 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 10, 2024.

10. *Docket No(s).:* MC2025–579 and K2025–578; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 861 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 10, 2024.

11. *Docket No(s).:* MC2025–580 and K2025–579; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 862 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 10, 2024.

12. *Docket No(s).:* MC2025–581 and K2025–580; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 863 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* December 10, 2024.

13. *Docket No(s).:* MC2025–582 and K2025–581; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 864 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* December 10, 2024.

14. *Docket No(s).:* MC2025–583 and K2025–582; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 498 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 10, 2024.

15. *Docket No(s).:* MC2025–584 and K2025–583; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 865 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 10, 2024.

16. *Docket No(s).:* MC2025–585 and K2025–584; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage 866 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* December 10, 2024.

17. *Docket No(s).:* MC2025–586 and K2025–585; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 499 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* December 10, 2024.

18. *Docket No(s).:* MC2025–587 and K2025–586; *Filing Title:* USPS Request to Add USPS Ground Advantage Contract 11 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* December 10, 2024.

19. *Docket No(s).:* MC2025–588 and K2025–587; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 500 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 2, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public*

Representative: Jennaca Upperman; *Comments Due:* December 10, 2024.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–28843 Filed 12–6–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

International Product Change—Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of Notice:* December 9, 2024

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 8, 2024, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 51 to Competitive Product List. Documents are available at *www.prc.gov,* Docket Nos. MC2025–344 and K2025–342.

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–28860 Filed 12–6–24; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–126, OMB Control No. 3235–0287]

Submission for OMB Review; Comment Request; Extension: Form 4—Statement of Changes in Beneficial Ownership of Securities

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Under the Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) every person who is directly or indirectly the beneficial owner of more than 10 percent of any class of any equity security (other than an exempted security) which registered under Section 12 of the Exchange Act (15 U.S.C. 78l), or who is a director or any officer of the issuer of such security (collectively ''insider), must file a statement with the Commission reporting their ownership. Form 4 is a statement to disclose changes in an insider's ownership of securities. The information is used for the purpose of disclosing the equity holdings of insiders of reporting companies. Approximately 186,052 insiders file Form 4 annually and it takes approximately 0.5 hours to prepare for a total of 93,026 annual burden hours (0.5 hours per response × 93,026 responses).

Public Comment Instructions: The 30-day public comment period for this information collection request opens on December 10, 2024 and closes at the end of the day on January 9, 2025. The public may view the full information request and submit comments at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202412-3235-003* or email comments to *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov.*

Dated: December 4, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–28834 Filed 12–6–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101798; File No. SR–PEARL–2024–55]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Non-Substantive, Clarifying Changes to the Exchange's Rulebook

December 3, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 21, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to make non-substantive, clarifying changes to the Exchange's Rulebook.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Proposal To Amend Chapter III

The Exchange proposes to make non-substantive clarifying changes to the second paragraph of Chapter III to provide accuracy and precision within the rule text. For background, Regulation SCI and MIAX [3] Rule 321 require MIAX Pearl to designate certain members of both the options and equities trading facilities of MIAX Pearl to participate in business continuity and disaster recovery testing in a manner specified by MIAX Pearl and at a frequency of not less than once every 12 months.[4] Such testing ordinarily is part of an annual industry-wide test. MIAX Rule 321, as incorporated into the MIAX Pearl Rulebook, governs mandatory participation in testing of MIAX Pearl's backup systems. In particular, MIAX Rule 321, as incorporated, requires MIAX Pearl to designate certain Members [5] and Equity Members [6] that account for a specified percentage of executed volume on MIAX Pearl (separately, with respect to the options and equities trading facilities of MIAX Pearl), measured on quarterly basis, to connect to the MIAX Pearl backup systems and participate in functional and performance testing of such system.[7]

On August 14, 2020, the U.S. Securities and Exchange Commission (''Commission'') approved the Exchange's proposal to adopt rules governing the trading of equity securities, referred to as MIAX Pearl Equities.[8] MIAX Pearl Equities began trading on September 25, 2020.[9] For calendar year 2020, the annual business continuity and disaster recovery industry-wide test was scheduled for October 24, 2020. MIAX Pearl Equities did not have two quarters of trading data on which to base its Equity Member designation prior to the October 24, 2020 test. Thus, MIAX Rule 321 would not permit MIAX Pearl Equities to designate any Equity Members to participate in the industry-wide test for 2020 because no Equity Members would have the requisite trading volume on MIAX Pearl Equities upon which a designation could be made at that time.

To address the unique circumstances for disaster recovery testing in 2020, the year in which MIAX Pearl Equities became operational, the Exchange amended Chapter III of the Exchange's Rules to provide that for calendar year 2020, notwithstanding paragraph (b) and Interpretations and Policies .01 of MIAX Rule 321, which assigns the Exchange responsibility of ''identifying Members that account for a meaningful percentage of the Exchange's overall volume,'' the Exchange instead designated at least three Equity Members on MIAX Pearl Equities who have a meaningful percentage of trading volume in NMS Stocks across the other equity exchanges in 2020.[10] This allowed MIAX Pearl Equities to identify Equity Members for industry-wide disaster recovery testing in the absence of the metrics that are used in the ordinary course to designate such firms.

MIAX Pearl Equities now has sufficient trading data each year to designate Equity Members that account for a specified percentage of executed volume on MIAX Pearl Equities, measured on quarterly basis, to require certain Equity Members to connect to the MIAX Pearl backup systems and participate in functional and performance testing of such system. Since the unique circumstances for disaster recovery testing in 2020 no longer exists, the Exchange now proposes to delete the second paragraph of Chapter III. The purpose of the purposed change is to delete the outdated rule text.

Proposal To Amend Exchange Rule 503

The Exchange proposes to make non-substantive, clarifying changes to subparagraphs (a)(3)–(4) of Exchange Rule 503 to provide consistency within the rule text.

Specifically, the Exchange proposes to amend the announcement method by requiring announcements through a Regulatory Circular, instead of a post on the Exchange's website, for the purpose of Exchange Rule 503. The Exchange proposes to replace ''on the Exchange's website'' with ''through a Regulatory Circular'' at the end of subparagraph (a)(3) of Exchange Rule 503. The Exchange proposes to replace ''published by the Exchange on its website'' with ''announced to Members through a Regulatory Circular'' at the end of the first sentence of subparagraph (a)(4) of Exchange Rule 503. The Exchange proposes to replace ''posted by MIAX Pearl on its website'' with ''announced to Members through a Regulatory Circular'' at the end of the second sentence of subparagraph (a)(4) of Exchange Rule 503. The purpose of the proposed changes is to harmonize the Exchange's rules and provide consistency within the Exchange's Rulebook as the Exchange, and its affiliates, historically announce such information through a Regulatory Circular.[11] The proposed changes do not impact or alter the information provided to any Member. Accordingly, with the proposed changes, subparagraphs (a)(3)–(4) of Exchange Rule 503 will provide as follows:

(3) ''Market for the Underlying Security'' shall mean either the primary listing market, the primary volume market (defined as the market with the most liquidity in that underlying security for the previous two calendar months), or the first market to open the underlying security, as determined by the Exchange on a class by class basis and announced to Members through a Regulatory Circular.

(4) ''Valid Width National Best Bid or Offer'' or ''Valid Width NBBO'' shall mean the combination of all away market quotes and any combination of MIAX Pearl Market Maker orders and quotes received from a minimum number of away markets and a minimum number of MIAX Pearl Market Makers within a specified bid/ask differential each as established and announced to Members through a Regulatory Circular. The Valid Width NBBO will be configurable by the underlying, and tables with valid width

[3] The term ''MIAX'' means Miami International Securities Exchange, LLC. *See* Exchange Rule 100. The rules contained in MIAX Chapter III, as such rules may be in effect from time to time, are incorporated by reference into MIAX Pearl Chapter III, and are thus MIAX Pearl Rules and thereby applicable to MIAX Pearl Members. *See* Chapter III of Exchange's Rulebook.

[4] *See* MIAX Rule 321(a)–(b).

[5] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of these Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. See Exchange Rule 1901. The term ''MIAX Pearl Equities'' shall mean MIAX Pearl Equities, a facility of MIAX PEARL, LLC. *See id.*

[7] *See* MIAX Rule 321(b).

[8] *See* Securities Exchange Act Release No. 89563 (August 14, 2020), 85 FR 51510 (August 20, 2020) (SR–PEARL–2020–03).

[9] *See* ''MIAX PEARL Receives Approval to Operate Equities Exchange; Launch Date Confirmed for September 25, 2020,'' *available at https://www.miaxglobal.com/sites/default/files/alert-files/MIAX_Press_Release_08182020.pdf.*

[10] *See* Securities Exchange Act Release No. 89736 (September 2, 2020), 85 FR 55730 (September 9, 2020) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Designation of Members for Mandatory Disaster Recovery Testing Pursuant to Regulation SCI for Calendar Year 2020).

[11] *See, e.g.,* MIAX Rule 503(d); *see also* MIAX Pearl Options Exchange Regulatory Circular 2024–58, Market for Underlying Security Used for Openings on MIAX Options, MIAX Pearl Options, MIAX Emerald Options and MIAX Sapphire Options for Newly Listed Symbols Effective Wednesday, October 23, 2024, *available at https://www.miaxglobal.com/sites/default/files/circular-files/MIAX_Pearl_Options_RC_2024_58.pdf.*

differentials will be announced to Members through a Regulatory Circular. Away markets that are crossed will void all Valid Width NBBO calculations. If any Market Maker orders or quotes on MIAX Pearl are crossed internally, then all such orders and quotes will be excluded from the Valid Width NBBO calculation. If any Market Maker orders or quotes on MIAX Pearl are locking or crossing the ABBO, the Market Maker's orders or quotes will be considered to be at the locked or crossed ABBO price for purposes of calculating the Valid Width NBBO.

Proposal To Delete All References to Mini-Options

The Exchange proposes to delete all outdated references to mini-options in the rule text.[12] On September 8, 2016, the Commission approved the Exchange's Form 1 application to register as a national securities exchange under Section 6 of the Exchange Act.[13] At that time, the Exchange established rule text for mini-options. Mini-options never gained significant market acceptance and have not achieved the expected level of traction or success in its target market. Accordingly, all mini-options were delisted several years ago and the Exchange does not have plans to re-list them in the foreseeable future. As the Exchange no longer offers mini-option contracts, the Exchange proposes to delete all references to mini-options to provide greater clarity to Members and the public regarding the Exchange's offerings and Rulebook. The Exchange also notes that other exchanges filed similar proposals to delete references to mini-options.[14] In the event that the Exchange desires to list mini-options in the future, the Exchange will file a rule change with the Commission to adopt rules to list mini-options and corresponding fees and rebates for transactions in mini-options, if applicable.

Specifically, the Exchange proposes to delete the content in Interpretations and Policies .08 of Exchange Rule 404 and then insert ''Reserved'' so as to keep the remainder of the Rulebook as currently formatted. The Exchange proposes to delete the content in subparagraph (c) of Exchange Rule 509 and then insert ''Reserved'' so as to keep the remainder of the Rulebook as currently formatted. The Exchange proposes to delete the content in Interpretations and Policies .02 of Exchange Rule 510 and then insert ''Reserved'' so as to keep the remainder of the Rulebook as currently formatted.

Proposal To Update Citations to Rule 600(b) of Regulation NMS

The Exchange proposes to update citations to Rule 600(b) of Regulation NMS in Exchange Rule 100, Definitions, Rule 530, Limit Up-Limit Down, Rule 2612, Minimum Price Variations, Rule 2614, Orders and Order Instructions, and Rule 2705, Prohibition Against Trading Ahead of Customer Orders.

In 2024, the Commission amended Regulation NMS under the Act to update the rule that requires disclosures for order executions in national market system (''NMS'') stocks.[15] As part of that initiative, the Commission adopted new definitions in Rule 600(b) of Regulation NMS and renumbered the remaining definitions, including the definitions of Trading Center (formerly Rule 600(b)(95)), Regular Trading Hours (formerly Rule 600(b)(77)), NMS Stock (formerly Rule 600(b)(55)), and Intermarket Sweep Orders (formerly Rule 600(b)(38)).

The Exchange accordingly proposes to update the relevant citations to Rule 600(b) in its rules as follows:

- The citation to the definition of Trading Center in Rule 100 would be changed to Rule 600(b)(106).
- The citation to the definition of Regular Trading Hours in Rule 530, Limit Up-Limit Down, would be changed to Rule 600(b)(88).
- The citation to the definition of NMS Stock in Rule 2612 would be changed to Rule 600(b)(65).
- The citation to the definition of Intermarket Sweep Orders in Rule 2614 would be changed to Rule 600(b)(47).

The citation to the second requirement of the definition of Intermarket Sweep Order would be changed to Rule 600(b)(47)(ii).

2. Statutory Basis

The Exchange believes that the proposed changes are consistent with Section 6(b) of the Act[16] in general, and further the objectives of Section 6(b)(1) of the Act[17] in particular, in that they are designed to enforce compliance by the Exchange's Members and persons associated with its Members and Equity Members, with the provisions of the rules of the Exchange.

In particular, the Exchange believes that the proposed changes are designed to enforce compliance by the Exchange's Members and Equity Members with the provisions of the rules of the Exchange because the changes will provide greater clarity to Members, Equity Members and the public regarding the Exchange's Rulebook by deleting the outdated rule text in Chapter III that is no longer applicable, amending the announcement method for certain types of openings on the Exchange, deleting outdated references to mini-options that are no longer offered by the Exchange, and updating the citations to Rule 600(b) of Regulation NMS.

The proposed change to delete the second paragraph of Chapter III of the Rulebook is to delete the outdated rule text since the unique circumstances for disaster recovery testing in 2020 no longer exists for Equity Members of MIAX Pearl Equities. The proposed changes to amend the announcement method for certain types of openings on the Exchange are to harmonize the rules and provide consistency within the Exchange's Rulebook as the Exchange, and its affiliates, historically announce such information through a Regulatory Circular. The proposed changes to remove outdated references to mini-options will help enforce compliance with the Exchange's rules by removing obsolete rule text. Mini-options were delisted from the Exchange years ago since mini-options failed to gain significant market acceptance and never achieved the expected level of traction or success in its target market.

The proposed changes to update the citations to Rule 600(b) of Regulation NMS are to correct inaccurate rule citations, thereby reducing potential confusion and ensuring that those subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules. The Exchange believes that the proposed changes will help enforce compliance with the Exchange's rules by providing clarity and consistency within the Exchange's

[12] The Exchange anticipates it will file a separate rule filing pursuant to Rule 19b–4 of the Exchange Act with the Commission to remove references to ''mini-options'' in the MIAX Pearl Options Exchange Fee Schedule, including outdated tables that still list fees (or rebates) for transactions by market participants in mini-options.

[13] *See* Securities Exchange Act Release No. 78793 (September 8, 2016), 81 FR 63238 (September 14, 2016) (File No. 10–227) (Exhibit B) (establishing rules for mini-options).

[14] *See* Securities Exchange Act Release No. 88374 (March 12, 2020), 85 FR 15522 (March 18, 2020) (SR–Phlx–2020–08) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Certain Phlx Rules To Remove References to Mini Options); *see also* Securities Exchange Act Release No. 88458 (March 23, 2020), 85 FR 17372 (March 27, 2020) (SR–MRX–2020–07) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Removal of Obsolete Listing Rules); *see also* Securities Exchange Act Release No. 88456 (March 23, 2020), 85 FR 17126 (March 26, 2020) (SR–ISE–2020–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Removal of Obsolete Listing Rules).

[15] *See* Securities Exchange Act Release No. 99679, 89 FR 26428 (April 15, 2024) (S7–29–22).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(1).

Rulebook, thereby making it easier for Members and Equity Members to interpret the Exchange's Rulebook. The Exchange believes that Members and Equity Members would benefit from the increased clarity and consistency, thereby alleviating potential investor or market participant confusion.

The Exchange believes that the proposed rule changes also further the objectives of Section 6(b)(5) of the Act. In particular, they are designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest.

The Exchange believes the proposed changes promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed rule changes will provide greater clarity to Members and Equity Members and the public regarding the Exchange's Rulebook by deleting the outdated rule text in Chapter III of the Rulebook that is no longer applicable to Equity Members, amending the announcement method for certain types of openings on the Exchange to provide consistency within the Rulebook, deleting outdated references to mini-options that are no longer offered by the Exchange, and updating citations to Rule 600(b) of Regulation NMS. It is in the public interest for the Exchange's Rulebook to be accurate and consistent so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition as there is no functional change to the Exchange's System [18] and because the rules of the Exchange apply to all Members and Equity Members equally.

The proposed change to delete the second paragraph of Chapter III of the Rulebook is to delete the outdated rule text applicable to Equity Members since the unique circumstances for disaster recovery testing in 2020 no longer exists. The proposed changes to amend the announcement method for certain types of openings on the Exchange are to harmonize the rules and provide consistency within the Exchange's Rulebook as the Exchange, and its affiliates, historically announce such information through a Regulatory Circular. The proposed changes to remove obsolete rule text include the removal of outdated references to mini-options. Mini-options are no longer offered by the Exchange since mini-options failed to gain significant market acceptance and have not achieved the expected level of traction or success in its target market. The proposed changes to update the citations to Rule 600(b) of Regulation NMS are to correct inaccurate rule citations, reduce potential confusion, and ensure that market participants can more easily navigate and understand the Exchange's rules. The proposed rule changes will have no impact on competition as they are not designed to address any competitive issue but rather are designed to remedy minor, non-substantive issues and provide added clarity to the Exchange's Rulebook.

In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal does not address any competitive issues but rather would provide additional clarity in the Exchange's rule by deleting the outdated rule text in Chapter III of the Rulebook that is no longer applicable, amending the announcement method for certain types of openings on the Exchange, deleting outdated references to mini-options that are no longer offered by the Exchange, and updating citations to Rule 600(b) of Regulation NMS. Since the proposal does not substantively modify System functionality or processes on the Exchange, the proposed changes will not impose any burden on competition nor are they meant to affect competition among the exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) [21] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[22] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Exchange states that waiver of the operative delay would permit the Exchange to delete outdated rule text regarding unique circumstances for disaster recovery that applied in 2020 and no longer exist, amend the announcement method for certain types of openings on the Exchange to make it consistent with the Exchange's historical announcement method, delete outdated references to mini-options that are no longer offered by the Exchange, and correct inaccurate rule citations, thereby alleviating potential confusion and adding clarity to its rules. For these reasons, and because the proposal does not raise any new or novel issues, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[23]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

[18] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6).

[22] 17 CFR 240.19b–4(f)(6)(iii).

[23] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [24] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–55 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2024–55. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–55 and should be submitted on or before December 30, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–28762 Filed 12–6–24; 8:45 am]

BILLING CODE 8011–01–P

[24] 15 U.S.C. 78s(b)(2)(B).

[25] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101803; File No. SR–MIAX–2024–44]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 1306 (Branch Offices) and Exchange Rule 1308 (Supervision of Accounts) To Harmonize With FINRA Rules

December 3, 2024.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 25, 2024, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to: (i) amend Rule 1306 (Branch Offices) to adopt the definition used by Financial Industry Regulatory Authority, Inc. (''FINRA'') of Office of Supervisory Jurisdiction (''OSJ''); (ii) amend Rule 1308 (Supervision of Accounts) to adopt FINRA's inspection requirement for non-branch location; (iii) harmonize Rule 1308 (Supervision of Accounts) with certain changes by FINRA to FINRA Rule 3110 to permit eligible Members [3] to participate in FINRA's remote inspections program (''FINRA Pilot Program''); [4] and (iv) adopt FINRA's Residential Supervisory Location (''RSL'') classification.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (i) amend Rule 1306 to adopt FINRA's definition of OSJ; (ii) amend Rule 1308 to adopt FINRA's inspection requirement for non-branch location; (iii) harmonize Rule 1308 with certain changes by FINRA to FINRA Rule 3110 to permit eligible Members to participate in FINRA's Remote Inspections Pilot Program; and (iv) adopt FINRA's RSL classification. The proposed changes would harmonize the Exchange's office and other location inspection rules with those of FINRA and thus promote uniform inspection standards across the securities industry resulting in less burdensome and more efficient regulatory compliance for common members.[5] Additionally, the proposed changes would allow Members who participate in FINRA's Remote Inspections Pilot Program to also satisfy the equivalent internal inspections requirements set out in Rule 1308. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Securities Exchange Act Release No. 97398 (April 28, 2023), 88 FR 28620 (May 4, 2023) (''Remote Inspections Pilot Program Proposal''); Securities Exchange Act Release No. 98982 (November 17, 2023), 88 FR 82464 (November 24, 2023) (''Remote Inspections Pilot Program Approval Order'') (SR–FINRA–2023–007).

[5] Currently, all Exchange Members are also FINRA members.

Exchange notes that Exchange Rules 1306 and 1308 as proposed to be amended by this filing, are incorporated by reference into the rulebooks of the Exchange's affiliate MIAX PEARL, LLC (''MIAX Pearl''), MIAX Emerald, LLC (''MIAX Emerald''), and MIAX Sapphire, LLC (''MIAX Sapphire''). As such, the amendment to Exchange Rules 1306 and 1308 proposed herein will also apply to MIAX Pearl, MIAX Emerald, and MIAX Sapphire members.

Proposal To Adopt FINRA's Definition of OSJ

The Exchange proposes to adopt paragraph (j) of Rule 1306 to adopt FINRA's definition of OSJ. Currently, Exchange Rule 1306(a) only requires Members to file with the Exchange and keep current a list of each of its branch offices showing the location of each such office and the name of the manager of each such office. FINRA Rule 3110.01 provides that a member's main office location is required to be registered and designated as a branch office or OSJ if it meets the definitions of a ''branch office'' or ''office of supervisory jurisdiction'' as set forth in FINRA Rule 3110(f). The purpose of the proposed change is to harmonize Exchange Rule 1306 with FINRA Rule 3110.01 to provide that both branch offices and OSJs will be subject to the office registration requirements set forth in Exchange Rule 1306(a). The proposed Exchange Rule 1306(j) is substantively identical to FINRA Rule 3110(f)(1). The proposed definition of OSJ defined in Rule 1306(j) will read as follows:

''Office of Supervisory Jurisdiction'' means any office of a member at which any one or more of the following functions take place: (1) order execution or market making; (2) structuring of public offerings or private placements; (3) maintaining custody of customers' funds or securities; (4) final acceptance (approval) of new accounts on behalf of the Member; (5) review and endorsement of customer orders; (6) final approval of retail communications for use by persons associated with the Member, pursuant to FINRA Rule 2210(b)(1), except for an office that solely conducts final approval of research reports; or (7) responsibility for supervising the activities of persons associated with the Member at one or more other branch offices of the Member.

The Exchange proposes to add ''offices of supervisory jurisdictions'' to Exchange Rule 1306(a) as follows:

Every Member approved to do options business with the public under this Chapter shall file with the Exchange and keep current a list of each of its branch offices and offices of supervisory jurisdictions showing the location of each such office and the name of the manager of each such office.

Additionally, the Exchange proposes to add ''OSJ'' to Exchange Rule 1308(d)(1) and its subparagraph (i) to provide that both branch offices and OSJs that supervise one or more non-branch locations must be inspected no less than once each calendar year. In the event that it has been demonstrated to the satisfaction of the Exchange that because of proximity, special reporting or supervisory practice, other arrangements may satisfy this Rule's requirements for a particular branch office or OSJ, the Member does not have inspect such office no less than once every calendar year. The proposed Rule 1308(d)(1) is substantively identical to FINRA Rule 3110(c)(1)(A). The purpose of the proposed change is to harmonize Exchange Rule 1308(d) with FINRA Rule 3110(c), resulting in less burdensome and more efficient regulatory compliance for common members. The proposed rule change would enable Exchange Rule 1308 to continue to be incorporated into the agreement between the Exchange and FINRA to allocate regulatory responsibility for common rules (the ''17d–2 Agreement''), thereby facilitating FINRA's performance of its regulatory performance on the 17d–2 Agreement.[6]

Proposal To Adopt FINRA's Inspection Requirement for Non-Branch Location

Next, the Exchange propose to amend Rule 1308(d)(3) to adopt FINRA's inspection requirement for non-branch location. Exchange Rule 1308 sets forth the main requirements for inspections. An inspection of an office or location must occur on a designated frequency. The periodicity of the required inspection varies depending on the classification of the location or the nature of the activities that take place. Currently, Exchange Rule 1308(d) provides that each branch office that supervises one or more non-branch locations must be inspected no less often than once each calendar year; [7] and every branch office, without exception, must be inspected at least once every three calendar-years.[8] The Exchange proposes to amend Rule 1308(d)(3) to provide that each non-branch office should be inspected on a regular periodic schedule. The Member shall consider the nature and complexity of the securities activities for which the location is responsible and the nature and extent of contact with customers when establishing the schedule. In addition, the Member should have written supervisory and inspection procedures to set forth the schedule and an explanation regarding how the Member determined the frequency of the examination. FINRA Rule 3110(c) requires Members to inspect every branch office that supervises one or more non-branch locations at least annually, every branch office that does not supervise one or more non-branch locations at least every three years, and every non-branch location on a regular periodic schedule. The proposed Exchange Rule 1308(d)(3) is substantively identical to FINRA Rule 3110(c)(1)(C). The purpose of the proposed change is to harmonize Exchange Rule 1308(d) with FINRA Rule 3110(c), resulting in less burdensome and more efficient regulatory compliance for common members and facilitating FINRA's performance of its regulatory performance on the 17d–2 Agreement.[9] The proposed Exchange Rule 1308(d)(3) will read as follows:

Each Member shall inspect on a regular periodic schedule every non-branch location. In establishing such schedule, the Member shall consider the nature and complexity of the securities activities for which the location is responsible and the nature and extent of contact with customers. The Member's written supervisory and inspection procedures shall set forth the schedule and an explanation regarding how the Member determined the frequency of the examination.

The Exchange proposes to amend the hierarchical headings in Exchange Rule 1308 so that subparagraphs (d)(3)–(5) will be renumbered as (d)(4)–(6). In addition, the Exchange proposes to amend proposed renumbered subparagraph (d)(6) of Rule 1308 to replace certain internal cross references to other paragraphs of Rule 1308 in light of the hierarchical heading changes described above. In particular, the Exchange propose to amend the cross references contained in proposed renumbered subparagraph (d)(6) of Rule 1308 that are to subparagraphs (d)(4) and (d)(5), to now to be subparagraphs (d)(5) and (d)(6), respectively. The Exchange proposes to add the reference to subparagraph (d)(3) in the sentence describing Member complying with the requirements of the New York Stock Exchange or FINRA in proposed renumbered Rule 1308(d)(4). With the proposed changes, proposed

[6] *See* Securities Exchange Act Release No. 68363 (December 5, 2012), 77 FR 73711 (December 11, 2012) (File No. S7–966). The 17d–2 Agreement includes a certification by the Exchange that states that the requirements contained in certain Exchange rules are identical to, or substantially similar to, certain FINRA rules that have been identified as comparable.

[7] *See* Exchange Rule 1308(d)(1).

[8] *See* Exchange Rule 1308(d)(2).

[9] *See supra* note 6.

renumbered Rule 1308(d)(4) will provide that a Member that complies with requirements of the New York Stock Exchange or FINRA that are substantially similar to the requirements in paragraphs (d)(1), (d)(2), and (d)(3) of Rule 1308 as well as other related requirements in paragraphs (e) and (f) of Rule 1308 will be deemed to have met inspection requirements set forth in Rule 1308.

Proposal To Adopt FINRA Remote Inspections Pilot Program

The Exchange proposes to adopt subparagraph (d)(7) of Rule 1308, which would provide that any Member that participates in the FINRA Remote Inspections Pilot Program, [10] thereby satisfying the internal inspections requirements in FINRA Rule 3110(c), would also satisfy the equivalent annual branch office inspections requirements in Exchange Rule 1308(d). This proposed rule change would supplant Rule 1308(d)(5) (to be renumbered as Rule 1308(d)(6)), which allowed Members to fulfill any calendar year 2024 internal inspection obligations set forth in Rule 1308(d)(5) (to be renumbered as Rule 1308(d)(6)) by conducting remote inspections of the applicable branch offices [11] or non-branch locations.[12] This temporary relief, which was analogous to relief that FINRA provided for, automatically sunset on June 30, 2024.[13] As described below, adding proposed subparagraph (d)(7) of Rule 1308 would harmonize the Exchange's annual branch office inspections obligations for its Members with FINRA's comparable obligations for its members, thereby avoiding confusion to Members with respect to the applicability of participation in the FINRA Remote Inspections Pilot Program and compliance with Exchange Rule 1308. Additionally, because the proposed subparagraph (d)(7) of Rule 1308 would incorporate by reference FINRA Rule 3110.18, this rule change would enable Exchange Rule 1308 to continue to be incorporated into the 17d–2 Agreement.[14]

Standards for Supervision of Remote Offices

The responsibility of firms to supervise their associated persons is a critical component of broker-dealer regulation.[15] Members must supervise all of their associated persons, regardless of their location, compensation or employment arrangement, or registration status. Exchange Rule 1308(d), which is substantially identical to FINRA Rule 3110(c), requires any Member, regardless of size or type, to have a supervisory system for the activities of its associated persons that is reasonably designed to achieve compliance with the applicable securities laws and regulations and Exchange rules, and that sets forth the minimum requirements for such supervisory system.[16] The internal inspection obligation under Exchange Rule 1308(d) and FINRA Rule 3110(c) is one component of such system.

Exchange Rule 1308(d), as amended herein, sets forth three main requirements for inspections. First, an inspection of an office or location must occur on a designated frequency. The periodicity of the required inspection varies depending on the classification of the location or the nature of the activities that take place: each branch office that supervises one or more non-branch locations must be inspected no less often than once each calendar year; [17] and every branch office, without exception, must be inspected at least once every three calendar-years.[18] Second, written reports reflecting the results of such inspections are to be maintained with the Member for the longer of three years or until the next branch office inspection.[19] Third, to prevent compromising the effectiveness of inspections due to conflicts of interest, the rule requires a Member to ensure that the person conducting the inspection is independent of the direct supervision and control of the branch office in question (*i.e.,* not the branch office manager, or any person who directly or indirectly reports to such manager, or any person to whom such manager directly reports).[20]

Further, Rule 1306(i) sets out factors that should be considered when developing risk-based sampling techniques to determine the appropriateness of on-site for cause reviews of selected residences and other remote locations shall include, but not be limited to, the following: (1) the firm's size; (2) the firm's organizational structure; (3) the scope of business activities; (4) the number and location of offices; (5) the number of associated persons assigned to a location; (6) the nature and complexity of products and services offered; (7) the volume of business done; (8) whether the location has a Series 9/10-qualified person on-site; (9) the disciplinary history of the registered persons or associated persons, including a review of such person's customer complaints and Forms U4 and U5; and (10) the nature and extent of a registered person's or associated person's outside business activities, whether or not related to the securities business. Rule 1306(h) further states that the written supervisory procedures pertaining to supervision of sales activities conducted at the associated person's primary residence and other remote locations must be designed to assure compliance with applicable securities laws and regulations and with Exchange Rules.

Notably, all of the above requirements about supervision and inspections of branch offices reflected a business environment in which Members conducted in-person inspections of all of their offices.[21]

FINRA's Recent Attempts To Change the In-Person Inspection Requirements of Offices of Supervisory Jurisdiction, Branch Offices, and Non-Branch Locations

In the Remote Inspections Pilot Program Proposal, FINRA described its efforts during the past several years to offer its members the option of remotely conducting internal inspections of their OSJs, branch offices, and non-branch locations.[22] As stated therein, FINRA believed that as more recordkeeping moved from paper to electronic records, and as more meetings were conducted virtually using platforms such as Zoom and WebEx, the burden on FINRA members of conducting in-person inspections for all their remote office locations became harder to justify.[23]

Thus, when the COVID–19 pandemic required many securities industry professionals to work from home,

[10] *See* FINRA Rule 3110.18.

[11] *See* Exchange Rule 1306(c).

[12] *See* Exchange Rule 1308(d)(5) (to be renumbered as Rule 1308(d)(6)) (Temporary Relief to Allow Remote Inspections for Calendar Years 2021, 2022, 2023, and Through the Earlier of the Effective Date of the Remote Inspections Pilot Program or June 30, 2024).

[13] *See Id.* The equivalent temporary relief offered by FINRA also sunset on June 30, 2024. *See* FINRA Rule 3110.17

[14] *See supra* note 6.

[15] *See generally* SEC Division of Market Regulation, Staff Legal Bulletin No. 17: Remote Office Supervision (March 19, 2004) (''SLB 17'') (SEC guidance on remote office supervision), *available at https://www.sec.gov/interps/legal/mrslb17.htm;* and Regulatory Notice 11–54 (November 2011) (''Notice 11–54'') (joint SEC and FINRA guidance on effective policies and procedures for broker-dealer branch inspections).

[16] *See* Exchange Rule 1308(d).

[17] *See* Exchange Rule 1308(d)(1).

[18] *See* Exchange Rule 1308(d)(2).

[19] *Id.*

[20] *Id.*

[21] *See* SLB 17 and Notice 11–54, *supra* note 15.

[22] *See* Remote Inspections Pilot Program Proposal, *supra* note 4.

[23] *See Id.*

FINRA implemented several forms of regulatory relief to its members, including introducing FINRA Rule 3110.17, which the Exchange also introduced as subparagraph (d)(5) of Exchange Rule 1308 (to be renumbered as Rule 1308(d)(6)), to permit remote internal inspections of their branch offices.

The pandemic accelerated the industry's adoption of a broad remote work environment and the Exchange recognizes that the pandemic has profoundly changed attitudes on where work can occur. As a result of this change many firms have adopted, in varying scale, hybrid work models involving personnel who are working at least part time from alternative work locations (*e.g.,* private residences). As part of an effort to modernize its rules to reflect evolving technologies and business models, in April 2023, FINRA filed the Remote Inspections Pilot Program Proposal with the Securities and Exchange Commission (''SEC'') to establish a voluntary, three-year remote inspections pilot program that would allow eligible firms to conduct inspections of all or some offices or locations, remotely, subject to the specified terms therein.[24] The SEC approved the FINRA Remote Inspection Pilot Program Proposal in November 2023,[25] and FINRA commenced the pilot program on July 1, 2024.[26]

FINRA's Remote Inspections Pilot Program

FINRA's Remote Inspection Pilot Program builds on the terms of the temporary relief in FINRA Rule 3110.17, while requiring members to provide even more information about their remote inspections to allow FINRA to assess the overall impact and effectiveness of remote inspections.[27] The pilot program is designed to provide broader systemized information to supplement the information obtained through the FINRA examination process in an environment where offices and locations were closed. The information firms would be required to produce as a pilot program participant will help FINRA more accurately assess the overall impact and effectiveness of remote inspections.[28]

FINRA's Remote Inspection Pilot Program includes, among other things, the following requirements for participating firms:

- Risk Assessment. Prior to electing a remote inspection for an office or location, participating firms must develop a reasonable risk-based approach to using remote inspections and conduct and document a risk assessment for that office or location.[29]
- Written Supervisory Procedures for Remote Inspections. Participating firms must establish, maintain, and enforce written procedures that are reasonably designed for conducting remote inspections and reasonably designed to achieve compliance with applicable securities laws and regulations.[30]
- Effective Supervisory System. Participating firms must have an effective supervisory system for remote inspections that will be held to the same standards of review (set forth under FINRA Rule 3110.12). Where a member's remote inspection of an office or location identifies any ''red flags,'' the member may need to impose additional supervisory procedures for that office or location or may need to provide for more frequent monitoring of that office or location, including potentially a subsequent on-site visit on an announced or unannounced basis.[31]
- Documentation Requirement. Participating firms must maintain and preserve a centralized record for each of the Pilot Years specified in the pilot program that separately identifies: (1) all offices or locations that were inspected remotely; and (2) any offices or locations for which the member determined to impose additional supervisory procedures or more frequent monitoring, as provided in FINRA Rule 3110.18(d). A member's documentation of the results of a remote inspection for an office or location must identify any additional supervisory procedures or more frequent monitoring for that office or location that were imposed as a result of the remote inspection, including whether an on-site inspection was conducted at such office or location.[32]
- Firm Level Requirements. Participating firms must meet certain firm- level eligibility requirements to participate in the program set forth in FINRA Rule 3110.18(f)(1). For example, a firm cannot participate if it is designated as: (i) Restricted Firm under FINRA Rule 4111 or (ii) a Taping Firm under FINRA Rule 3170. Additionally, firms with suspended or new (effective less than 12 months) FINRA memberships or that have been found by the SEC or FINRA to have violated FINRA Rule 3110(c) are ineligible to participate. Participating firms must also comply with firm- level conditions to participate in the program. For example, a firm must have a recordkeeping system that keeps records current and promptly accessible, and that does not maintain physical or electronic records at the location subject to remote inspection. Additionally, participating firms must have firm-wide tools such as electronic recordkeeping systems, system security tools such as secure network connections and effective cybersecurity protocols, and tools specifically applied to each office or location based on the activities of associated persons, products offered, or any restrictions on the activity of the office or location.[33]
- Location Level Requirements. Participating firms must exclude from participating in the program any locations that do not meet the location level eligibility criteria set forth in FINRA Rule 3110.18(g)(1) (*e.g.,* the location includes: (i) persons subject to a disciplinary action, a statutory disqualification, or a mandated heightened supervisory plan; (ii) persons engaged in proprietary trading; or (iii) the handling of customer funds or securities). Additionally, eligible locations must use the firm's electronic communication system and may not maintain any original copies of books or records at the location.[34]
- Data and Information Collection Requirement. Participating firms must collect and on a quarterly basis produce to FINRA data consisting of separate counts for OSJs, supervisory branch offices, non-supervisory branch offices, and non-branch locations. This data must include information about the number of remote inspections conducted and any significant findings. Firms shall establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with the data collection and transmission requirements.[35]
- Election to Participate in Remote Inspections Pilot Program. Participating firms must opt-in to the pilot program in a manner specified by FINRA.[36]
- Failure to Satisfy Conditions and Determination of Ineligibility. Participating firms that fail to satisfy terms of the Remote Inspections Pilot Program will be ineligible to participate in the pilot program and return to

[24] *See Id.*

[25] *See* Remote Inspections Pilot Program Approval Order, *supra* note 4.

[26] *See* FINRA Regulatory Notice 24–02.

[27] *See* Remote Inspections Pilot Program Proposal, *supra* note 4.

[28] *See Id.*

[29] *See* FINRA Rule 3110.18(b).

[30] *See* FINRA Rule 3110.18(c).

[31] *See* FINRA Rule 3110.18(d).

[32] *See* FINRA Rule 3110.18(e).

[33] *See* FINRA Rule 3110.18(f).

[34] *See* FINRA Rule 3110.18(g).

[35] *See* FINRA Rule 3110.18(h).

[36] *See* FINRA Rule 3110.18(i).

conducting only on-site inspections.[37] FINRA may also make a determination to revoke a member's eligibility to participate if FINRA finds it to be in the public interest.[38]

• Definitions of Pilot Year periods. Includes clarifications that Pilot Year 1 is the second half of 2024, and Pilot Year 4 is the first half of 2027.[39]

Proposal

The Exchange now proposes to adopt subparagraph (d)(7) of Exchange Rule 1308. This proposed new paragraph reads as follows:

Members that are obligated to conduct an inspection of an office of supervisory jurisdiction, branch office or non-branch location pursuant to, as applicable, Rule 1308(d)(1), (2), and (3) may satisfy such obligation by participating in the FINRA Remote Inspections Pilot Program, as set forth in FINRA Rule 3110.18. The FINRA Remote Inspections Pilot Program shall cover required inspections of such offices or locations for a period of three years starting on [effective date] (''pilot period''), and such pilot period shall expire on July 1, 2027. If the pilot period is not extended, this subparagraph will automatically sunset on July 1, 2027. Members will not be able to participate in the FINRA Remote Inspections Pilot Program after such date.[40]

As stated in proposed new Exchange Rule 1308(d)(7), any Member that participates in the FINRA Remote Inspections Pilot Program, thereby satisfying the annual branch office inspections requirements in FINRA Rule 3110(c), will satisfy the equivalent annual branch office inspections requirements in Exchange Rule 1308(d).

The Exchange is not proposing to add the entire FINRA Remote Inspections Pilot Program to its rules, because it would be unnecessarily duplicative and burdensome for Members to submit the data and information required as part of the Remote Inspections Pilot Program to both the Exchange and FINRA.[41] The Exchange understands that adopting proposed paragraph (d)(7) of Exchange Rule 1308 would update Rule 1308 so that it remains substantially similar to FINRA Rule 3110, such that they remain common rules subject to the 17d–2 Agreement.[42] As a result, regulatory responsibility for Exchange Rule 1308(d) would continue to be allocated to FINRA.

As noted above, all Members were temporarily eligible to conduct remote office inspections until June 30, 2024. This proposed rule change would allow those Members who have enrolled in FINRA's Remote Inspections Pilot Program to continue to use remote inspections as part of an effective supervisory system.[43] The Exchange believes this Remote Inspections Pilot Program is a reasonable alternative for firms to fulfill their Rule 1308(d) obligations while permitting FINRA to collect data as the regulatory authority in this area under the 17d–2 Agreement to assess the efficacy and long-term viability of a permanent remote office inspections program. The Exchange emphasizes that the inspection requirement is one aspect of a firm's overall supervisory system, and that the inspection, whether done in accordance with the FINRA Remote Inspections Pilot Program, or on-site, would be held to the existing standards of review under Exchange Rule 1308(d).[44]

Adopt FINRA's RSL Classification

The Exchange proposes to adopt paragraph (d)(8) of Rule 1308, which would allow a location that is the private residence of a person associated with a Member where supervisory activities are conducted, including those described in proposed Rule 1306(j)(4) through (7) or Rule 1306(c)(2), that satisfies the conditions for designation as RSL set forth in FINRA Rule 3110.19 to also be considered a non-branch location (*i.e.,* an unregistered office) for those activities under the Exchange rules. Without this proposed rule change, any private residence at which a person associated with a member conducts supervisory activities is subject to registration, an annual inspection and, in some cases, additional licensing requirements.[45] As described below, adding proposed paragraph (d)(8) of Rule 1308 would harmonize the Exchange's internal inspections obligations for its Members with FINRA's comparable obligations for its members, thereby avoiding confusion to Members with respect to the applicability of FINRA's new RSL designation with respect to compliance with Rule 1308(d).[46] Additionally, because proposed paragraph (d)(8) of Rule 1308 would incorporate by reference FINRA Rule 3110.19, this rule change would enable Exchange Rule 1308 to continue to be incorporated into the 17d–2 agreement.[47]

Background

Early in 2020, the COVID–19 pandemic prompted FINRA to provide temporary relief to member firms from certain regulatory requirements to address the public health crisis.[48] As mentioned above, FINRA subsequently adopted temporary relief to allow remote inspections of an OSJ, branch office, or non-branch location for calendar years 2020 and 2021;[49] FINRA extended the temporary relief several times to include calendar years 2022, 2023, and the first half of 2024.[50] The Exchange, following FINRA, offered its Members the same temporary relief to allow remote inspections of OSJs, branch offices, and non-branch locations for calendar years 2021, 2022, 2023, and until June 30, 2024.[51] FINRA

[37] *See* FINRA Rule 3110.18(j).

[38] *See* FINRA Rule 3110.18(k).

[39] *See* FINRA Rule 3110.18(l).

[40] Proposed Exchange Rule 1308(d)(6).

[41] Pursuant to this proposed rule change, Members will be required to collect and on a quarterly basis produce to FINRA data regarding its participation in the Remote Inspections Pilot Program. *See* FINRA Rule 3110.18(h). But Members will not be required to produce that information directly to the Exchange.

[42] *See* supra note 6.

[43] The Exchange notes that any inspections conducted by its Members in the brief period between July 1, 2024 and the effective date of this filing will not satisfy Exchange Rule 1308(d), but believes this will not be an issue for its Members because the remote inspections process outlined in the pilot program is an ongoing process that cannot be completed in the few days between the start of the FINRA's pilot program and the effectiveness of this rule filing.

[44] Those standards provide, in part that based on the factors set forth under Exchange Rule 1308(d)(6)(ii), Members ''may need to provide for more frequent monitoring or oversight of that office or location.''

[45] *See* Exchange Rules 1306(d) and 1308(d)(1).

[46] The Exchange notes that all Members are currently FINRA members.

[47] *See supra* note 6.

[48] Among the temporary regulatory relief provided, FINRA adopted relief pertaining to branch office registration requirements through Form BR (Uniform Branch Office Registration Form) and FINRA Rule 3110(c) inspection requirements. Specifically, FINRA temporarily suspended the requirement for member firms to submit branch office applications on Form BR for any newly opened temporary office locations or space-sharing arrangements established as a result of the pandemic. *See* Regulatory Notice 20–08 (March 2020). With respect to inspection obligations, FINRA adopted temporary Rule 3110.16 that provided additional time for member firms to complete their calendar year 2020 inspection obligations. *See* Securities Exchange Act Release No. 89188 (June 30, 2020), 85 FR 40713 (July 7, 2020) (SR–FINRA–2020–019).

[49] *See* Securities Exchange Act Release No. 90454 (November 18, 2020), 85 FR 75097 (November 24, 2020) (SR–FINRA–2020–040).

[50] *See* Securities Exchange Act Release No. 96241 (November 4, 2022), 87 FR 67969 (November 10, 2022) (SR–FINRA–2022–030); Securities Exchange Act Release No. 93002 (September 15, 2021), 86 FR 52508 (September 21, 2021) (SR–FINRA–2021–023); Securities Exchange Act Release No. 94018 (January 20, 2022), 87 FR 4072 (January 26, 2022) (SR–FINRA–2022–001); and Securities Exchange Act Release No. 98560 (September 27, 2023), 88 FR 68258 (October 3, 2023) (SR–FINRA–2023–012).

[51] *See* Securities Exchange Act Release Nos. 90937 (January 15, 2021), 86 FR 6944 (January 25, 2021) (SR–MIAX–2021–01) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 1308, Supervision of Accounts, To Adopt Temporary Rules To Extend the Time by Which Members Must Complete Their Branch Office Inspections for the Calendar Year 2020 and To Provide Temporary Remote Inspection Relief for Their Office Inspections for Calendar

replaced the temporary remote inspections relief with the Remote Inspections Pilot Program [52] that impacts the internal inspections requirements of FINRA Rule 3110(c); the Exchange proposes to amend its supervision rules such that any Member that participates in the FINRA pilot shall be deemed to satisfy the equivalent internal inspection requirements in Exchange Rule 1308(d) as above.

In response to the pandemic, many private and government employers closed their offices and their employees continued with their work from alternative locations such as private residences. The Exchange, like FINRA, believes this model will endure, irrespective of the state of the pandemic. The pandemic accelerated reliance on technological advances in surveillance and monitoring capabilities and prompted significant changes in lifestyles and work habits, including the growing expectation for workplace flexibility. Moreover, the technology advancements that facilitated the transition to working outside the conventional office setting on a broad scale have not only effected a profound change in lifestyle and workplace practices for member firms, but provided SROs such as FINRA and the Exchange an opportunity to consider aspects of their supervision rules that may benefit from modernization.[53] As such, the Exchange, like FINRA, believes measured changes to its regulatory approach would allow firms to effectively and more efficiently carry out their supervisory responsibilities to review the activities of each office or location while preserving investor protections.

Years 2020 and 2021); 94251 (February 15, 2022), 87 FR 9764 (February 22, 2022) (SR–MIAX–2022–09) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by Miami International Securities Exchange, LLC To Amend Exchange Rule 1308, Supervision of Accounts); 96867 (February 9, 2023), 88 FR 9919 (February 15, 2023) (SR–MIAX–2023–04) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 1308, Supervision of Accounts); and 99548 (February 15, 2024), 89 FR 13386 (February 22, 2024) (SR–MIAX–2024–10) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rule1308 To Extend the Temporary Remote Inspection Relief for Members Through June 30, 2024).

[52] *See* FINRA Rule 3110.18.

[53] *See* Securities Exchange Act Release No. 97237 (March 31, 2023), 88 FR 20568 n. 8 (April 6, 2023) (SR–FINRA–2023–006) (''FINRA RSL Proposal'') (describing FINRA's ''practice of periodically reviewing its rules to ensure they continue to promote their intended investor protection objectives in a manner that is effective and efficient, without imposing undue burdens, particularly in light of technological, industry and market changes.'')

Requirements To Register and Inspect Offices

Exchange Rule 1308 requires a Member, regardless of size or type, to have a supervisory system for the activities of its associated persons. Proposed Exchange Rule 1306(a) would set forth the minimum requirements of a Member's supervisory system that includes registering a location as an OSJ or branch office that meets the definitions under paragraph (c) and proposed paragraph (j) of Exchange Rule 1306. Proposed Exchange Rule 1308(d) would require Members to inspect all offices and locations. The proposed rule would categorize offices or locations as an OSJ or supervisory branch office, a non-supervisory branch office, or a non-branch location.[54] The requirements to register, inspect and have a principal on-site vary based on the categorization. Specifically, proposed Rule 1306(a) would require the registration as an OSJ or branch office of each location, that meets their respective definition under paragraph (c) and proposed paragraph (j) of Exchange Rule 1306, as described in more detail below.[55]

An OSJ is a type of branch office. The Exchange defines a ''branch office'' as ''any location where one or more associated persons of a Member regularly conduct the business of effecting any transactions in, or inducing or attempting to induce the purchase or sale of any security, or is held out as such[.]'' [56] In addition, any location that is responsible for supervising the activities of persons associated with a Member at one or more non-branch locations of such Member is considered to be a branch office.[57] A location registered as a branch office must file with the Exchange and keep current a list of each of its branch offices showing the location of each such office and the name of the manager of each such office,[58] and is subject to an inspection at least every three years, unless it is a supervisory branch office in which case it is subject to at least an annual inspection.[59]

Depending upon the functions occurring at a branch office, it may be further classified as an OSJ. As described above, proposed paragraph (j) of Rule 1306 would define as any office of a member at which any one or more of the following functions take place: (1) order execution or market making; (2) structuring of public offerings or private placements; (3) maintaining custody of customers' funds or securities; (4) final acceptance (approval) of new accounts on behalf of the Member; (5) review and endorsement of customer orders; (6) final approval of retail communications for use by persons associated with the Member, pursuant to FINRA Rule 2210(b)(1), except for an office that solely conducts final approval of research reports; or (7) responsibility for supervising the activities of persons associated with the Member at one or more other branch offices of the Member.[60] Under the proposed rule change, each OSJ would need to be inspected at least annually.[61]

However, subject to specified conditions, an office or location may be deemed a ''non-branch location,'' and excluded from registration as a branch office. Currently, Exchange Rule 1306(c) sets forth seven exclusions—often referred to as unregistered offices or non-branch locations—of which two pertain to residential locations.[62] One such exclusion appears under Exchange Rule 1306(c)(2) and exempts from registration as a branch office an associated person's primary residence subject to the following express conditions: (1) only one associated person, or multiple associated persons who reside at that location and are members of the same immediate family, conduct business at the location; (2) the location is not held out to the public as an office and the associated person does not meet with customers at the location; (3) neither customer funds nor securities are handled at that location; (4) the associated person is assigned to a

[54] *See* proposed Exchange Rules 1308(d)(1), (2), and proposed paragraph (3).

[55] *See* Exchange Rule 1306(a).

[56] *See* Exchange Rule 1306(c).

[57] *See* Exchange Rule 1306(d).

[58] *See* Exchange Rule 1306(a).

[59] *See* proposed Exchange Rules 1308(d)(1) and (2).

[60] *See* proposed Exchange Rules 1306 (j)(1)–(7).

[61] *See* proposed Exchange Rule 1308(d)(1).

[62] *See* generally Rule 1306(c)(1) and Rule 1306(c)(4)(7) which, in addition to the primary residence and the non-primary residence exclusions that are further described, excludes the following from the definition of ''branch office'': (1) any location that is established solely for customer service or back office type functions where no sales activities are conducted and that is not held out to the public as a branch office; (2) any office of convenience, where associated persons occasionally and exclusively by appointment meet with customers, which is not held out to the public as an office; (3) any location that is used primarily to engage in non-securities activities and from which the associated person(s) effects no more than 25 securities transactions in any one calendar year; provided that any retail communication identifying such location also sets forth the address and telephone number of the location from which the associated person(s) conducting business at the non-branch locations are directly supervised; (4) the Floor of a registered national securities exchange where a member conducts a direct access business with public customers; or (5) a temporary location established in response to the implementation of a business continuity plan.

designated branch office, and such designated branch office is reflected on all business cards, stationery, retail communications and other communications to the public by such associated person; (5) the associated person's correspondence and communications with the public are subject to all supervisory provisions of the Exchange's Rules; (6) electronic communications (*e.g.,* email) are made through the Member's electronic system; (7) all orders are entered through the designated branch office or an electronic system established by the Member that is reviewable at the branch office; (8) written supervisory procedures pertaining to supervision of sales activities conducted at the residence are maintained by the Member; and (9) a list of the residence locations is maintained by the Member (''primary residence exclusion'').[63] The second exclusion that pertains to a residential location appears under Rule 1306(c)(3) is any location, other than a primary residence, that is used for securities business for less than 30 business days in any one calendar year, provided that the Member complies with the provisions of (ii) through (viii) of Exchange Rule 1306(c) (2) (''non-primary residence exclusion'').[64] In general, the non-primary residence exclusion typically refers to a vacation or second home.[65] Under the proposed rule change, a non-branch location would need to be inspected on a periodic schedule, presumed to be at least every three years.[66]

Notwithstanding either of these two residential exclusions or the other exclusions listed under Exchange Rule 1306(c)(1),[67] a primary or non-primary residence location that is responsible for either the supervisory activities set forth in the OSJ definition or for supervising the activities of persons associated with the Member at one or more non-branch locations of the Member is considered an OSJ or (supervisory) branch office, respectively.[68] Consequently, such residential supervisory offices would be subject to registration, an annual inspection and, in some cases, additional licensing requirements.[69]

FINRA Residential Supervisory Location Rule

Effective June 1, 2024, FINRA implemented a rule change that establishes a new RSL designation for a private residence at which an associated person engages in specified supervisory activities, subject to specified investor protection safeguards and limitations.[70] This new non-branch location designation targets the subset of residential locations that have many of the attributes contained in the primary residence exclusion, but must be registered as an OSJ or branch office because of the supervisory functions taking place there.

As described in the FINRA RSL Proposal,[71] the definition of an RSL is based largely on several existing aspects of FINRA Rule 3110(f) (and therefore on the functionally identical to Exchange Rule 1306). In particular, the RSL definition incorporates the existing supervisory functions appearing in the OSJ definition (FINRA Rule 3110(f)(1)) and branch office definition (FINRA Rule 3110(f)(2)(A)) with the existing residential exclusions set forth in the branch office definition to classify an RSL as a non-branch location. Under current Exchange rules, a private residence at which these supervisory functions occur must be registered as a branch office under Exchange Rule 1306(d), and inspected at least annually under proposed Exchange Rule 1308(d)(1). By treating such location as a non-branch location, the private residence would become subject to inspections on a regular periodic schedule under proposed Exchange Rule 1308(d)(3).[72]

FINRA Rule 3110.19 incorporates some existing safeguards and limitations members must already satisfy to rely on the primary residence exclusion.[73] As described in the FINRA RSL Proposal, FINRA intends for the terms underlying the RSL designation to be interpreted consistently with their meaning in FINRA Rule 3110(f) and existing related guidance.[74] The requirements for designation of a location as an RSL, which are set forth in FINRA Rule 3110.19, include the following key elements:

- A location where supervisory activities are conducted shall be considered for those activities a non-branch location provided that:[75]
  - only one associated person (or members of the same immediate family) may conduct business at the location;[76]
  - the location is not held out to the public as an office:[77]
  - the associated person does not meet with customers or prospective customers at the location;[78]
  - any sales activity that takes place at the location complies with the conditions set forth under FINRA Rule 3110(f)(2)(A)(ii) (the primary residence exclusion[79]) or FINRA Rule 3110(f)(2)(A)(iii) (the non-primary residence exclusion;[80])[81]
  - neither customer funds nor securities are handled at that location;[82]
  - the associated person is assigned to a designated branch office, and such designated branch office is reflected on all business cards, stationery, retail communications and other communications to the public by such associated person;[83]
  - the associated person's correspondence and communications with the public are subject to the firm's supervision in accordance with FINRA's supervision rule;[84]
  - the associated person's electronic communications are made through the member's electronic system;[85]
  - the member must have a recordkeeping system to make and keep current, and preserve records required to be made and kept current, and preserved under applicable securities laws and regulations, FINRA rules, and the member's own written supervisory procedures under Rule 3110; such records are not physically or electronically maintained and preserved at the office or location; and the member has prompt access to such records;[86] and
  - the member must determine that its surveillance and technology tools are appropriate to supervise the types of risks presented by each Residential Supervisory Location, and these tools may include but are not limited to: firm-wide tools such as, electronic recordkeeping system; electronic surveillance of email and correspondence; electronic trade

[63] *See* Exchange Rule 1306(c)(2)(i)–(ix). The primary residence exclusion is also set forth in FINRA Rule 3110(f)(2)(A)(ii).

[64] *See* Exchange Rule 1306(c)(3).

[65] *See* NASD [FINRA] Notice to Members 06–12 (March 2006).

[66] *See* proposed Exchange Rule 1308(d)(3).

[67] *See* generally Exchange Rule 1306(c)(1) and Exchange Rules 1306(c)(4)–(7).

[68] *See* proposed Exchange Rules 1306(j)(4)–(7).

[69] *See* proposed Exchange Rule 1308(d)(1) and Exchange Rule 1306(d).

[70] *See* FINRA Regulatory Notice 24–02.

[71] *See* Securities Exchange Act Release No. 97237 (March 31, 2023), 88 FR 20568 n. 8 (April 6, 2023) (SR–FINRA–2023–006) (''FINRA RSL Proposal'').

[72] *See* proposed Exchange Rule 1308(d)(3).

[73] *See* FINRA Rule 3110(f)(2)(A)(ii)a., b., c., d., e., f., and i.

[74] *See, e.g.,* NASD [FINRA] Notice to Members 06–12 (March 2006).

[75] *See* FINRA Rule 3110.19(a).

[76] *See* FINRA Rule 3110.19(a)(1).

[77] *See* FINRA Rule 3110.19(a)(2).

[78] *See* FINRA Rule 3110.19(a)(3).

[79] *See* Exchange Rule 1306(c)(2)(i)–(ix).

[80] *See* Exchange Rule 1306(c)(3).

[81] *See* FINRA Rule 3110.19(a)(4).

[82] *See* FINRA Rule 3110.19(a)(5).

[83] *See* FINRA Rule 3110.19(a)(6).

[84] *See* FINRA Rule 3110.19(a)(7).

[85] *See* FINRA Rule 3110.19(a)(8).

[86] *See* FINRA Rule 3110.19(a)(9).

blotters; regular activity-based sampling reviews; and tools for visual inspections; tools specific to the RSL based on the activities of associated person assigned to the location, products offered, restrictions on the activity of the RSL; and system tools such as secure network connections and effective cybersecurity protocols.[87]

• FINRA members shall not be eligible to designate an office or location as an RSL if, among other things, the FINRA member is designated as: (i) Restricted Firm under FINRA Rule 4111 or (ii) a Taping Firm under FINRA Rule 3170. Additionally, firms with suspended or new (effective less than 12 months) FINRA memberships or that have been found within the past three years by the SEC or FINRA to have violated FINRA Rule 3110(c) are ineligible to participate.[88]

• An office or location shall not be eligible for designation as an RSL if one or more associated persons at such office or location: [89]

○ is a designated supervisor who has less than one year of direct supervisory experience with the member, or an affiliate or subsidiary of the member that is registered as a broker-dealer or investment adviser; [90]

○ is functioning as a principal for a limited period in accordance with FINRA Rule 1210.04; [91]

○ is subject to a mandatory heightened supervisory plan under the rules of the SEC, FINRA or state regulatory agency; [92]

○ is statutorily disqualified, unless such disqualified person has been approved (or is otherwise permitted pursuant to FINRA rules and the federal securities laws) to associate with a member and is not subject to a mandatory heightened supervisory plan under FINRA Rule 3110.19(c)(3) or otherwise as a condition to approval or permission for such association; [93]

○ has an event in the prior three years that required a ''yes'' response to any item in Questions 14A(1)(a) and 2(a), 14B(1)(a) and 2(a), 14C, 14D and 14E on Form U4; [94] or

○ has been notified in writing that such associated person is now subject to, any Investigation or Proceeding, as such terms are defined in the Explanation of Terms for the Form U4 (Uniform Application for Securities Industry Registration or Transfer), by the SEC, an SRO, including FINRA, or state securities commission (or agency or office performing like functions) (each, a ''Regulator'') expressly alleging they have failed reasonably to supervise another person subject to their supervision, with a view to preventing the violation of any provision of the Securities Act, the Exchange Act, the Investment Advisers Act, the Investment Company Act, the Commodity Exchange Act, any state law pertaining to the regulation of securities or any rule or regulation under any of such Acts or laws, or any of the rules of the MSRB or other self-regulatory organization, including FINRA; provided, however, such office or location may be designated or redesignated as an RSL subject to the requirements of FINRA Rule 3110.19 upon the earlier of: (i) the member's receipt of written notification from the applicable Regulator that such Investigation has concluded without further action; or (ii) one year from the date of the last communication from such Regulator relating to such Investigation.[95]

• FINRA members that elect to designate an office or location of the member as an RSL shall provide FINRA with a current list of all locations designated as RSLs by the 15th day of the month following each calendar quarter in the manner and format as FINRA may prescribe.[96]

• FINRA members must conduct a risk assessment prior to designating an office or location as an RSL. Specifically, the FINRA member must develop a reasonable risk-based approach to designating such office or location as an RSL, and conduct and document a risk assessment for the associated person assigned to that office or location. The assessment must document the factors considered, including among others, whether the associated person at such office or location is now subject to: (1) customer complaints, taking into account the volume and nature of the complaints; (2) heightened supervision other than where such office or location is ineligible for RSL designation under FINRA Rule 3110.19(c)(3); (3) any failure to comply with the member's written supervisory procedures; (4) any recordkeeping violation; and (5) any regulatory communications from a Regulator, indicating that the associated person at such office or location failed reasonably to supervise another person subject to their supervision, including but not limited to, subpoenas, preliminary or routine regulatory inquiries or requests for information, deficiency letters, ''blue sheet'' requests or other trading questionnaires, or examinations. The FINRA member must take into account any higher risk activities that take place or a higher risk associated person that is assigned to that office or location. Consistent with its obligation under FINRA Rule 3110(a), the member's supervisory system must take into consideration any indicators of irregularities or misconduct (*i.e.,* ''red flags'') when designating an office or location as an RSL. Red flags should also be reviewed in determining whether it is reasonable to maintain the RSL designation of such office or location in accordance with the requirements of FINRA Rule 3110.19 and the member should consider evidencing steps taken to address those red flags where appropriate.[97]

Proposal

The Exchange proposes to adopt subparagraph (d)(8) of Exchange Rule 1308. This proposed new paragraph reads as follows:

> Residential Supervisory Location. A location that is the private residence of a person associated with a Member where supervisory activities are conducted, including those described in Rule 1306(j)(4) through (7) or Rule 1306(c)(2), which satisfies the conditions for designation as a Residential Supervisory Location set forth in FINRA Rule 3110.19 shall also be considered a non-branch location for those activities pursuant to the Exchange Rules.[98]

As stated in proposed new paragraph (d)(8) of Rule 1308, any location that a Member designates as an RSL pursuant to FINRA Rule 3110.19 shall also be considered a non-branch location for those activities pursuant to Exchange rules.

Pursuant to this proposed rule change, Members will be required to share information about designated RSLs with FINRA on a quarterly basis. The Exchange is not proposing to add the entire FINRA Residential Supervisory Location designation rule to its rules, because it would be unnecessarily duplicative and burdensome for Members to share the same quarterly RSL designation information with the Exchange. The Exchange understands that adopting paragraph (d)(8) of Rule 1308 would update Exchange Rule 1308 so that it remains substantially similar to FINRA Rule 3110, such that they remain common rules subject to the 17d–2

[87] *See* FINRA Rule 3110.19(a)(10).
[88] *See* FINRA Rule 3110.19(b).
[89] *See* FINRA Rule 3110.19(c).
[90] *See* FINRA Rule 3110.19(c)(1).
[91] *See* FINRA Rule 3110.19(c)(2).
[92] *See* FINRA Rule 3110.19(c)(3).
[93] *See* FINRA Rule 3110.19(c)(4).
[94] *See* FINRA Rule 3110.19(c)(5).
[95] *See* FINRA Rule 3110.19(c)(6).
[96] *See* FINRA Rule 3110.19(d).
[97] *See* FINRA Rule 3110.19(e).
[98] *See* proposed paragraph (d)(8) of Rule 1308.

Agreement. As a result, regulatory responsibility for Exchange Rule 1308 would continue to be allocated to FINRA.

The Exchange, like FINRA, believes that the current work environment merits a reevaluation of the regulatory benefit of requiring firms to designate a private residence, at which specified supervisory functions occur, as an OSJ or branch office. The Exchange's proposal to incorporate by reference FINRA's RSL designation is intended to reflect a pragmatic balance between the hybrid workforce model and the parameters that should ensure that all locations, including residential locations, are appropriately supervised.

Separate and apart from the classification of the office or location and the attendant inspection obligations, Members will continue to have an ongoing obligation to supervise the activities of each associated person in a manner reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable the Exchange and FINRA rules.[99] The Exchange, like FINRA, emphasizes that Members have a statutory duty to supervise their associated persons, regardless of their location, compensation or employment arrangement, or registration status, in accordance with the Exchange and FINRA rules.[100]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)[101] of the Act in general, and furthers the objectives of Section 6(b)(5) of the Act[102] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange's rule proposal is intended to harmonize the Exchange's supervision rules, specifically with respect to the definition of OSJ, the requirements for inspections of Members' all offices and locations, and designation of certain non-branch offices as RSL, with those of FINRA, on which they are based. As discussed in the Purpose section, because proposed Exchange Rules 1308(d)(7) and (8) would incorporate by reference FINRA Rule 3110.18 and 3110.19, the proposed rule changes would enable Exchange Rule 1308 to continue to be incorporated into the 17d–2 Agreement, resulting in less burdensome and more efficient regulatory compliance. Specifically, the proposed change will conform the Exchange's rules to changes made to corresponding FINRA rules insofar as a Member's compliance with FINRA Rule 3110.18 and 3110.19 shall mean the Member would be also in compliance with Exchange Rule 1308, thus promoting the application of consistent regulatory standards with respect to rules that FINRA enforces. Adopting the definition of OSJ is to harmonize Exchange Rule 1306 with FINRA Rule 3110.01 to provide that both branch offices and OSJs will be subject to the office registration requirements set forth in Exchange Rule 1306(a). Adopting FINRA's inspection requirement for non-branch locations is to harmonize Exchange Rule 1308(d) with FINRA Rule 3110(c) so that a Member's compliance with FINRA Rule 3110(c) shall mean the Member would be also in compliance with Exchange Rule 1308(d). As such, the proposed rule changes would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system in accordance with Section 6(b)(5) of the Act.[103]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule changes are not designed to address any competitive issue but rather to provide greater harmonization among the Exchange and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance for common members and facilitating FINRA's performance of its regulatory performance.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[104] and Rule 19b–4(f)(6)[105] thereunder. Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder. In addition, the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing.[106]

A proposed rule change filed under Rule 19b–4(f)(6)[107] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[108] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Exchange stated that this proposed rule change is non-controversial because it does not present any new or novel issues. In particular, MIAX is harmonizing the Exchange's supervision rules with those of FINRA, on which they are based and which have been previously approved by the Commission. By conforming the Exchange's rules to FINRA's, the proposed rule change would promote the application of consistent regulatory standards with respect to rules that FINRA enforces pursuant to the 17d–2 Agreement. As such, the Exchange believes that the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market

[99] *See* FINRA Rule 3110.12.

[100] *See* 15 U.S.C. 78o(b)(4)(E) and 15 U.S.C. 78o(b)(6)(A).

[101] 15 U.S.C. 78f(b).

[102] 15 U.S.C. 78f(b)(5).

[103] 15 U.S.C. 78f(b)(5).

[104] 15 U.S.C. 78s(b)(3)(A).

[105] 17 CFR 240.19b–4(f)(6).

[106] 17 CFR 240.19b–4(f)(6)(iii).

[107] 17 CFR 240.19b–4(f)(6).

[108] 17 CFR 240.19b–4(f)(6)(iii).

system in accordance with Exchange Act Section 6(b)(5).

Further, the Exchange stated that waiver of the operative delay would be consistent with the protection of investors and the public interest because such waiver would allow the Exchange to immediately harmonize its supervision rule with the FINRA rule on which it is based without delay, thereby eliminating the possibility of a significant regulatory gap between the FINRA and Exchange rules, providing more uniform inspection standards across the securities industry, and helping to avoid confusion for Exchange Members that are also FINRA members. For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposed rule change is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[109]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [110] of the Act to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2024–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2024–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.
All submissions should refer to file number SR–MIAX–2024–44 and should be submitted on or before December 30, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[111]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–28769 Filed 12–6–24; 8:45 am]

BILLING CODE 8011–01–P

[109] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[110] 15 U.S.C. 78s(b)(2)(B).

[111] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, December 12, 2024.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: December 5, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–28987 Filed 12–5–24; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101802; File No. SR–CboeBZX–2024–115]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Fee Schedule Relating to Fee Codes and Volume Tiers

December 3, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

notice is hereby given that on November 20, 2024, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BZX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Effective November 1, 2024, the Exchange proposes to amend its Fee Schedule applicable to its equities trading platform by: (i) updating the criteria for BZX Add Volume Tier 3 and Add Volume Tier 5; (ii) removing the rebate and implementing a fee for fee code, AA; and (iii) removing fee code, BJ.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Securities Exchange Act of 1934 (the ''Act''), to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 16% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[5] For orders in securities priced below $1.00, the Exchange does not provide a rebate for orders that add liquidity and assesses a fee of 0.30% of the total dollar value for orders that remove liquidity.[6] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Add/Remove Volume Tiers

Under footnote 1 of the Fee Schedule, the Exchange offers various Add/Remove Volume Tiers. In particular, the Exchange offers nine Add/Remove Volume Tiers that each provide an enhanced rebate for Members' qualifying orders yielding fee codes B,[7] V,[8] and Y,[9] where a Member reaches a certain volume-based criteria offered in each tier.

The Exchange now proposes to update the criteria for Add Volume Tier 3, as follows:

- The current Add Volume Tier 3 provides an enhanced rebate of $0.0027 per share in securities priced at or above $1.00 to qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y), where a Member has an ADAV [10] as a percentage of TCV [11] ≥ 0.30% or a Member has an ADAV ≥ 35,000,000.

Now, the Exchange proposes to amend the second prong of criteria in proposed Add Volume tier 3 by reducing the ADAV requirement. The proposed criteria are as follows:

- Proposed Add Volume Tier 3 provides an enhanced rebate of $0.0027 per share in securities price at or above $1.00 to qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y), where a Member has an ADAV as percentage of TCV ≥ 0.30% or a Member has an ADAV ≥ 30,000,000 (as compared to 35,000,000).

In addition, the Exchange also proposes to update the criteria for Add Volume Tier 5, as follows:

- The current Add Volume Tier 5 provides an enhanced rebate of $0.0029 per share in securities priced at or above $1.00 to qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y), where a Member has an ADAV as a percentage of TCV ≥ 0.35% or a Member has an ADAV ≥ 40,000,000.

Now, the Exchange proposes to amend the second prong of criteria in proposed Add Volume Tier 5 by reducing the ADAV requirement. The proposed criteria are as follows:

- Proposed Add Volume Tier 5 provides an enhanced rebate of $0.0029 per share in securities priced at or above $1.00 to qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y), where a Member has an ADAV as a percentage of TCV ≥ 0.35% or a Member has an ADAV ≥ 35,000,000 (as compared to 40,000,000).

[3] The Exchange initially filed the proposed fee change on November 1, 2024 (SR–CboeBZX–2024–110). On November 14, 2024, the Exchange withdrew SR–CboeBZX–2024–110 and submitted SR–CboeBZX–2024–114. On November 20, 2024, the Exchange withdrew SR–CboeBZX–2024–114, and submitted this filing.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (June 21, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[5] *See* BZX Equities Fee Schedule, Standard Rates, available at: .

[6] *Id.*

[7] Fee code B is appended to displayed orders that add liquidity to BZX (Tape B). Orders appended with fee code, B, for securities priced below $1.00 neither pay a fee nor receive a rebate.

[8] Fee code V is appended to displayed orders that add liquidity to BZX (Tape A). Orders appended with fee code, B, for securities priced below $1.00 neither pay a fee nor receive a rebate

[9] Fee code Y is appended to displayed orders that add liquidity to BZX (Tape C). Orders appended with fee code, B, for securities priced below $1.00 neither pay a fee nor receive a rebate

[10] ADAV means average daily added volume calculated as the number of shares added per day, calculated on a monthly basis.

[11] TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which fees apply.

The proposed amended ADAV requirements for Add Volume Tier 3 and Add Volume Tier 5 are intended to incentivize Members to earn an enhanced rebate by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. Incentivizing an increase in liquidity adding volume through enhanced rebate opportunities encourages liquidity-adding Members to increase transactions and take execution opportunities provided by such increased liquidity, together providing for overall enhanced price discovery and price improvement opportunities on the Exchange. As such, increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem. While the proposed criteria in Add Volume Tier 3 and Add Volume Tier 5 is less difficult to achieve than the current criteria, the revised criteria continue to remain commensurate with rebates (which remain unchanged) that will be paid to a Member satisfying the proposed criteria.

Fee Codes

The Exchange also proposes to modify the rebate for fee code, AA. The proposed changes are as follows:

• For securities priced above $1.00,[12] fee code AA is appended to orders that are routed to EDGA using the ALLB [13] routing strategy. Currently, orders appended with fee code AA receive a rebate of $0.0016.

The Exchange now proposes to amend fee code, AA, as follows:

• For securities priced above $1.00, fee code AA will continue to be appended to orders that are routed to EDGA using the ALLB routing strategy. However, orders appended with fee code AA will now pay a fee of $0.0030. The Exchange does not propose to add a fee or rebate for removing liquidity for securities priced below $1.00.

The Exchange also proposes to remove fee code, BJ. For securities priced above $1.00,[14] fee code BJ is currently appended to orders that are routed to EDGA using the TRIM [15] or SLIM [16] routing strategies. Currently, orders appended with fee code, BJ, receive a rebate of $0.0016. However, effective November 1, 2024,[17] EDGA will be transitioning from an inverted fee model [18] to a maker taker fee model.[19] As such, orders that remove liquidity from EDGA will pay a remove fee, rather than receive a rebate. Because Members typically utilize routing options TRIM and SLIM, and fee code BJ, to seek low-cost executions, it does not make sense to maintain fee code, BJ, as Members would not expect to pay a fee for removing liquidity from EDGA. Therefore, the Exchange proposes to discontinue this fee code, as it is no longer necessary, and BZX does not desire to charge such orders a fee for removing liquidity from EDGA.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4) [23] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to adjust the criteria to Add Volume Tier 3 and Add Volume Tier 5 reflects a competitive pricing structure designed to incentivize current levels of liquidity provision, as well as encourage Members to add even more volume on the Exchange, by offering Members an enhanced rebated for reaching a reduced ADAV volume threshold Tier 3, 30,000,000 compared to 35,000,000; Tier 5: 40,000,000 compared to 45,000,000). In turn, such liquidity provision will help contribute to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[24] including the Exchange,[25] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

The Exchange believes that its proposal to update the criteria for Add Volume Tier 3 and Add Volume Tier 5

[12] The Exchange notes for securities priced below $1.00, there is no fee or rebate for removing liquidity from EDGA using the ALLB routing strategy.

[13] ALLB is a routing option under which an order checks the System for available shares and is then sent to Cboe BZX Exchange, Inc., Cboe EDGA Exchange, Inc., and/or Cboe EDGX Exchange, Inc., in accordance with the System routing table. If shares remain unexecuted after routing, they are posted on the BZX Book, unless otherwise instructed by the User. *See* Rule 11.13(b)(3)(O).

[14] For securities priced below $1.00, there is no fee or rebate.

[15] TRIM is a routing strategy under which an order checks EDGA for available shares if so instructed by the entering User, and then is sent to destinations on the applicable System routing table. *See generally* Rule 11.13(b)(3)(G).

[16] SLIM is a routing strategy under which an order checks EDGA for available shares if so instructed by the entering User, and then is sent to destinations on the applicable System routing table. *See generally* Rule 11.13(b)(3)(G).

[17] *See* SR–CboeEDGA–2024–042; *see also,* SR–CboeEDGA–2024–045.

[18] The inverted fee model is a pricing structure in which a market, such as an exchange, charges its participants a fee to provide liquidity in securities, and provides a rebate to participants that remove liquidity in securities. *See* SEC Market Structure Advisory Committee, Memorandum on ''Maker-Taker Fees on Equities Exchanges,'' October 20, 2015, available at: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-fees-on-equities-exchanges.pdf.*

[19] The maker-taker fee model is a pricing structure in which a market, such as an exchange, generally pays its members a per share rebate to provide (*i.e.,* ''make'') liquidity in securities and assesses on them a fee to remove (*i.e.,* ''take'') liquidity. *Id.*

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] 15 U.S.C. 78f(b)(4).

[24] *See e.g.,* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[25] *See e.g.,* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

is reasonable as the proposed criteria does not represent a significant departure from the criteria currently offered in the Fee Schedule. The Exchange also believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members will be eligible for the proposed Add Volume Tier 3 and Add Volume Tier 5 and have the opportunity to meet the tiers' criteria and receive the corresponding enhanced rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitively result in any Members qualifying for proposed Add Volume Tier 3 and Add Volume Tier 5. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on the prior month's volume, the Exchange anticipates that at least one Member will be able to satisfy the proposed Add Volume Tier 3 and Add Volume Tier 5. The Exchange also notes that proposed changes will not adversely impact any Member's ability to qualify for enhanced rebates offered under other tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

Adjusting fee code AA and removing fee code, BJ, is necessary to reflect the transition of EDGA to a maker-taker fee model, effective November 1, 2024. Prior to the November 1, 2024, orders entered onto BZX, that were appended with fee code, AA, and were routed to EDGA using routing option ALLB, received a rebate of $0.0016 for removing liquidity from the EDGA Book for securities priced at or above $1.00. However, given EDGA's transition to a maker-taker fee model, orders that remove liquidity will now need to pay a liquidity removal fee, rather than receive a rebate. Accordingly, removal of the current $0.0016 rebate associated with fee code, AA, and implementation of a $0.0030 remove fee is appropriate and consistent with the economics of a maker-taker model, as well as the expectations of Members that remove liquidity from EDGA (*i.e.,* Members would expect to pay a fee to remove liquidity). Moreover, the proposed fee is not unfairly discriminatory because it applies to all Members equally, in that all Members will pay the same fee for orders routed to EDGA using the ALLB routing strategy, and appended with fee code, AA.

The Exchange also believes that its removal of fee code, BJ, is reasonable, equitable, and not unfairly discriminatory as it does not change the fees or rebates assessed by the Exchange, but rather updates the BZX Fee Schedule to remove a fee code that the Exchange no longer desires to, nor is required to, offer to its Members. Therefore, the proposed rule change is reasonably designed to update the Fee Schedule to accurately reflect the Exchange's current product offerings and is designed to reduce any potential confusion regarding the routing of orders with fee code, BJ, from BZX to EDGA. Furthermore, as noted above, orders appended with fee code, BJ, entered onto BZX and routed to EDGA using the routing option TRIM or SLIM, previously received a rebate of $0.0016 for removing liquidity from the EDGA Book. However, effective November 1, 2024, EDGA transitioned from an inverted fee model to a maker taker fee model. As such, orders that remove liquidity from EDGA will pay a remove fee, rather than receive a rebate. Because Members typically utilize routing options TRIM and SLIM, and fee code BJ, to seek low-cost executions, it does not make sense to maintain the BJ fee code, as Members utilizing this fee code would not expect to pay a fee for removing liquidity from EDGA. Therefore, the Exchange proposes to discontinue this fee code, as it is no longer necessary, and BZX does not desire to charge such orders a fee for removing liquidity from EDGA.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed changes will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed modifications to Add Volume Tier 3 and Add Volume Tier 5 would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. Additionally, the proposed changes to Add Volume Tier 3 and Add Volume Tier 5 do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the Exchange's proposal to modify the criteria for Add Volume Tier 3 and Add Volume Tier applies to all Members equally. All Members will be eligible for the modified tier and have a reasonable opportunity to meet the proposed tier's reduced criteria and receive the enhanced rebate on their qualifying orders if such criteria is met. In addition, the Exchange does not believe the proposed changes to Add Volume Tier 3 and Add Volume Tier 5 burden competition, but rather, enhance competition as these changes are intended to increase the competitiveness of BZX by amending existing pricing incentives in order to attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

Furthermore, the Exchange believes the proposed changes to Add Volume Tier 3 and Add Volume Tier 5 do not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 16% of the market share.[26] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [27] The fact that this market is competitive has

[26] *Supra* note 3.

[27] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[28] Accordingly, the Exchange does not believe its proposed fee changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed adjustment to the AA fee will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Given EDGA's transition to a maker-taker fee model, orders that remove liquidity will now need to pay a liquidity removal fee, rather than receive a rebate. Accordingly, removing the current $0.0016 rebate associated with fee code, AA, and implementing a $0.0030 remove fee is appropriate and consistent with the economics of a maker-taker model, as well as the expectations of Members that remove liquidity from EDGA (*i.e.,* Members would expect to pay a fee to remove liquidity). Moreover, the proposed fee is not unfairly discriminatory because it applies to all Members equally, in that all Members will pay the same fee for orders routed to EDGA using the ALLB routing strategy, and appended with fee code, AA.

The Exchange also believes that its removal of fee code, BJ, is reasonable, equitable, and not unfairly discriminatory as it does not change the fees or rebates assessed by the Exchange, but rather updates the BZX Fee Schedule to remove a fee code that the Exchange no longer desires to, nor is required to, offer to its Members. Therefore, the proposed rule change is reasonably designed to update the Fee Schedule to accurately reflect the Exchange's current product offerings and is designed to reduce any potential confusion regarding the routing of orders with fee code, BJ, from BZX to EDGA. Furthermore, as noted above, orders appended with fee code, BJ, entered onto BZX and routed to EDGA using the routing option TRIM or SLIM, previously received a rebate of $0.0016 for removing liquidity from the EDGA Book. However, effective November 1, 2024, EDGA transitioned from an inverted fee model to a maker taker fee model. As such, orders that remove liquidity from EDGA will pay a remove fee, rather than receive a rebate. Because Members typically utilize routing options TRIM and SLIM, and fee code BJ, to seek low-cost executions, it does not make sense to maintain the BJ fee code, as Members utilizing this fee code would not expect to pay a fee for removing liquidity from EDGA. Therefore, the Exchange proposes to discontinue this fee code, as it is no longer necessary, and BZX does not desire to charge such orders a fee for removing liquidity from EDGA.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[29] and paragraph (f) of Rule 19b–4[30] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–115 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–115. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–115 and should be submitted on or before December 30, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–28768 Filed 12–6–24; 8:45 am]

BILLING CODE 8011–01–P

[28] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[29] 15 U.S.C. 78s(b)(3)(A).

[30] 17 CFR 240.19b–4(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101806; File No. SR–NYSEARCA–2024–70]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the COtwo Advisors Physical European Carbon Allowance Trust Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares)

December 3, 2024.

I. Introduction

On August 19, 2024, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the COtwo Advisors Physical European Carbon Allowance Trust. The proposed rule change was published for comment in the **Federal Register** on September 5, 2024.[3]

On October 16, 2024, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On November 22, 2024, the Exchange filed Amendment No. 1 to the proposed rule change, described in Item II below, which Item has been prepared by the Exchange.[6]

The Commission is publishing this notice and order to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons and to institute proceedings pursuant to Section 19(b)(2)(B) of the Act [7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (''Shares'') of the COtwo Advisors Physical European Carbon Allowance Trust (the ''Trust''), under NYSE Arca Rule 8.201–E, which governs the listing and trading of Commodity-Based Trust Shares.[8]

The Trust was formed as a Delaware statutory trust on January 12, 2023.[9] The Trust has no fixed termination date. The Trust will not be registered as an investment company under the Investment Company Act of 1940, as amended,[10] and is not required to register under such act. The Trust is not a commodity pool for purposes of the Commodity Exchange Act, as amended.[11]

The sponsor of the Trust is COtwo Advisors LLC, a Delaware limited liability company (''Sponsor''). State Street Bank and Trust Company serves as the Trust's administrator (the ''Administrator'') to perform various administrative, accounting and recordkeeping functions on behalf of the Trust. Wilmington Trust serves as trustee of the Trust (the ''Trustee''). State Street Bank and Trust Company serves as the Trust's transfer agent (the ''Transfer Agent'') and as custodian of the Trust's cash, if any (''Cash Custodian'').[12]

The Exchange represents that the Shares will satisfy the requirements of NYSE Arca Rule 8.201–E and thereby will qualify for listing on the Exchange.

Operation of the Trust [13]

The investment objective of the Trust will be for the Shares to reflect the performance of the price of EU Carbon Emission Allowances for stationary installations (''EUAs''), less the Trust's expenses. The Trust intends to achieve its objective by investing all of its assets in EUAs on a non-discretionary basis (*i.e.,* without regard to whether the value of EUAs is rising or falling over any particular period). Shares of the Trust will represent units of fractional undivided beneficial interest in and ownership of the Trust. The Trust's only ordinary recurring expense will be the Sponsor's annual fee. The Trust will not hold any assets other than EUAs and cash. The Trust may purchase or sell EUAs in connection with the creation or redemption of Shares by Authorized Participants (as defined below). In addition to selling EUAs to distribute cash to Authorized Participants redeeming Shares, the Trust may sell EUAs to pay the Sponsor's annual fee. All EUAs will be held in the Union Registry (defined below).

The Trust will not invest in futures, options, options on futures, or swap contracts. The Trust will not hold or trade in commodity futures contracts, ''commodity interests,'' or any other instruments regulated by the Commodity Exchange Act.

The Trust is not a proxy for investing in EUAs. Rather, the Shares are intended to provide a cost-effective means of obtaining investment exposure through the securities markets that is similar to an investment in EUAs. Specifically, the Shares are intended to constitute a simple and cost-efficient means of gaining investment benefits similar to those of holding EUAs directly, by providing investors an opportunity to participate in the EUA market through an investment in the Shares, instead of the traditional means

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 100877 (Aug. 29, 2024), 89 FR 72524. The Commission has not received any comments.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 101360, 89 FR 84406 (Oct. 22, 2024). The Commission designated December 4, 2024, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[6] The full text of Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2024-70/srnysearca202470.htm.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] Commodity-Based Trust Shares are securities issued by a trust that represent investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the trust.

[9] On May 12, 2023, the Trust filed with the Commission a registration statement on Form S–1, as amended on January 16, 2024 and April 4, 2024 (File No. 333–271910) (the ''Registration Statement'') under the Securities Act of 1933 (15 U.S.C. 77a) (the ''Securities Act''). The description of the operation of the Trust herein is based, in part, on the Registration Statement. The Registration Statement in not yet effective and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

[10] 15 U.S.C. 80a–1.

[11] 17 U.S.C. 1.

[12] The Cash Custodian is responsible for holding the Trust's cash as well as receiving and dispensing cash on behalf of the Trust. Deposits of cash held by the Cash Custodian will be used in connection with the purchase of an applicable amount of EUAs for creations and redemptions of Creation Units and in connection with the payment of Trust expenses.

[13] The description of the operation of the Trust, the Shares, and the carbon credit industry contained herein are based, in part, on the Registration Statement. *See* note 9, *supra.*

of purchasing and storing EUAs. Trust shareholders will be exposed to the risks of investing in EUAs, as well as to additional risks that are unrelated to EUAs. For example, the public trading price at which an investor buys or sells Shares during the day from their broker may be different from the value of the Trust's holdings. Price differences may relate primarily to supply and demand forces at work in the secondary trading market for the Trust's Shares that are closely related to, but not identical to, the same forces influencing the prices of EUAs, cash and cash equivalents that constitute the Trust's assets. In addition, EUAs will have to be sold to pay Trust expenses that would not be associated with an investment in EUAs. Additional risks related to the Trust's structure, the Sponsor's management of the Trust, and the tax treatment of an investment in Shares are further in the Registration Statement.

EUAs and the EUA Industry

Description of EU Emissions Trading Scheme

According to the Registration Statement, the European Union Emissions Trading System (''EU ETS'') is a ''cap and trade'' system that caps the total volume of greenhouse gas (''GHG'') emissions from installations and aircraft operators responsible for around 40% of European Union (''EU'') GHG emissions.[14] The EU ETS is the largest cap and trade system in the world and covers more than 11,000 power stations and industrial plants in 31 countries, and flights between airports of participating countries. The EU ETS is administered by the EU Commission, which issues a predefined amount of EUAs through auctions or free allocation. An EUA represents the right to emit one metric ton of carbon dioxide equivalent into the atmosphere by operators of stationary installations (''Covered Entities''). By the end of April each year, all Covered Entities are required to surrender EUAs equal to the total volume of actual emissions from their installation for the last calendar year. EU ETS operators can buy or sell EUAs to achieve EU ETS compliance.

In 2012, EU ETS operations were centralized into a single EU registry operated by the EU Commission (the ''Union Registry''), which covers all countries participating in the EU ETS. According to the Registration Statement, the Union Registry is an online database that holds accounts for all entities covered by the EU ETS as well as for participants (such as the Trust) not covered under the EU ETS. The Union Registry can be accessed online in a similar manner to online banking systems. An account must be opened in the Union Registry by a legal or natural person before being able to participate in the EU ETS and transact in EUAs. The European Union Transaction Log (''EUTL'')[15] checks, records and authorizes all transactions that take place between accounts in the Union Registry to ensure that transfers are in accordance with the EU ETS rules. The Union Registry is at all times responsible for holding the EUAs. All EUAs are held in the Union Registry, regardless of whether the EUAs are acquired through transactions on an exchange or in over-the-counter (''OTC'') transactions.

Major Holders and Allowance Use Cases

According to the Registration Statement, while there is limited publicly available data on individuals or individual organizations' holdings in physical carbon allowances, carbon allowances are primarily held for three different use cases:

(a) Complying with the EU ETS: Companies that need to surrender allowances under the EU ETS hold allowances to surrender them annually. These positions are typically built over time and ultimately surrendered at time of compliance. Therefore, the largest emitters in the EU ETS hold a significant amount of allowances, which include entities such as large utilities with a substantial share of fossil fuel fired power plants, cement companies, steel producers, chemical producers, oil and gas majors and airlines.

(b) Providing financial services for hedging purposes or speculation, such as clearing houses for the European Energy Exchange or the Intercontinental Exchange, or banks holding allowances for their clients.

(c) Trading on and speculating around price moves, using physical emission allowances. This can take many forms, including ''yield trades'', which includes holding a physical allowance and selling an EUA future at a premium to gain the yield in the forward curve; or outright positions for short term or long term speculation.

In addition to holding physical allowances, there is a liquid secondary futures and options market that is primarily used for hedging future emissions or speculating.

Trading Location

According to the Registration Statement, the EU ETS is linked to small emissions trading systems in Europe (Norway, Switzerland, Iceland and Liechtenstein), but not to any other major cap and trade markets. Therefore, allowances handed out in the EU ETS are not transferable to any registry outside of the EU ETS and cannot be used for compliance in any other cap and trade market.

There are a number of other trading systems globally, and like the EU ETS, no allowances of any of these systems can be used in any other system:

(a) Western Climate Initiative (WCI): The State of California and the Canadian province Quebec created a linked cap and trade market, that covers >80% of emissions.

(b) Regional Greenhouse Gas Initiative (RGGI): a group of US east coast states created a linked market that covers power generators only.

[14] There are two types of EU emissions allowance: (i) general allowances for stationary installations, or EUA; and (ii) allowances for the aviation sector (''EUAA''). The Trust will hold EUAs only.

[15] The EUTL is a central transaction log that checks and records all transactions taking place within the EU ETS. It is run by the European Commission and provides an easy access to emission trading data contained in the EUTL. *See https://www.eea.europa.eu/data-and-maps/dashboards/emissions-trading-viewer-1.*

(c) The China National ETS: Technically not a cap and trade scheme (as the amount of allowances is not fixed but calculated according to historic production of units).

(d) South Korea ETS: A comprehensive market covering the majority of Korean emissions.

Pricing of Allowances and Trading Volume

According to the Registration Statement, there are currently two primary avenues for trading EUAs: a primary market and a secondary market. The primary market involves participation in a regularly scheduled auction. The secondary market involves transactions between buyers and sellers on regulated markets. The instruments offered for trading are the following (1) instruments with a daily expiry, including spot EUAs and the Daily EUA Future (as defined below), (2) futures contracts with various maturities; and (3) options on futures contracts. There are also over-the-counter transactions, but they comprise a negligible percentage of transactions.

The spot and futures markets for EUAs have existed since 2005 after the formal launch of the EU ETS on January 1, 2005. Spot EUAs are traded exclusively on the European Energy Exchange AG (''EEX''),[16] and futures contracts and options on futures contracts are traded on EEX, ICE Endex Markets B.V. (''ICE Endex'') [17] and Nasdaq Oslo, although the latter's market share is marginal.

According to the Registration Statement, the EUA markets are generally liquid. The classifications for market participants include five basic categories—(1) investment firms or credit institutions, (2) investment funds, (3) other financial institutions, (4) operators with compliance obligations and (5) commercial undertakings which are non-financial firms without compliance obligations under the EU ETS.[18] According to the European Union Transaction Log, there are over 18,773 registry accounts.[19] The number of participants in the market have a direct bearing on the quality of trading. An Oxera report indicates that as the number of participants trading EUA futures has increased consistently since January 2017, relative spreads, calculated as the average quoted spread divided by the closing price, have decreased significantly—from just under 0.4% in January 2017 to roughly 0.06% in October 2021.[20] In an October 2024 publication, the European Securities Markets Authority (''ESMA'') estimated that approximately 10.75 billion EUAs were traded across all markets in 2023, amounting to approximately €764.1 billion.[21] Out of the total EUA market, approximately 523 million EUAs (amounting to €43.6 billion) were attributable to the EUA primary (auction) market, 9.3 billion EUAs (€648 billion) were attributable to the EUA on-exchange secondary market,[22] and 900 million EUAs (€72.5 billion) were attributable to OTC transactions. In this context, the ''on-exchange secondary market'' includes (1) the EEX spot EUA market, (2) the Daily EUA Futures market, (3) the markets for other EUA futures contracts (together with Daily EUA Futures, ''EUA Futures''), and (4) options contracts on EUA Futures. Data regarding each of the trading of each of these instruments is provided below. During 2023, approximately 99% of on-exchange secondary market transactions in EUAs, representing 81% of total trading volumes, occurred through futures contracts.[23]

[16] EEX is an exchange under the German Exchange Act and a Regulated Market (''RM''), as defined in the Markets in Financial Instruments Directive (Directive 2014/65/EC) (''MIFID II''). As a RM for spot and derivatives transactions, EEX is supervised by the Saxon State Ministry for Economic Affairs, Labour and Transport (the ''Exchange Supervisory Authority''). The Exchange Supervisory Authority is in charge of the legal supervision of EEX and of market supervision of the trading participants according to the German Exchange Act. The members of EEX are supervised by the Federal Financial Supervisory Authority (BaFin). All trading participants are required to comply with the market abuse regulations within the German Securities Trading Act. Beside this supervision, the market behavior at the spot and derivatives markets of all exchange participants is supervised on a daily basis by the Market Surveillance Office, an independent body of the exchange according to Section 7 of the German Exchange Act. *See https://www.esma.europa.eu/sites/default/files/EEX_1.pdf. See also* Rules and Regulations at *https://www.eex.com/en/markets/trading-ressources/rules-and-regulations.* EEX is also recognized by the CFTC as an authorized Foreign Board of Trade. *See https://www.cftc.gov/sites/default/files/filings/documents/2019/orgeexregistrationorder11519.pdf.*

[17] ICE Endex is regulated in the Netherlands by the Dutch Authority for the Financial Markets (''AFM'') as a RM, as defined in MIFID II, which is implemented in Dutch Act on Financial Supervision (''DFSA''). The license as a RM is obtained under Section 5:26(1) of the DFSA, resulting in an authorization by the Minister of Dutch Ministry of Finance to operate a RM and supervised by the AFM. In the UK, ICE Endex is a Recognized Overseas Investment Exchange by the Financial Conduct Authority. *See https://www.ice.com/endex/regulation#:~:text=The%20Dutch%20Authority%20for%20Consumers,energy%20industry%20and%20wholesale%20trading.* ICE Endex is also recognized by the CFTC as an authorized Foreign Board of Trade. *See https://www.cftc.gov/sites/default/files/idc/groups/public/@otherif/documents/ifdocs/orgiceeregorder170110.pdf.*

[18] *See esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf (europa.eu).*

[19] *See https://ec.europa.eu/clima/ets/.*

[20] Carbon trading in the European Union: An economic assessment of market functioning in 2021, Oxera, p. 42 (February 15, 2022); available at *https://www.oxera.com/wp-content/uploads/2022/02/Oxera-EU-carbon-trading-report-3.pdf.*

[21] *See* ''ESMA Market Report: EU carbon markets 2024'' (October 2024): available at *https://www.esma.europa.eu/sites/default/files/2024-10/ESMA50-43599798-10379_Carbon_markets_report_2024.pdf.*

[22] The EUA on-exchange secondary market in 2023 included 7.6 billion EUAs traded through EUA Futures (as defined below), 1.7 billion EUAs traded through options of EUA Futures, and 30 million EUAs traded through other instruments, including spot EUAs. *Id.*

[23] *Id.*

EUA auctions are held on a near-daily basis throughout the year, other than between mid-December to mid-January, when auctions are paused. Twenty-eight countries (25 EU member states plus Liechtenstein, Norway, and Iceland) have agreed to use EEX to conduct their regularly scheduled auctions. Germany and Poland have opted out of the common auction but also utilize the EEX for auctions. Hence, EUA auctions take place exclusively on EEX. These auctions take place on a regularly scheduled basis; the number of allowances being auctioned is disclosed on a schedule prior to auction. Prices achieved in these auctions are published on various publicly-accessible websites, including the European Commission's primary website. For the year-to-date period ended September 30, 2024, the year ended December 31, 2023 and year ended December 31, 2022, the number of EUAs auctioned off on the EEX was 453,034,000, 523,307,500 and 491,194,000, respectively. The auctions cleared at an average discount to the current EUA on-exchange secondary market price of €0.04, €0.08 and €0.11, respectively, for the same time periods, based on the prevailing best bid and offer for EUA instruments with daily expiry (as discussed below) at the time the auction clears. These narrowing discounts as the auction volumes increase is indicative of a maturing marketplace that can provide accurate price discovery.

Below is a discussion of the secondary markets for EUAs and associated derivatives. The Trust will only hold EUAs and possibly cash, and will not hold any of the EUA derivatives.

Exchange-Traded Instruments With a Daily Expiry

Exchange-traded instruments with daily expiry traded on an exchange include spot EUAs traded on the EEX and the Daily EUA Future traded on ICE Endex. The Exchange notes that the settlement and economic outcome for a spot purchase on the EEX and a same day futures purchase on the ICE Endex are identical (as further detailed below). In fact, ESMA, in its ''Final Report: Emission Allowances and Associated Derivatives,'' uses the term ''spot'' EUAs to include both spot EUAs traded on EEX and the Daily EUA Future traded on ICE Endex.[24]

Secondary Spot EUA Market

As noted above, exchange-traded spot EUAs are traded exclusively on the EEX. The current value (spot price) for an EUA is greatly influenced by a number of factors, including regulatory changes, world events and general levels of economic activity. The trading hours for spot EUAs on EEX are 8:00 a.m. to 6:00 p.m. Central European Time (''C.E.T.''), and trade registrations are possible until 6:45 p.m. C.E.T. Trades concluded before 4:00 p.m. C.E.T. are settled on the next business day, or T+1, while trades after 4:00 p.m. C.E.T. are settled on the day after the first business day, or T+2. In the twelve-month period ended September 30, 2024, the average daily, monthly and annual trading volumes of spot EUAs on the EEX was 146, 2,917 and 35,009 round lots of 1000 EUAs, respectively. Over the same period, spot EUAs traded in the secondary market on EEX at their highest volume of 5,010 round lots of EUAs on December 1, 2023, and their lowest volume of 0 EUAs on five different occasions. The EEX calculates and publishes each trading day an index (the ''EUA End of Day Index'') reflecting the end of day price of EUAs traded in the secondary market on EEX.[25]

Daily EUA Futures

Most liquidity in the secondary market is achieved by trading futures contracts. These contracts have expiration going out as far as 2030. A single day futures contract on EUAs is exclusively traded on the ICE Endex (the ''Daily EUA Future''), which settles each day at the close of trading.[26] The Daily EUA Future is a deliverable contract where each person with a position open at cessation of trading is obliged to make or take physical delivery of EUAs upon the expiration of the contract at the end of each trading day. Settlement of the Daily EUA Future does not occur through cash transactions. Each Daily EUA Future represents one lot of 1,000 EUAs, with each EUA providing an entitlement to emit one ton of carbon dioxide equivalent gas. Generally, Daily EUA Futures trade on ICE Endex from approximately 2:00 a.m. Eastern Time (''E.T.'') to approximately 12:00 p.m. E.T. The settlement price is fixed each business day and is published by the exchange at approximately 12:15 E.T. Final settlement of the requisite number of EUAs versus cash occurs the first business day following the expiry day (T+1). In the twelve-month period ended September 30, 2024, the average daily, monthly and annual trading volumes of Daily EUA Futures was approximately 3,829, 78,189 and 938,279, respectively, which represents trading volumes of 3,829,000, 78,189,000 and 938,279,000 EUAs, respectively. Over the same period, Daily EUA Futures traded at their highest volume of 27,749 on April 17, 2024, representing 27,749,000 EUAs, and their lowest volume of 174 on July 26, 2024, representing 174,000 EUAs.

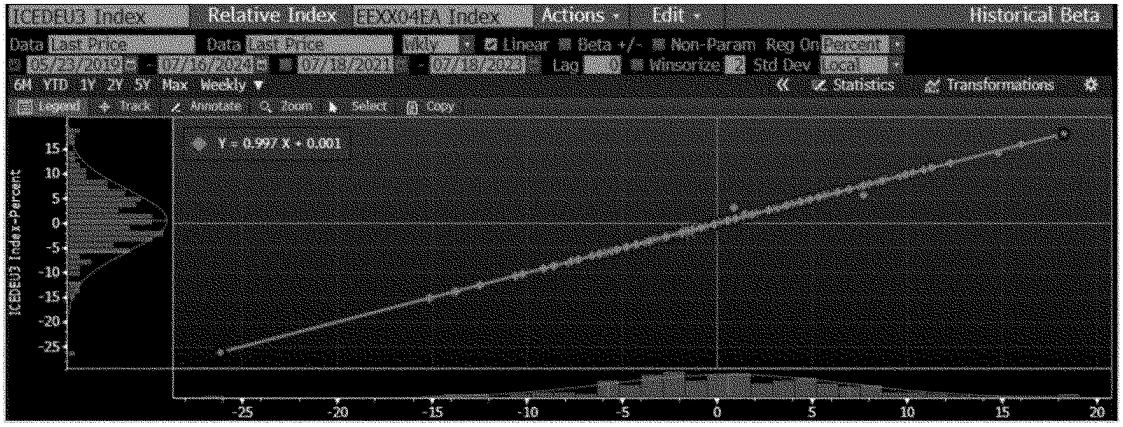
Comparison of Spot EUA Market and Daily EUA Futures Market

The daily EUA End of Day Index value can be expected to be substantially identical to the daily settlement price of the Daily EUA Future. The comparison below shows a 99.8% correlation between the movements of the two values over the five years from May 23, 2019 through May 23, 2024.

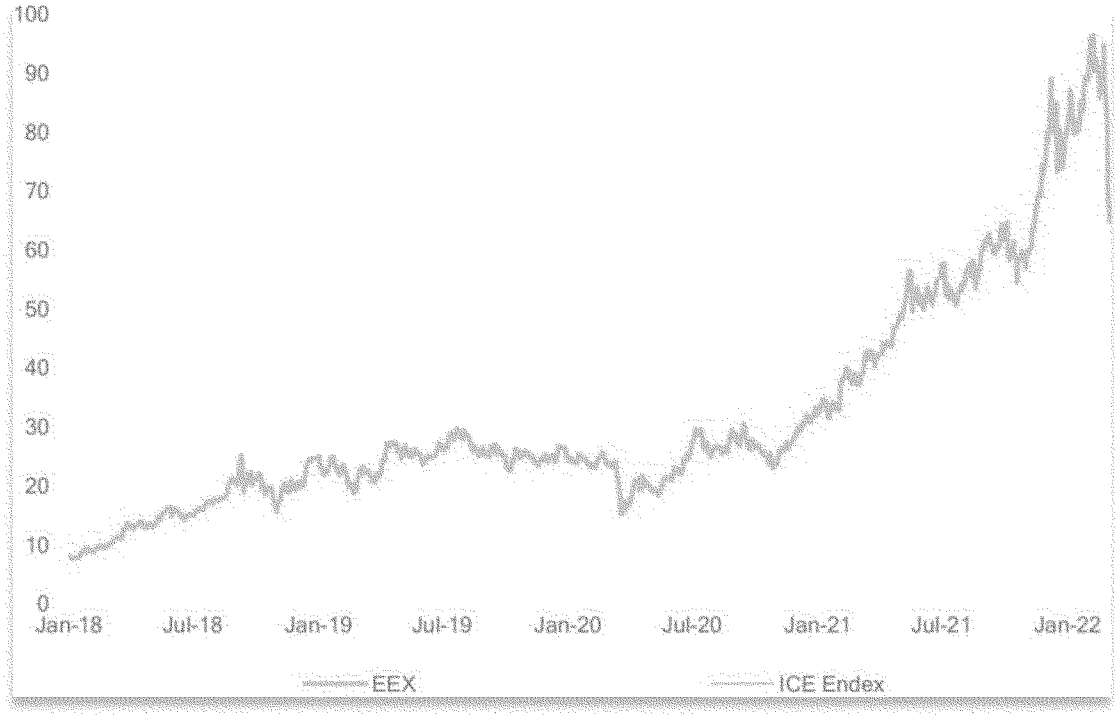
[24] *See esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf (europa.eu).*

[25] The EUA End of Day Index methodology is available at *https://www.eex.com/fileadmin/EEX/Downloads/Trading/Specifications/Indeces/DE/20211005_Index_Description_v010.pdf.*

[26] All references to the ''Daily EUA Future'' refer to the single day EUA futures contract traded on ICE Endex. NASDAQ Oslo also offers a single day futures contract on EUAs, but the contract is not traded.



Additionally, the chart below illustrates how closely the Daily EUA Future, in fact, reflects the EUA spot price during the trading day. This chart shows the prices of EUAs on the EEX and the Daily EUA Futures on ICE Endex, in EUR/tCO2 from January 2018 to January 2022. No major differences can be observed, with an average absolute difference of €0.015 between the daily settlement prices for EUAs on the EEX and ICE Endex.



(https://www.esma.europa.eu/sites/default/files/library/esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf :p37)

Other EUA Futures Contracts

EEX offers monthly EUA futures contracts for the current and next two months unless a quarterly or December future expires at that month's maturity date; quarterly futures for the current and next 11 quarters unless a December future expires at that quarter's maturity date; and yearly, or December, futures for the next 8 years which mature in December of each respective year. ICE Endex offers up to seven December futures contracts, nine quarterly futures contracts, three August futures contracts and two monthly futures contracts. Nasdaq Oslo offers quarterly futures contracts over a rolling six year period. There is only *de minimis* trading volume in EUA Futures on Nasdaq Oslo.[27] The EUA Futures are fungible, meaning any EUA Futures contract acquired on one exchange can be sold on the other exchange.

During 2023, approximately 7.6 billion EUAs, amounting to €643 billion, were traded through EUA Futures (including the Daily EUA Future). The trading volumes of the EUA Futures, including Daily EUA Futures, with expiration dates through

[27] For 2023, Nasdaq Oslo reported only 64 transactions in EUA Futures, for a total volume of 417 EUA Futures contracts. *See https://www.nasdaq.com/path-file/11506.*

the end of 2026 on EEX and ICE Endex for the period from January 1, 2024, through September 30, 2024, were as follows:

YEAR-TO-DATE TRADING VOLUMES, JANUARY 1, 2024—SEPTEMBER 30, 2024

	EEX (in round lots of 1,000 EUAs)	ICE Endex (in round lots of 1,000 EUAs)
Spot EUAs/Daily EUA Future	22,239 (Spot)	741,416 (Daily EUA Futures).
October 2024 EUA Future		38,816.
November 2024 EUA Future		4.
December 2024 EUA Future	222,168	5,482,537.
March 2025 EUA Future	1,228	57,386.
June 2025 EUA Future	2	5,535.
August 2025 EUA Future		17,471.
September 2025 EUA Future	602	25,726.
December 2025 EUA Future	55,075	558,240.
March 2026 EUA Future		14,348.
June 2026 EUA Future.		
August 2026 EUA Future		5,873.
September 2026 EUA Future.		
December 2026 EUA Future	7,027	120,807.
Total	308,341	7,068,159.

Options on EUA Futures Contracts

Options on EUA futures contracts are also traded on EEX and ICE Endex for many of the available EUA Futures. In 2023, approximately 1.7 billion EUAs, amounting to €900 million, were traded through options on EUA Futures. The options on EUA Futures, like the EUA Futures, are fungible and can be traded on any of the participating exchanges, regardless of the exchange on which a particular contract is acquired.

Section 6(b)(5) and the Applicable Standards

The Commission has approved numerous Commodity-Based Trust Shares, to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) the requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices; and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that this filing sufficiently demonstrates that ICE Endex is a regulated market of significant size for trading EUAs.

Designed To Prevent Fraudulent and Manipulative Acts and Practices

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices and to protect investors and the public interest, consistent with Section 6(b)(5) of the Act because (1) the Exchange has entered into a comprehensive surveillance-sharing agreement (''CSSA'') with ICE Endex, a regulated market of ''significant size'' and (2) there are sufficient ''other means to prevent fraudulent and manipulative acts and practices.''

Comprehensive Surveillance-Sharing Agreement

The Commission has explained that a proposal could satisfy the requirements of the Act in the first instance by demonstrating that the listing exchange has entered into a CSSA with a regulated ''market of significant size'' relating to the underlying assets.[28] With respect to the Trust, the underlying assets are EUAs. The relevant analysis, therefore, is whether the Exchange has a CSSA with a regulated market of significant size related to EUAs. The Commission has further stated that ''[c]onsistent with the discussion of 'significant market' . . . , the Commission has not previously, and does not now, require that [a] listing exchange be able to enter into a surveillance-sharing agreement with each regulated spot or derivatives market relating to an underlying asset, provided that the market or markets with which there is such an agreement constitute a 'significant market.' '' [29]

The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance-sharing agreement with markets trading the underlying assets for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules.[30] Comprehensive surveillance-sharing agreements ''provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' [31] The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable

[28] *See* Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (Order Disapproving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) and to List and Trade Shares of the United States Bitcoin and Treasury Investment Trust Under NYSE Arca Rule 8.201–E).

[29] *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, to List and Trade Shares of the Winklevoss Bitcoin Trust) (the ''Winklevoss Order'').

[30] *See* Amendment to Rule Filing Requirements for Self-Regulatory Organizations Regarding New Derivative Securities Products, Securities Exchange Act Release No. 40761 (Dec. 8, 1998), 63 FR 70952, 70959 (Dec. 22, 1998).

[31] *Id. See also* Winklevoss Order, 83 FR 37594.

ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.[32]

The ICE Endex Futures Market is a Regulated Market

As discussed more below, ICE Endex is subject to the EU regulatory framework for EUAs and EUA derivatives.[33] The EU regulatory framework includes the Markets in Financial Instruments Directive and Regulation (''MiFID II'' and ''MiFIR''), the Market Abuse Regulation (''MAR'') and the European Market Infrastructure Regulation (''EMIR''). MiFID II and MiFIR together is a framework governing investment firms, trading venues, data reporting service providers and non-EU investment firms that provide investment services in the EU. The MAR prohibits insider dealing, unlawful disclosure of inside information and market manipulation and provides broad powers to the national competent authorities (''NCAs'') for detection and prosecution of violations. EMIR regulates OTC derivatives transactions, central counterparties and trade repositories. It is critical for ICE Endex to maintain fair and orderly markets. A fair and orderly market is necessary to maintain a level playing field for trading participants, to attract new participants, and to attract trading activity. ICE Endex has an extensive framework in place to facilitate the existence of such fair and orderly markets, including the performance of market surveillance activities that allow for the monitoring of market activity, including intra-day activity, and the detection of irregular trading behavior that could negatively impact the integrity of ICE Endex or constitute breaches of statutory law or regulations in the form of market abuse by market participants.

The ICE Endex Futures Market is a Market of Significant Size

In the Winklevoss Order, the Commission stated that the term ''significant market'' or ''market of significant size'' includes a market (or group of markets) as to which (1) there is a reasonable likelihood that a person attempting to manipulate the Trust would also have to trade on that market to successfully manipulate the Trust, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (2) it is unlikely that trading in the Trust would be the predominant influence on prices in that market.[34] The Commission explained that this definition is illustrative and not exclusive, and that there could be other types of ''significant markets'' and ''markets of significant size.'' [35]

Any Manipulator Would Have To Trade on ICE Endex

The first prong of the analysis addresses whether the surveillance-sharing agreement on which the fund's listing exchange proposes to rely would assist in detecting and deterring fraudulent or manipulative misconduct related to the assets held by the fund. In the present proposal, the Trust's only non-cash holdings will be EUAs. The predominant market for trading EUA instruments with daily expiry is the ICE Endex Daily EUA Futures market, with de minimis secondary market trading taking place on EEX or over-the-counter. The EEX's primary role in the EUA ecosystem is to serve as the venue for the daily auctions of EUAs.

The regulated market of significant size test does not require that the spot EUA market be subject to direct surveillance by the Exchange in order for the Commission to approve this proposal, and precedent makes clear that an underlying market for a spot commodity or currency being a surveilled market would actually be an exception to the norm. These largely un-surveilled currency and commodity markets do not provide the same protections as the markets that are subject to the Commission's oversight, but the Commission has consistently looked to surveillance sharing agreements with the underlying futures market in order to determine whether such products were consistent with the Act. With this in mind, the ICE Endex EUA Futures market is an appropriate market to consider in determining whether there is a related regulated market of significant size.

ICE Endex is the only market for trading Daily EUA Futures and, as noted above, for the twelve-months ended September 30, 2024, the average daily trading volume of Daily EUA Futures on the ICE Endex was 3,829 contracts, representing 3,829,000 EUAs, whereas the average daily trading volume on the EEX was 146 round lots, representing 146,000 EUAs. Therefore, over that one year period, over 96% of all on-exchange secondary market trading of EUA spot instruments with daily expiry (which, as described above, includes spot EUAs and Daily EUA Futures) occurred on the ICE Endex. With respect to EUAs and EUA based derivatives more broadly, the chart above shows that, year-to-date through September 30, 2024, approximately 96% of all trades in EUAs and EUA Futures dated through December 2026 occurred on ICE Endex.[36]

Given the size of the ICE Endex futures markets, especially the Daily EUA Futures market, the Sponsor believes such markets meet the Commission's definition of ''significant market'' because there is a reasonable likelihood that a person attempting to manipulate the Trust would also have to trade on that market to successfully manipulate the Trust, since arbitrage between the derivative and spot markets would tend to counter an attempt to manipulate the spot market alone. Of the 256 members of ICE Endex, 151 are also members of EEX. Each of these exchange members acts on behalf of their clients, each member in common between the exchanges represents potentially hundreds of accounts that can and do act on both markets to effect arbitrage transactions. Therefore, a sufficient number of arbitrageurs have access to both the EEX and ICE Endex such that any attempt to manipulate one market that causes a difference between the EUA spot price and the Daily EUA Futures price will quickly be exploited. This will serve to maintain the EUA price correlation between EEX and ICE Endex. Any attempt to manipulate the spot EUA market alone would be impossible because arbitrage would correct any movements in the spot market to bring the prices of spot EUAs back in line with the settlement price of the Daily EUA Future. Therefore, any person attempting to manipulate the Trust Shares would also have to trade in the Daily EUA Futures market (ICE Endex) to manipulate the spot and futures markets in tandem.[37]

[32] *See* Winklevoss Order, 83 FR 37592–93 (discussing Letter from Brandon Becker, Director, Division of Market Regulation, Commission, to Gerard D. O'Connell, Chairman, Intermarket Surveillance Group (June 3, 1994), available at *https://www.sec.gov/divisions/marketreg/mr-noaction/isg060394.htm*).

[33] *See supra,* note 17.

[34] *See* Winklevoss Order, 83 FR 37594.

[35] *Id.*

[36] *See esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf (europa.eu).*

[37] The Commission has granted several prior proposals to list and trade shares of physical commodity-based exchange-traded products, noting in every case that there was at least one regulated market of significant size for trading futures in the underlying commodity—whether gold, silver, platinum, palladium or copper—and the product's listing exchange has entered into surveillance-sharing agreements with, or held Intermarket Surveillance Group (''ISG'') membership in common with, that market. *See* Securities Exchange Act Release Nos. 61220 (December 22, 2009), 74 FR 68895, 68896 (December 29, 2009) (SR–NYSEArca–2009–94) (notice of proposed rule change included

Similarly, it is impossible to manipulate the prices of EUAs by trading the other EUA based derivatives on the EEX alone. With respect to EUA Futures other than the Daily EUA Future, the size and predominance of ICE Endex would make it impossible to manipulate the price of EUAs through trading EUA Futures on the EEX alone. The fungibility of EUA Futures and the significant overlap in exchange membership would cause arbitrage activity to bring the settlement prices of EUA Futures traded on EEX in line with the settlement price of EUA Futures traded on ICE Endex. In addition, because the options on EUA Futures reference EUA Futures, the prices of EUA Futures would reflect any attempt by a would-be manipulator to manipulate the price of the Fund's Shares through the use of options. Therefore, any would-be manipulator would have to manipulate the prices of EUA Futures Contracts in order to manipulate the price of the Fund's Shares, and the size of predominance of the ICE Endex would require that would-be manipulator to trade on ICE Endex.

The Trust Is Unlikely To Be the Predominant Influence on Price

It is unlikely that trading in the Trust Shares would be the predominant influence on Daily EUA Futures prices traded on ICE Endex for a number of reasons, including the significant volume in and size of the EUA daily expiry market (meaning the Daily EUA Futures market, in effect). In 2023, the total EUA market size was approximately €764.1 billion with approximately €67.1 billion of that attributable to the Daily EUA Futures market and €3.4 billion attributable to spot EUAs. The daily average trading volume in 2023 for EUAs across the on-exchange secondary market was approximately €2.6 billion, with approximately €266.3 million attributable to trading in the Daily EUA Futures market and €13.5 million attributable to trading in spot EUAs. The Trust has not yet launched and cannot predict its future inflows; however, given the size of the Daily EUA Futures market and the EUA market, as a whole, the Sponsor does not anticipate that the Trust will have available capital to buy and sell EUAs in an amount that would move the EUA market or that investors would be able to trade Trust Shares at such a volume as to influence Daily EUA Futures prices on ICE Endex. Additionally, the trading hours for the ICE Endex (*i.e.,* EUA Futures market) are approximately 2:00 a.m. E.T. to approximately 12:00 p.m. E.T. The majority of this time period (7.5 hours) is outside of the Trust's trading hours of 9:30 a.m. E.T. to 4:00 p.m. E.T. As such, it is unlikely that trading in the Trust's Shares would be the primary influencer of the EUA Futures prices traded on ICE Endex, because the ICE Endex is actively traded for 7.5 hours during which the Trust Shares cannot be traded.

Other Means To Prevent Fraudulent and Manipulative Acts and Practices

The Exchange has a CSSA With the Market on Which the Trust's Sole Asset Trades

In the present proposal, the Trust's only non-cash holdings will be EUAs. Moreover, the proposed ''significant'' regulated market (*i.e.,* the ICE Endex) with which the listing exchange has a surveillance-sharing agreement is the principal market on which these assets trade.

The Daily EUA Futures market functions as the ''spot'' market for EUAs. The purchase and sale of Daily EUA Futures is the functional and economic equivalent of transactions in spot EUAs. The settlement, functionality and economic outcome for a spot purchase on the EEX and a Daily EUA Future purchase on the ICE Endex are identical. Because the Daily EUA Future is physically settled through the delivery of one lot of EUAs to the purchaser of the Daily EUA Future, whether the Trust acquires an EUA through a transaction on the EEX or through the acquisition of a Daily EUA Future on ICE Endex, the Trust will acquire the same EUA on a T+1 basis. It is not possible for an acquirer to roll a same day futures contract to a later dated future, as each day it would expire and the market participant would end up holding physical EUAs. Therefore, the Daily EUA Futures market functions as a spot market.

The EEX's primary role in the EUA ecosystem is to serve as the venue for the daily auctions of EUAs. The predominant market for trading EUA instruments with daily expiry is the ICE Endex Daily EUA Futures market, with *de minimis* secondary market trading taking place on EEX or in the OTC market. As noted above, for the twelve-month period ended September 30, 2024, the average daily trading volume of Daily EUA Futures on ICE Endex was approximately 3,829 contracts, representing 3,829,000 EUAs, whereas the average daily trading volume of spot EUAs on the EEX was 146 lots, representing 146,000 EUAs. Therefore, over that one year period, approximately 96% of all secondary market trading of EUA spot instruments with daily expiry occurred on the ICE Endex. Therefore, because a Daily EUA Future is functionally identical to a physical EUA, and the ICE Endex serves as the predominant market for the trading of ''spot'' EUAs, the Exchange's CSSA with ICE Endex will serve to detect and deter fraudulent and manipulative acts and practices in the EUA market.

NYSE Arca's representation that ''[t]he most significant palladium futures exchanges are the NYMEX and the Tokyo Commodity Exchange,'' that ''NYMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which NYMEX is a member; 61219 (December 22, 2009), 74 FR 68886, 68887–88 (December 29, 2009) (SR–NYSEArca–2009–95) (notice of proposed rule change included NYSE Arca's representation that ''[t]he most significant platinum futures exchanges are the NYMEX and the Tokyo Commodity Exchange,'' that ''NYMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which NYMEX is a member; 62692 (August 11, 2010), 75 FR 50789, 50790 (August 17, 2010) (SR–NYSEArca–2010–56) (notice of proposed rule change included NYSE Arca's representation that ''the most significant gold, silver, platinum and palladium futures exchanges are the COMEX and the TOCOM'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member; 62875 (September 9, 2010), 75 FR 56156, 56158 (September 15, 2010) (SR–NYSEArca–2010–71) (notice of proposed rule change included NYSE Arca's representation that ''the most significant silver, platinum and palladium futures exchanges are the COMEX and the TOCOM'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member; 63464 (December 8, 2010), 75 FR 77926, 77928 (December 14, 2010) (SR–NYSEArca–2010–95) (notice of proposed rule change included NYSE Arca's representation that ''the most significant gold futures exchanges are the COMEX and the Tokyo Commodity Exchange,'' that ''COMEX is the largest exchange in the world for trading precious metals futures and options,'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member; 68430 (December 13, 2012), 77 FR 75239, 75240–41 (December 19, 2012) (SR–NYSEArca–2012–111) (notice of proposed rule change included NYSE Arca's representation that ''[f]utures on platinum and palladium are traded on two major exchanges: The New York Mercantile Exchange . . . and Tokyo Commodities Exchange'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' of which COMEX is a member; 71378 (January 23, 2014), 79 FR 4786, 4786–87 (January 29, 2014) (SR–NYSEArca–2013–137) (notice of proposed rule change included NYSE Arca's representation that ''COMEX is the largest gold futures and options exchange'' and that NYSE Arca ''may obtain trading information via the Intermarket Surveillance Group,'' including with respect to transactions occurring on COMEX pursuant to CME and NYMEX's membership, or from exchanges ''with which [NYSE Arca] has in place a comprehensive surveillance sharing agreement.'')

EU's Oversight and Monitoring of EUA Markets Serves To Prevent Fraudulent and Manipulative Acts and Practices

In addition to Exchange's CSSA with ICE Endex, there are other mechanisms in place to deter and detect misconduct across both the EUA spot and derivatives markets. Both EEX and ICE Endex are subject to the EU regulatory framework for EUAs and EUA derivatives. The EU regulatory framework includes the Markets in Financial Instruments Directive and Regulation (''MiFID II'' and ''MiFIR''), the Market Abuse Regulation (''MAR'') and the European Market Infrastructure Regulation (''EMIR'').[38] MiFID II and MiFIR together is a framework governing investment firms, trading venues, data reporting service providers and non-EU investment firms that provide investment services in the EU.[39] The MAR prohibits insider dealing, unlawful disclosure of inside information and market manipulation and provides broad powers to the national competent authorities (''NCAs'') for detection and prosecution of violations.[40] EMIR regulates OTC derivatives transactions, central counterparties and trade repositories.[41] ESMA is the EU's overall financial markets regulator that has supervisory authority over the NCAs.[42] Under the EU regulatory framework, there are three lines of defense against market abuse.[43] At the firm level (first line), firms are required to have systems and procedures in place to ensure that abusive trading is detected and reported to NCAs. At the market operator, investment firm and trading venue level (second line), these entities are required to identify and report suspicious transactions and maintain policies and procedures to prevent market abuse. Additionally, exchanges such as EEX and ICE Endex are required to report information to the relevant authorities on a daily basis. At the NCA level (third line), NCAs have market surveillance systems in place to monitor markets and identify and investigate suspicious transactions. NCAs have broad enforcement power and cooperate with each other and ESMA to obtain the information needed for optimal surveillance and in order to prosecute violations.[44] Exchanges (such as EEX and ICE Endex) and governmental authorities share information and communicate frequently regarding monitoring activities.[45]

While the Exchange is not a participant in the EU regulatory framework, the Exchange believes that the EU's robust oversight and monitoring regime, in addition to the Exchange's CSSA with ICE Endex which would allow for the sharing of information and thus provide sufficient means to prevent fraudulent and manipulative acts and practices.

Designed To Protect Investors and the Public Interest

The Exchange believes that the proposal is designed to protect investors and the public interest. The Exchange believes that the concerns related to the prevention of fraudulent and manipulative acts and practices have been sufficiently addressed for this proposal to be consistent with the Act. As such, the Exchange believes that approving this proposal provides the Commission with the opportunity to allow U.S. investors to access EUAs in a regulated and transparent exchange-traded vehicle that would act to limit risk and benefit U.S. investors by: (i) reducing premium and discount volatility as compared to OTC investment vehicles; (ii) increasing competitive pressure on management fees resulting in fee compression/reductions; (iii) reducing risks and costs as compared to those associated with investing in EUAs; and (iv) providing an alternative to maintaining custody of EUAs.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will create and redeem Shares on a continuous basis in one or more Creation Units. A ''Creation Unit'' equals a block of 50,000 Shares, which amount may be revised from time-to-time. The Trust will issue Shares in Creation Units to certain authorized participants (''Authorized Participants'') on an ongoing basis. Each Authorized Participant must be a registered broker-dealer or other securities market participant such as a bank or other financial institution which is not required to register as a broker-dealer to engage in securities transactions, a participant in The Depository Trust Company (''DTC'') and have entered into an agreement with the Sponsor and the Transfer Agent (the ''Participant Agreement'').

Creation Units may be created or redeemed only by Authorized Participants. The creation and redemption of Creation Units is made in exchange for the delivery to the Trust or the distribution by the Trust of the amount of EUAs, or the amount of cash sufficient to purchase the amount of EUAs, represented by the Creation Units being created or redeemed. The amount of EUAs or cash required to be delivered to the Trust in connection with any creation, or paid out upon redemption, is based on the combined net asset value of the number of Shares included in the Creation Units being created or redeemed as determined on the day the order to create or redeem Creation Units is properly received and accepted. Orders must be placed by 11:00 a.m. New York time. The day on which the Administrator receives a valid purchase or redemption order is the order date. Creation Units may only be issued or redeemed on a day that the Exchange is open for regular trading.

For a cash creation, an Authorized Participant will deliver the cash to the Trust's account at the Cash Custodian, which the Sponsor will then use to purchase EUAs from a third party selected by the Sponsor who (1) is not an Authorized Participant and (2) will not be acting as an agent, nor at the discretion, of the Authorized Participant with respect to the delivery of EUAs to the Trust (such third party, a ''Liquidity Provider''). For a cash redemption, the Sponsor shall arrange for the EUAs represented by the Creation Units to be sold to a Liquidity Provider selected by the Sponsor and the cash proceeds distributed from the Trust's account at the Cash Custodian to the Authorized Participant in exchange for its Shares. In the case of ''in-kind'' creation or redemption orders for Shares, an Authorized Participant may deliver or direct the delivery of EUAs by third parties, or take delivery or direct the taking of delivery of EUAs by third parties.

For cash creations, an Authorized Participant who places a purchase order is responsible for arranging for the delivery to the Trust's account with the Cash Custodian of the required cash deposit by 2:00 p.m. New York time on the first business day following the

[38] Carbon trading in the European Union: An economic assessment of market functioning in 2021, Oxera, p. 26 (February 15, 2022); available at *https://www.oxera.com/wp-content/uploads/2022/02/Oxera-EU-carbon-trading-report-3.pdf.*

[39] MiFID II Overview, Practical Law Financial Services.

[40] *See esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf (europa.eu).*

[41] Carbon trading in the European Union: An economic assessment of market functioning in 2021, Oxera, p. 61 (February 15, 2022); available at *https://www.oxera.com/wp-content/uploads/2022/02/Oxera-EU-carbon-trading-report-3.pdf.*

[42] *https://www.esma.europa.eu/about-esma.*

[43] *See esma70-445-38_final_report_on_emission_allowances_and_associated_derivatives.pdf (europa.eu).*

[44] *Id.*

[45] Carbon trading in the European Union: An economic assessment of market functioning in 2021, Oxera, p. 26–27 (February 15, 2022); available at *https://www.oxera.com/wp-content/uploads/2022/02/Oxera-EU-carbon-trading-report-3.pdf.*

purchase order date. The Liquidity Provider delivers EUAs to the Trust's Union Registry account in exchange for the cash purchase price. Upon settlement of the EUA purchase from the Liquidity Provider into the Trust's Union Registry account, the Trust instructs the Transfer Agent to release the Shares to the Authorized Participant, and the Transfer Agent directs DTC to credit the number of Shares ordered to the applicable DTC account, by close of business on the purchase settlement date.

For in-kind creation orders, an Authorized Participant who places a purchase order is responsible for arranging for the delivery to the Trust's Union Registry account the required EUA deposit by 2:00 p.m. New York time on the first business day following the order date. Upon receipt of the EUA deposit amount in the Trust's Union Registry account, the Union Registry will notify the Sponsor that the EUAs have been deposited. Upon receipt of confirmation from the Union Registry that the EUA deposit amount has been received, the Administrator will direct DTC to credit the number of Shares created to the Authorized Participant's DTC account.

According to the Registration Statement, the redemption distribution due from the Trust will be delivered once the Administrator notifies the Sponsor that the Authorized Participant has delivered the Shares to be redeemed to the Trust's DTC account. The redemption distribution will be delivered to the Authorized Participant on the first business day following the order date.

For cash redemptions, on the redemption settlement date, the Liquidity Provider delivers cash to the Trust's account with the Cash Custodian in exchange for the redemption EUAs amount. Upon settlement of the EUA sale by the Trust to the Liquidity Provider and the receipt of the Liquidity Provider's cash in the Trust's Cash Custodian account, the Trust instructs the Transfer Agent to deliver the Authorized Participant's Shares to be redeemed back to the Trust, in exchange for which the Trust instructs the Cash Custodian to transfer the requisite cash to the Authorized Participant's designated bank account and the redemption order is settled.

For in-kind redemptions, once the Administrator notifies the Sponsor that the Shares have been received in the Trust's DTC account, the Sponsor instructs the Union Registry to transfer the redemption EUA amount from the Trust's Union Registry account to the Union Registry account of the Authorized Participant or its agent.

The Sponsor is the only entity that may initiate a withdrawal of EUAs from the Trust's Union Registry account, and the only accounts that may receive EUAs from the Trust's Union Registry account are the Union Registry accounts of the Authorized Participants and Liquidity Providers, their agents or the Sponsor.

Net Asset Value (''NAV'')

The Trust's NAV is calculated by taking the current market value of its total assets, less any liabilities of the Trust, and dividing that total by the total number of outstanding Shares.

The Administrator will calculate the NAV of the Trust once each Exchange trading day. The NAV for a normal trading day will be released after the end of the Core Trading Session, which is typically 4 p.m. New York time. The NAV for the Trust's Shares will be disseminated daily to all market participants at the same time. The Administrator will use the settlement price for the Daily EUA Futures established by ICE Endex to calculate the NAV. The Administrator also converts the value of Euro denominated assets into US Dollar equivalent using published foreign currency exchange prices by an independent pricing vendor. Third parties supplying quotations or market data may include, without limitation, dealers in the relevant markets, end-users of the relevant product, information vendors, brokers and other sources of market information.

Indicative Fund Value (''IFV'')

In order to provide updated information relating to the Trust for use by investors and market professionals, an updated IFV will be made available through on-line information services throughout the Exchange Core Trading Session (normally 9:30 a.m. to 4:00 p.m. E.T.) on each trading day. The IFV will be calculated by using the prior day's closing NAV per Share of the Trust as a base and updating that value throughout the trading day to reflect changes in the most recently reported mid-point of the bid-ask spread of the Daily EUA Future. The IFV disseminated during NYSE Arca Core Trading Session hours should not be viewed as an actual real time update of the NAV, because the NAV will be calculated only once at the end of each trading day based upon the relevant end of day values of the Trust's investments. Although the IFV will be disseminated throughout the Core Trading Session, the customary trading hours for EUAs are 2 a.m. to 12 p.m. Eastern Time. During the gap in time at the end of each trading day during which the Shares are traded on the Exchange, but real-time trading prices for EUAs are not available, the IFV will be calculated based on the last reported mid-point of the bid-ask spread of the Daily EUA Future in the immediately preceding trading session until the day's settlement price is reported, in which case the day's settlement price will be used.

The IFV will be disseminated on a per Share basis every 15 seconds during regular NYSE Arca Core Trading Session.

Availability of Information

The NAV for the Trust's Shares will be disseminated daily to all market participants at the same time. The intraday, closing prices, and settlement prices for EUAs will be readily available from the applicable futures exchange websites, automated quotation systems, published or other public sources, or major market data vendors. The IFV per Share for the Shares will be disseminated by one or more major market data vendors on at least a 15 second delayed basis as required by NYSE Arca Rule 8.201–E(e)(2)(v).

Complete real-time data for EUAs and Daily EUA Futures is available by subscription through on-line information services. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association. The IFV will be available through on-line information services. The trading prices for EUAs and Daily EUA Futures will be disseminated by on-line subscription services or by one or more major market data vendors during the NYSE Arca Core Trading Session of 9:30 a.m. to 4:00 p.m. E.T.

EEX also provides on its website, on a daily basis, transaction volumes and transaction prices for the EUA spot market. ICE Endex provides on its website, on a daily basis, transaction volumes, transaction prices, daily settlement prices and historical settlement prices for Daily EUA Futures that were traded outside of block trades by EUA futures brokers. In addition, transaction volumes, transaction prices, daily settlement prices and historical settlement prices for Daily EUA Futures traded in block trades by futures brokers are available on a daily basis through a subscription service to ICE Endex. However, ICE Endex provides the daily settlement price change of the Daily EUA Future on its website.

In addition, the Trust's website (*www.cotwoadvisors.com*) will contain

the following information, on a per Share basis, for the Trust: (a) the prior business day's end of day closing NAV; (b) the Official Closing Price [46] or the midpoint of the national best bid and the national best offer (''NBBO'') as of the time the NAV is calculated (''Bid-Ask Price''); (c) calculation of the premium or discount of the Official Closing Price against the NAV expressed as a percentage of such NAV; (d) the prospectus; and (e) other applicable quantitative information. The Trust will also provide website disclosure of its EUA holdings before 9:30 a.m. E.T. on each trading day.

The Trust's website will be publicly available prior to the public offering of Shares and accessible at no charge. The website disclosure of the Trust's daily holdings will occur at the same time as the disclosure by the Trust of the daily holdings to Authorized Participants so that all market participants are provided daily holdings information at the same time. Therefore, the same holdings information will be provided on the public website as well as in electronic files provided to Authorized Participants. Accordingly, each investor will have access to the current daily holdings of the Trust through the Trust's website. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Trading in the Shares on the Exchange will occur in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.201–E. The trading of the Shares will be subject to NYSE Arca Rule 8.201–E(g), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered Market Makers in Commodity-Based Trust Shares to facilitate surveillance. The Exchange represents that, for initial and continued listing, the Trust will be in compliance with Rule 10A–3 [47] under the Act, as provided by NYSE Arca Rule 5.3–E. A minimum of 50,000 Shares will be outstanding at the commencement of trading on the Exchange.

As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. To the extent the Exchange may be found to lack jurisdiction over a subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts, the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading on the Exchange in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) the extent to which conditions in the underlying carbon credit market have caused disruptions and/or lack of trading, or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's ''circuit breaker'' rule.[48]

The Exchange may halt trading during the day in which an interruption occurs to the dissemination of the IFV, as described above. If the interruption to the dissemination of the IFV persists past the trading day in which it occurs, the Exchange will halt trading no later than the beginning of the trading day following the interruption. In addition, if the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority Inc. (''FINRA''), on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[49] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange has entered into a CSSA with ICE Endex. Pursuant to the CSSA, the Exchange will communicate as needed regarding trading in the Shares and Daily EUA Futures with ICE Endex, and the Exchange may obtain trading information regarding trading in the Shares and Daily EUA Futures from ICE Endex.

The Exchange represents that all EUAs held by the Trust will be held and maintained in the Union Registry and that the Trust will not invest in futures, options, options on futures, or swap contracts. It is possible that EUAs and Daily EUA Futures may become listed on other exchanges that are members of ISG [50] or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Additionally, the Exchange is able to obtain information regarding trading in the Shares in connection with ETP Holders' proprietary or customer trades

[46] The term ''Official Closing Price'' is defined in NYSE Arca Rule 1.1(ll) as the reference price to determine the closing price in a security for purposes of Rule 7–E Equities Trading, and the procedures for determining the Official Closing Price are set forth in that rule.

[47] With respect to the application of Rule 10A–3 (17 CFR 240.10A–3) under the Act, the Trust relies on the exemption contained in Rule 10A–3(c)(7).

[48] *See* NYSE Arca Rule 7.12–E.

[49] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[50] For a list of the current members of ISG, *see www.isgportal.org.*

which they effect through ETP Holders on any relevant market. Additionally, under NYSE Arca Rule 8.201–E(g), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its accounts for trading in any underlying commodity, related futures or options on futures, or any other related derivatives. Commentary .04 of NYSE Arca Rule 11.3–E requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures, and any related derivative instruments (including the Shares). As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. To the extent the Exchange may be found to lack jurisdiction over a subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts and that subsidiary or affiliate is a member of another regulatory organization, the Exchange could obtain information regarding the activities of such subsidiary or affiliate through a surveillance sharing agreement with that regulatory organization.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The Trust has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) the procedures for purchases and redemptions of Shares in Creation Units (including noting that Shares are not individually redeemable); (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how information regarding the IFV is disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (5) the possibility that trading spreads and the premium or discount on the Shares may widen as a result of reduced liquidity of EUAs during the Core and Late Trading Sessions; and (6) trading information. For example, the Information Bulletin will advise ETP Holders, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Trust. The Exchange notes that investors purchasing Shares directly from the Trust will receive a prospectus. ETP Holders purchasing Shares from the Trust for resale to investors will deliver a prospectus to such investors.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as will be described in the Registration Statement. The Information Bulletin will also reference the fact that last sale information regarding EUAs is subject to regulation by EEX and ICE Endex, that the Commission and the CFTC do not have jurisdiction over the trading of EUAs as a commodity, and that jurisdiction over the trading of EUAs is held by the relevant competent authority of the individual EU member states in which the trading takes place, namely the Bundesanstalt für Finanzdienstleistungsaufsicht (BaFIN) in Germany and the Autoriteit Financiële Markten (AFM) in the Netherlands.[51] The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

The Information Bulletin will also disclose the trading hours of the Shares and that the NAV for the Shares will be calculated after 4:00 p.m. E.T. each trading day. The Information Bulletin will disclose that information about the Shares will be publicly available on the Trust's website.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[52] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. Further, the Exchange has demonstrated that the proposed rule change satisfies Section 6(b)(5) of the Act by showing that the ICE Endex is a regulated market of significant size that shares surveillance with the Exchange. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange may obtain information regarding trading in the Shares and Daily EUA Futures from ICE Endex with which the Exchange has entered into a CSSA. Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying commodity through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary trades which they effect on any relevant market. The Exchange represents that all EUAs held by the Trust will be held and maintained in the Union Registry and that the Trust will not invest in futures, options, options on futures, or swap contracts. The Exchange further represents that ICE Endex is the principal market for EUAs in which the Trust may invest, and that

[51] Article 22 of Regulation (EU) No. 596/2014 on market abuse (market abuse regulation) (''MAR'') requires each EU member state to designate a single administrative competent authority to ensure that the provisions of MAR are applied on its territory. Commission Regulation 596/2014, 2014 O.J. (L 173) 42. For a list of the competent authorities for each EU Member State. *See https://www.esma.europa.eu/sites/default/files/mar.pdf.*

[52] 15 U.S.C. 78f(b)(5).

the Exchange can monitor those EUAs through its CSSA with ICE Endex.[53]

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of information on EUAs and Daily EUA Futures available on public websites and through professional and subscription services. The trading prices for EUAs will be disseminated by on-line subscription services or by one or more major market data vendors during the NYSE Arca Core Trading Session. EEX also provides on its website, on a daily basis, transaction volumes and transaction prices for the EUA spot market. Additionally, ICE Endex provides on its website, on a daily basis, transaction volumes, transaction prices, daily settlement prices and historical settlement prices for Daily EUA Futures that were traded outside of block trades by EUA futures brokers. In addition, transaction volumes, transaction prices, daily settlement prices and historical settlement prices for Daily EUA Futures traded in block trades by futures brokers are available on a daily basis through a subscription service to ICE Endex. ICE Endex also provides the daily settlement price change of the Daily EUA Future on its website.

In addition, the Trust's website (*www.cotwoadvisors.com*) will provide pricing information for EUAs and the Shares. Market prices for the Shares will be available from a variety of sources including brokerage firms, information websites and other information service providers. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association. The NAV of the Trust will be published on each day that NYSE Arca is open for regular trading and will also be posted on the Trust's website. The IFV relating to the Shares will be widely disseminated by one or more major market data vendors at least once every 15 seconds as required by NYSE Arca Rule 8.201–E(e)(2)(v). The Trust's website will also provide its prospectus and other relevant quantitative information regarding the Shares. The Trust will also provide website disclosure of its EUA holdings before 9:30 a.m. E.T. on each trading day. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information regarding trading in the Shares, EUAs and Daily EUA Futures from ICE Endex pursuant to the CSSA between the Exchange and ICE Endex. In addition, as noted above, investors will have ready access to information regarding the Trust's NAV, IFV, and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change will enhance competition by accommodating Exchange trading of an additional exchange-traded product, and the first such product relating to physical carbon credits, which will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSEARCA–2024–70, as Modified by Amendment No. 1, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[54] to determine whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change, as modified by Amendment No. 1, as discussed below. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change, as modified by Amendment No. 1.

Pursuant to Section 19(b)(2)(B) of the Act,[55] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposal's consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,'' and ''to protect investors and the public interest.'' [56]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal, as modified by Amendment No. 1. In particular, the Commission invites the written views of interested persons concerning whether the proposal, as modified by Amendment No. 1, is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[57]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change, as modified by Amendment No. 1, should be approved or disapproved by December 30, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by January 13, 2025.

[53] *See* the discussion in the ''Section 6(b)(5) and the Applicable Standards'' section, *supra.*

[54] 15 U.S.C. 78s(b)(2)(B).

[55] *Id.*

[56] 15 U.S.C. 78f(b)(5).

[57] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Pub. L. 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in Amendment No. 1,[58] in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. Given the nature of the underlying assets held by the Trust, what are commenters' views on whether the proposed Trust and Shares would be susceptible to manipulation? What are commenters' views generally on whether the Exchange's proposal is designed to prevent fraudulent and manipulative acts and practices? What are commenters' views generally with respect to the liquidity and transparency of the EUA spot and futures markets and such markets' susceptibility to manipulation? Are there particular features related to the EUA markets and the EUA ecosystem that raise unique concerns about whether the proposed Trust, which would hold EUAs and, possibly, a very limited amount of cash, would be susceptible to fraud or manipulation?

2. Based on data and analysis provided by the Exchange,[59] do commenters agree with the Exchange that ICE Endex, on which EUA Futures (including Daily EUA Futures) trade, represents a regulated market of significant size related to spot EUAs? [60] What are commenters' views on whether there is a reasonable likelihood that a person attempting to manipulate the Shares would also have to trade on ICE Endex to manipulate the Shares? [61] Do commenters agree with the Exchange that trading in the Shares would not be the predominant influence on prices in the Daily EUA Futures market? [62]

3. The Exchange further states that the ''Daily EUA Futures market functions as the 'spot' market for EUAs'' and that the ''purchase and sale of Daily EUA Futures is the functional and economic equivalent of transactions in spot EUAs.'' [63] What are commenters' views on whether the Daily EUA Futures market functions as a spot EUA market? What are commenters' views on the extent to which a surveillance sharing agreement with ICE Endex would assist in detecting and deterring fraud and manipulation that impacts an ETP that holds spot EUAs, and on whether the Exchange's analysis provides evidence to this effect?

4. In addition to the Exchange's CSSA with ICE Endex, the Exchange asserts that there are other mechanisms in place to deter and detect misconduct across both the EUA spot and derivatives markets. Specifically, the Exchange states that both EEX and ICE Endex are subject to the EU regulatory framework [64] and represents that both EEX and ICE Endex are recognized by the CFTC as authorized Foreign Boards of Trade.[65] Do commenters agree with the Exchange that the EU's oversight and monitoring regime, combined with the Exchange's CSSA with ICE Endex, may provide other means to prevent fraudulent and manipulative acts and practices? [66]

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NYSEARCA–2024–70 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–70. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–70 and should be submitted on or before December 30, 2024. Rebuttal comments should be submitted by January 13, 2025.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[67]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–28763 Filed 12–6–24; 8:45 am]

BILLING CODE 8011–01–P

[58] *See supra* Item II. *See also supra* note 6.

[59] *See supra* Item II.A.1.

[60] *See id.*

[61] *See supra* note 37 and accompanying text.

[62] *See supra* Item II.A.1.

[63] *Id.*

[64] *See supra* notes 38–45 and accompanying text.

[65] *See supra* notes 16–17 and accompanying text.

[66] *See supra* note 64.

[67] 17 CFR 200.30–3(a)(12) and 17 CFR 200.30–3(a)(57).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20589 and #20590; HAVASUPAI TRIBE Disaster Number AZ–20006]

Presidential Declaration Amendment of a Major Disaster for the Havasupai Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Havasupai Tribe (FEMA–4840–DR), dated October 25, 2024.

Incident: Flooding.

DATES: Issued on December 3, 2024.

Incident Period: August 22, 2024 through August 23, 2024.

Physical Loan Application Deadline Date: January 17, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: July 25, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Havasupai Tribe, dated October 25, 2024, is hereby

amended to extend the deadline for filing applications for physical damages as a result of this disaster to January 17, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28822 Filed 12–6–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20734 and #20735; SOUTH CAROLINA Disaster Number SC–20013]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of South Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 5.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of South Carolina (FEMA–4829–DR), dated October 6, 2024.

Incident: Hurricane Helene.

DATES: Issued on December 3, 2024.

Incident Period: September 25, 2024 through October 7, 2024.

Physical Loan Application Deadline Date: 01/02/2025.

Economic Injury (EIDL) Loan Application Deadline Date: July 7, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of South Carolina, dated October 6, 2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to January 2, 2025. This notice is further amended to include the following areas as adversely affected by the disaster.

Primary Counties: Berkeley.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28821 Filed 12–6–24; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20613 and #20614; CHEYENNE RIVER SIOUX TRIBE Disaster Number SD–20004]

Presidential Declaration Amendment of a Major Disaster for the Cheyenne River Sioux Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Cheyenne River Sioux Tribe (FEMA–4842–DR), dated November 1, 2024.

Incident: Severe Storm, Straight-line Winds, and Flooding.

DATES: Issued on December 3, 2024.

Incident Period: July 13, 2024 through July 14, 2024.

Physical Loan Application Deadline Date: January 20, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: August 1, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Cheyenne River Sioux Tribe, dated November 1, 2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to January 20, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28815 Filed 12–6–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20757 and #20758; VIRGINIA Disaster Number VA–20013]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Virginia

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Virginia (FEMA–4831–DR), dated October 10, 2024.

Incident: Tropical Storm Helene.

DATES: Issued on December 03, 2024.

Incident Period: September 25, 2024 through October 03, 2024.

Physical Loan Application Deadline Date: December 09, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: July 10, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Virginia, dated October 10, 2024, is hereby amended to include the following area as adversely affected by the disaster.

Primary County:

Roanoke County.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28818 Filed 12–6–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20852 and #20853; CHEYENNE RIVER SIOUX TRIBE Disaster Number SD–20009]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Cheyenne River Sioux Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Cheyenne River Sioux Tribe (FEMA–4842–DR), dated November 1, 2024.

Incident: Severe Storm, Straight-line Winds, and Flooding.

DATES: Issued on December 3, 2024.

Incident Period: July 13, 2024 through July 14, 2024.

Physical Loan Application Deadline Date: January 20, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: August 1, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Cheyenne River Sioux Tribe, dated November 1, 2024, is hereby amended to extend the deadline for filing applications for physical damage as a result of this disaster to January 20, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28817 Filed 12–6–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20610 and #20611; SAINT REGIS MOHAWK TRIBE Disaster Number NY–20016]

Presidential Declaration Amendment of a Major Disaster for the Saint Regis Mohawk Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Saint Regis Mohawk Tribe (FEMA–4818–DR), dated November 1, 2024.

Incident: Severe Storm and Flooding.

DATES: Issued on December 3, 2024.

Incident Period: August 8, 2024 through August 10, 2024.

Physical Loan Application Deadline Date: January 31, 2025.

Economic Injury (EIDL) Loan Application Deadline Date: August 1, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Saint Regis Mohawk Tribe, dated November 1, 2024, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to January 31, 2025.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–28793 Filed 12–6–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12555]

RIN 1400–AF92

Public Notice of Revised Exchange Visitor Skills List

AGENCY: Department of State.

ACTION: Public notice.

SUMMARY: The Department of State (''Department'') is announcing an update of the Exchange Visitors Skills List (''Skills List''). The Skills List is a list of countries designated by the Secretary of State as clearly requiring the services of persons engaged in certain fields of specialized knowledge or skills. This list is used by the Department of State and the Department of Homeland Security to determine whether an individual who has been admitted into the United States as a ''J'' nonimmigrant exchange visitor, or who acquired such status, is subject to the two-year foreign residence requirement under Section 212(e) of the Immigration and Nationality Act (''INA''), as amended.

DATES: The Exchange Visitor Skills List is applicable on December 9, 2024.

FOR FURTHER INFORMATION CONTACT: Jami Thompson, Senior Regulatory Coordinator, Visa Office, Bureau of Consular Affairs, Department of State; email: *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION: INA 212(e) (8 U.S.C. 1182(e)) provides that certain individuals who have been admitted to the United States as ''J'' nonimmigrant exchange visitors, or who acquired such status in the United States, are ineligible to apply for an immigrant visa, for permanent residence, or for certain nonimmigrant visas until they have resided and been physically present in their country of nationality or last residence for an aggregate of at least two years following departure from the United States. More specifically, under INA 212(e) (8 U.S.C. 1182(e)), this requirement attaches to J nonimmigrants who, among other criteria, are a national or resident of a country that the Secretary of State, pursuant to Department regulations, has designated as clearly requiring the services of persons engaged in the field of specialized knowledge or skill in which the individual was engaged. Department regulations at 22 CFR 41.62(c) implement the Secretary's designation authority under this provision, providing that an exchange visitor is subject to the two-year foreign residence requirement if they are a national or legal permanent resident of a ''country which the Secretary of State has designated, through publication by public notice in the **Federal Register**, as clearly requiring the services of persons engaged in the field of specialized knowledge or skill'' during their exchange visitor program. The Department also implements INA 212(e), 8 U.S.C. 1182(e) through regulations at 22 CFR 41.63 and 22 CFR 40.202.

Pursuant to the provisions of INA 212(e), 8 U.S.C. 1182(e), 22 CFR 41.62, and 22 CFR 41.63, the Department is announcing a revised Skills List. The Department has periodically updated the Skills List since the initial publication of the Skills List on April 25, 1972. New lists were published on February 10, 1978, June 12, 1984, January 16, 1997, and April 30, 2009. This revised Skills List supersedes the most recent Skills List published in 2009. Accordingly, J nonimmigrant exchange visitors who were subject to the two-year foreign residence requirement at the time of their admission or acquisition of J status based on designations in a previously published Skills List will no longer be subject to that requirement if their country is not designated in this revised

list. This Skills List was developed by the Bureau of Consular Affairs Visa Office in collaboration with the State Department's Office of the Chief Economist and the Bureau of Educational and Cultural Affairs.

The Department is updating the countries included on the Skills List based on criteria that is data driven, transparent, and consistent with U.S. goals for the development of foreign countries. The Department is not updating skills in this revision—for countries present on this revised Skills List, the skills listed remain the same as in the 2009 Skills List. The Skills List below accounts for overall economic development (as measured by per capita Gross Domestic Product (GDP)), country size, and overall outbound migration rate. [1]

- If a country has per capita GDP that is less than $7,500 [2] in 2023 dollars (calculated using the purchasing power parity (PPP) exchange rate), the Department presumes it would benefit from its nationals or residents possessing the specialized knowledge or skills designated on the Skills List.
- If a country is at or above the $ 7,500 GDP threshold, but below the median per capita GDP ($15,000 in 2023 dollars), and determined to be small, which makes it more difficult to develop internal hubs of specialized knowledge or skills, the Department presumes that country would benefit from its nationals or residents possessing the specialized knowledge or skills designated on the Skills List.
- If a country is at or above the $7,500 GDP threshold, but below the median per capita GDP ($15,000 in 2023 dollars), and has experienced a significant balance of outbound migration, which is likely to have resulted in the loss of talent and skills over the preceding decade, the Department presumes that country would benefit from its nationals or residents possessing the specialized knowledge or skills designated on the Skills List.

The Department has chosen these indicators and thresholds as an objective, measurable proxy for a country's standard of living and development and is closely linked to the accumulation of human capital within a given country. These criteria are meant to ensure countries with low levels of development as well as those countries with higher levels of development that have other extenuating circumstances that stymie the development of a skilled workforce will remain on the Skills List to support the development of that country.

The Department has chosen these criteria to assist its determination that the listed countries clearly require the services of persons engaged in designated fields of specialized knowledge or skills, because these well-established measures of a country's standard of living are informative of whether the country in fact clearly requires the relevant knowledge or skill, as opposed to the country only benefiting from or otherwise not requiring additional expertise in the relevant fields.

The Department intends to review the Skills List every three years and will publish updates as appropriate.

Exchange Visitors who seek a definitive determination from the Department of whether the two-year foreign residence requirement applies to them may request an Advisory Opinion from the Waiver Review Division. Information on this process is available on our website at *travel.state.gov*.

This Notice is exempt from notice and comment as it involves a foreign affairs function of the United States. 5 U.S.C. 553(a)(1).). The Department has invoked the foreign affairs exemption from Administrative Procedure Act (APA) requirements for numerous rules involving the Exchange Visitor Program going back to 1949, including several rules specifically relating to the two-year foreign residence requirement.[3]

Under 5 U.S.C. 553(a)(1), notice-and-comment requirements of the APA do not apply ''to the extent there is involved . . . a military or foreign affairs function of the United States.'' This exemption applies when the rule in question ''is clearly and directly involved in a foreign affairs function.'' [4] In addition, although the text of the APA does not require an agency invoking this exemption to show that such procedures may result in ''definitely undesirable international consequences,'' some courts have required such a showing.[5] Both standards are satisfied here.

In designating countries and skills on the Skills List, the Secretary is carrying out authority vested by Congress to assess the needs of foreign countries. As this relates to the Exchange Visitor Program, a key diplomacy tool, the Secretary's designations of countries on the list directly involves a foreign affairs function as the designations are a vehicle to advancing U.S. foreign policy objectives in countries whose nationals and residents participate in exchange visitor programs. The Exchange Visitor Program's nexus to foreign affairs is reflected in the purpose of the United States Information and Educational Exchange Act of 1948 to ''promote the better understanding of the United States among the peoples of the world and to strengthen cooperative international relations,'' [6] and the Secretary's discretionary designation of countries as ''clearly requiring'' certain fields of knowledge or skills by nature reflects a quintessential foreign affairs function. The Mutual Educational and Cultural Exchange Act of 1961 (also known as the Fulbright-Hays Act), provides further evidence of the foreign affairs function served by the Exchange Visitor Program.

''The purpose of this [Act] is to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries by means of educational and cultural exchange; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations, and the contributions being made toward a peaceful and more fruitful life for people throughout the world; to promote international cooperation for educational and cultural advancement; and thus to assist in the development of friendly, sympathetic, and peaceful relations between the United States and the other countries of the world.'' 22 U.S.C. 2451.

The revised Exchange Visitors Skills List clearly and directly involves a foreign affairs function given the nature of the Secretary's express authority to designate countries under INA section 212(e), 8 U.S.C. 1182(e). Even more generally, courts have acknowledged that ''[t]he exchange visitor program—with its statutory mandate for international interaction through nonimmigrants—certainly relates to the foreign affairs and diplomatic duties conferred upon the Secretary of State and the State Department.'' *Raoof* v. *Sullivan,* 315 F. Supp. 3d 34, 44 (D.D.C. 2018).

Further, requiring the Department to subject this list of designations to the

[1] All data taken from the World Bank Group Data (*https://data.worldbank.org/*).

[2] $7500 in 2023 dollars is approximately 50% of global median income or about the 33 percentile of income distribution, which covers about ⅓ of all countries with lowest human development indicator measure.

[3] *See, e.g.,* 14 FR 4591 (July 22, 1949), 21 FR 6270 (Aug. 21, 1956), 37 FR 7156 (Apr. 11, 1972), 37 FR 17470 (Aug. 29, 1972), 38 FR 20319 (July 31, 1973), 72 FR 10060 (Mar. 7, 2007).

[4] *Mast Indus.* v. *Regan,* 596 F. Supp. 1567, 1582 (Ct. Int'l Trade 1984) (quotation marks omitted).

[5] *E.g., Yassini* v. *Crosland,* 618 F.2d 1356, 1360 n.4 (9th Cir. 1980).

[6] Public Law 80–402 (1948).

APA's notice and comment requirements would result in ''definitely undesirable international consequences.'' The foreign relations considerations of opening this list of designations to public comment, including comment from foreign governments whose policies are directly affected by this list and requiring the Department to respond publicly to questions regarding the balancing of foreign policy and other national interests, would have definitely undesirable international consequences.[7] For example, if a foreign country expresses dissatisfaction with the Skills List designations, requiring the Department to air this disagreement in a public forum could have larger implications for foreign relations between the United States and that other country.

The 2024 Exchange Visitor Skills List reads as follows:

(01) Agriculture, Agriculture Operations, and Related Sciences

(01.00)

- Agriculture, General

(01.01)

- Agricultural Business and Management
- Production Operations and Mechanization

(01.06)

- Applied Horticulture/Horticulture

(01.09)

- Animal Sciences
- Agricultural Animal Breeding
- Animal Health and Nutrition
- Dairy Science
- Livestock Management
- Poultry Science

(01.10)

- Food Science

(01.11)

- Plant Sciences
- Crop Science
- Horticulture Science
- Agricultural and Horticultural Plant Breeding
- Pest Management
- Range Science

(01.12)

- Soil Science and Agronomy

(03) Natural Resources and Conservation

(03.01)

- Natural Resources Conservation and Research
- Environmental Science
- Wildlife Studies
- Wildlands Studies
- Environmental Protection

(03.02)

- Natural Resources Management and Policy

(03.03)

- Fishing and Fisheries Sciences
- Fishing and Fisheries Management

(03.05)

- Forestry

(04) Architecture and Related Services

(04.02)

- Architecture
- Environmental Design
- Interior Design
- Landscape Design
- Architectural History
- Architectural Technology

(04.03)

- City/Urban Planning
- Community and Regional Planning
- Architectural Urban Design

(05) Area, Ethnic, Cultural, and Gender Studies

—

(09) Communication, Journalism, and Related Programs

(09.01)

- Communication and Media Studies

(09.04)

- Journalism
- Broadcast Journalism
- Photojournalism
- On-Line/Web page News

(09.07)

- Telecommunication
- Radio Communication
- Television Communication
- Digital Communication
- Media/Multimedia

(09.09)

- Public Relations
- Advertising
- Applied Communication

(09.10)

- Publishing

(10) Communications Technologies, Technicians and Support Services

(10.01)

- Communications Technology/ Technicians

(10.02)

- Audiovisual Communications Technologies/Technicians
- Photographic and Film/Video Technology
- Radio and Television Broadcasting
- Recording Arts

(10.03)

- Graphic Communications
- Printing Management
- Prepress/Desktop Publishing and Digital Imaging Design
- Animation
- Interactive Technology
- Video Graphics and Special Effects
- Graphic and Printing Equipment Operator
- Printing Press Operator
- Computer Typography
- Composition Equipment Operator

(11) Computer and Information Sciences and Support Services

(11.01)

- Computer and Information Sciences, General
- Web page Design
- Database Administration
- Cybernetics
- Artificial Intelligence
- Robotics
- Information Technology

(11.02)

- Computer Programming

(11.03)

- Data Processing

(11.04)

- Information Science/Studies

(11.05)

- Computer Systems Analysis

(11.06)

- Data Entry
- Microcomputer Applications
- Word Processing

(11.07)

- Computer Science
- Systems Engineering

(11.10)

- Computer/Information Technology Administration
- Computer/Information Technology Management

(12) Personal and Culinary Services

(12.03)

- Funeral & Mortuary Service

(12.05)

- Cooking, Culinary Arts and Related Services
- Baking and Pastry Arts
- Bartending
- Culinary Arts/Chef Training
- Restaurant Management

[7] *Yassini* v. *Crosland,* 618 F.2d 1356, 1360 n.4 (9th Cir. 1980).

- Culinary and Catering Management
- Food Preparation/Professional Cooking
- Meat Cutting
- Food Service
- Institutional Food Workers

(13) Education

(13.01)

- Education, General
- Educational Administration

(13.02)

- Bilingual, Multilingual, and Multicultural

(13.03)

- Curriculum and Instruction
- Media Design

(13.06)

- Educational Assessment, Evaluation, and Research

(13.09)

- Social and Philosophical Foundations of Education

(13.10)

- Special Education and Teaching

(13.11)

- Student Counseling and Personnel Services

(13.12)

Teacher Education and Professional Development, Specific Levels and Methods, including, but not limited to:

- Adult and Continuing Education
- Early Childhood
- Elementary
- Middle School and Secondary Education
- Montessori Teacher Education
- Waldorf/Steiner Teacher Education

(13.13)

Teacher Education and Professional Development, Specific Subject Areas, including, but not limited to:

- Agriculture
- Art
- Business
- Computers
- Drama
- Driver Safety
- English
- Foreign Languages
- Geography
- Health
- History
- Home Economics
- Industrial Arts
- Sales and Marketing
- Math
- Music
- Physical Education
- Psychology
- Reading
- Science
- Social Studies
- Speech

(14) Engineering

(14.01)

- Engineering, General

(14.02)

- Aerospace, Aeronautical and Astronautical Engineering

(14.03)

- Agricultural/Biological Engineering and Bioengineering

(14.05)

- Biomedical/Medical Engineering

(14.07)

- Chemical Engineering

(14.08)

- Civil Engineering
- Geotechnical Engineering
- Structural Engineering
- Water Resources
- Transportation and Highway Engineering

(14.09)

- Computer Hardware and Software Engineering

(14.10)

- Electrical, Electronics and Communications Engineering
- Radio Engineering

(14.14)

- Environmental Engineering
- Pollution Control
- Waste and Hazardous Material Disposal

(14.18)

- Materials Engineering

(14.19)

- Mechanical Engineering

(14.20)

- Metallurgical Engineering

(14.21)

- Mining and Mineral Engineering

(14.22)

- Naval Architecture and Marine Engineering

(14.23)

- Nuclear Engineering

(14.24)

- Ocean Engineering

(14.25)

- Energy Engineering & Tech.
- Petroleum and Natural Gas

(14.33)

- Construction Engineering

(14.35)

- Industrial/Manufacturing Engineering

(14.38)

- Surveying Engineering

(14.39)

- Geological/Geophysical Engineering

(16) Foreign Languages, Literatures, and Linguistics

Including:

- Foreign Languages and Literatures
- Linguistics
- Language Interpretation and Translation
- Comparative Literature
- Language
- Literature and Linguistics for all Languages in the world including various forms and study of sign language

(19) Family and Consumer Sciences/ Human Sciences

(19.01)

- Family and Consumer Sciences, General
- Human Sciences, General (formerly, Home Economics)

(19.05)

- Foods, Nutrition, and Related Services

(19.09)

- Apparel and Textiles
- Textile Manufacturing
  - Textile Science
- Apparel and Textile Marketing Management
- Fashion and Fabric Consulting

(22) Legal Professions and Studies

Including:

- Law
- Legal Research
- Judicature
- All branches and specialties in the practice of law

(23) English Language and Literature/ Letters

Including:

- English Literature
- Composition
- Various types of English Writing

(24) Liberal Arts and Sciences, General Studies and Humanities

—

(25) Library Science

(26) Biological and Biomedical Sciences

(26.01)

- Biology

(26.03)

- Botany/Plant Biology

(26.04)

- Anatomical Sciences
- Anatomy

(26.05)

- Microbiological Sciences and Immunology

(26.07)

- Zoology/Animal Biology

(26.08)

Genetics, all types, including:

- Animal
- Plant
- Molecular
- Microbial and Eukaryotic
- Human
- Genetic Engineering
- Biomathematics
- Bioinformatics

(26.12)

- Biotechnology

(26.13)

- Ecology, Population Biology

(27) Mathematics and Statistics

—

(31) Parks, Recreation, Leisure, and Fitness Studies

(31.01)

- Parks, Recreation and Leisure Studies

(31.05)

- Health and Physical Education/ Fitness

(36.0101)

- Camp Counselor

(38) Philosophy and Religious Studies

—

(39) Theology and Religious Vocations

—

(40) Physical Sciences

(40.01)

- Physical Sciences

(40.02)

- Astronomy
- Astrophysics
- Planetary Astronomy and Science
- Space Technology

(40.04)

- Atmospheric Sciences and Meteorology

(40.05)

- Chemistry

(40.06)

- Geological and Earth Sciences
- Geosciences
- Oceanography
- Hydrology

(40.08)

- Physics

(41) Science Technologies/Technicians

—

(42) Psychology

Including, but not limited to:

- Psychometrics
- Psychobiology

(43) Security and Protective Services

Including:

- Law Enforcement
- Fire Protection
- Corrections

(44) Public Administration and Social Service Professions

(44.04)

- Public Administration
- City Planning
- Urban Planning
- Urban Transportation

(44.07)

- Social Work
- Youth Services
- Welfare
- Probation

(45) Social Sciences

(45.02)

- Anthropology
- Physical Anthropology

(45.03)

- Archeology

(45.04)

- Criminology

(45.05)

- Demography and Population Studies

(45.06)

- Economics

(45.07)

- Geography
- Cartography

(45.09)

- International Relations and Affairs

(45.10)

- Political Science and Government

(45.11)

- Sociology

(45.99)

- Social Sciences, Other

(46) Construction Trades

—

(47) Mechanic and Repair Technologies/Technicians

—

(48) Precision Production

(48.00)

- Precision Production Trades
- Metal Working
- Woodworking
- Drafting

(49) Transportation and Materials Moving

(49.01)

Air Transportation, including:

- Aeronautics/Aviation/Aerospace Science and Technology, General
- Airline/Commercial/Professional Pilot and Flight Crew
- Aviation/Airway Management and Operations
- Air Traffic Controller
- Flight Instructor

(49.02)

Ground Transportation, including:

- Construction
- Heavy Equipment/Earthmoving Equipment Operation
- Commercial Vehicle Operation
- Mobil Crane Operation

(49.03)

Marine Transportation, including:

- Commercial Fishing
- Diver, Professional Instructor
- Marine Science
- Merchant Marine

(50) Visual and Performing Arts

(50.01)

Visual and Performing Arts, including, but not limited to:

- Music
- Theatre
- Sculpture
- Photography
- TV & Motion Picture Arts & Sciences

(50.04)

Design and Applied Arts, including:

- Commercial and Advertising Art
- Industrial Design
- Fashion/Apparel Design
- Interior Design
- Graphic Design
- Illustration

(51) Health Professions and Related Clinical Sciences

(51.01)

- Chiropractic

(51.02)

- Communication Disorders Sciences & Services
- Speech Language Pathology
- Sign Language Interpretation

(51.04)

- Dentistry
- Advanced/Graduate Dentistry
- Oral Sciences
- Dental Technology
- Orthodontics

(51.06)

- Dental Support Services/Assistant

(51.07)

- Health and Medical Administrative Services
- Health/Medical Statistics and Documentation

(51.08)

- Medical Support Services/Assistant

(51.09)

Allied Health Diagnostic, Intervention, and Treatment Professions, including, but not limited to the following fields:

- Emergency Medical
- Cardiovascular
- Electrocardiograph Electroneurodiagnostic/ Electroencephalographic
- Nuclear Medical
- Perfusionist
- Radiation Therapy
- Respiratory Care Therapy
- Surgical
- Sonography and Ultrasound
- Radiography
- Athletic Training
- Genetic Therapy
- Cardiopulmonary
- Radiation Protection/Health Physics

(51.10)

- Clinical/Medical Laboratory Science and Allied Professions

(51.12)

Medicine/Medical Research, all specialties and fields, including, but not limited to:

- Allergy and Immunology
- Anesthesiology
- Audiology
- Cancer
- Cardiography
- Cardiology
- Dermatology
- Embryology
- Emergency Medicine
- Epidemiology
- Family Practice
- Forensic Medicine
- Gastroenterology
- Geriatrics
- Hematology
- Internal Medicine
- Medical Genetics
- Neurology
- Nuclear Medicine
- Obstetrics and Gynecology
- Oncology
- Ophthalmology
- Orthopedic Surgery
- Otolaryngology
- Pathology
- Pediatrics
- Pharmacology and Pharmaceutics
- Physical Medicine and Rehabilitation
- Physiology
- Plastic Surgery
- Podiatry
- Preventive Medicine
- Proctology
- Psychiatry
- Radiology
- Radiation Oncology
- Speech Pathology
- Sports Medicine
- Surgery
- Toxicology
- Transitional
- Urology
- Virology

(51.15)

- Mental and Social Health Services
- Substance Abuse Counseling
- Marriage/Family Counseling
- Psychoanalysis

(51.16)

- Nursing (including all specialties)

(51.17)

- Optometry

(51.19)

- Osteopathic Medicine/Osteopathy

(51.20)

- Pharmacy (including Administration)

(51.22)

- Public Health, including, but not limited to:
- Environmental Health
- Occupational Health and Industrial Hygiene
- Public Health Education and Promotion
- International Health
- Community Health and Preventive Medicine
- Health Services Administration

(51.23)

- Rehabilitation and Therapeutic Professions

(51.24)

- Veterinary Medicine

(51.25)

Veterinary Biomedical and Clinical Sciences, including all Veterinary Sciences:

- Anatomy
- Physiology
- Microbiology
- Pathology
- Toxicology
- Animal/Veterinary Surgery and Medicine

(51.27)

- Medical Illustration
- Informatics & Medical Photography

(51.31)

- Dietetics and Clinical Nutrition

(51.33)

- Alternative Medicine

(52) Business, Management, Marketing, and Related Support Services

(52.02)

- Business Administration
- Management and Operations
- Industrial Administration & Management
- Small Business Administration/ Operations
- Franchising

(52.03)

- Accounting and Related Services

(52.04)

- Business Operations Support and Assistant Services

(52.06)

- Business/Managerial Economics
- Management Studies & Economic Information Analysis

(52.08)

- Finance
- Banking and Financial Management Services

(52.09)

- Hospitality Administration/ Management
- Hotel, Motel, and Restaurant Management & Tourism
- Travel Services Management

(52.10)

- Human Resources Management and Services
- Labor and Industrial Relations
- Organizational Behavior Studies
- Labor Studies

(52.11)

- International Business/Trade/ Commerce

(52.12)

- Management Information Systems and Services

(52.13)

- Management Sciences and Quantitative Methods

- Operations Research
- Statistics

(52.14)

- Marketing/Marketing Management

(52.15)

- Real Estate

(52.16)

- Taxation

(52.17)

- Insurance

(52.20)

- Construction Management

(54) History

(54.01)

- History
- Regional History, such as American, European and Asian
- History of Science and Technology
- Public/Applied History
- Archival Administration

(60) Medical Residency Programs

(60.01)

Dental Residency Programs:

(60.02)

Medical Residency Programs:

- The program sponsor for medical residency programs is The Educational Commission for Foreign Medical Graduates

(60.03)

- Veterinary Residency Programs

Country Skill Codes

*Belize **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Benin

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Burkina Faso **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Burma (Myanmar) **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Cambodia

- 01.01, 03.01, 04.03, 10.01, 13.01, 14.14, 44.04, 51.08, 51.12

Cameroon

- 03.01, 03.05, 04, 09, 10, 11, 13, 14, 16, 19.05, 23, 24, 25, 26, 27, 31.01, 38, 39, 40, 41, 43, 44, 45, 46, 47, 50, 51.01, 51.04, 51.06, 51.07, 51.08, 51.09, 51.10, 51.12, 51.15, 51.16, 51.17, 51.19, 51.20, 51.22, 51.23, 51.24, 51.25, 51.27, 51.31, 51.33, 52.02, 52.03, 52.04, 52.06, 52.08, 52.09, 52.11, 52.12, 52.13, 52.14, 52.15, 52.20, 54, 60

Cape Verde

- 01, 03, 10, 11, 13, 14, 16, 26, 27, 40, 41, 42, 43, 44, 51

*Congo, Dem. Rep.**

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Djibouti

- 01, 13, 19, 23, 24, 25, 26, 27, 31, 41, 42, 45, 46, 47, 48, 51, 52, 60

*Ecuador **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

El Salvador

- 01.00, 01.01, 01.06, 01.09, 01.10, 01.12, 03.01, 03.02, 03.03, 04.03, 09.01, 09.07, 09.10, 11, 12, 13.01, 13.02, 13.06, 13.09, 13.10, 13.11, 13.12, 13.13, 14.01, 14.02, 14.05, 14.07, 14.09, 14.18, 14.20, 14.22, 14.25, 14.33, 14.35, 14.39, 16, 19.05, 23, 24, 25, 26.04, 26.05, 26.07, 26.08, 26.11, 26.12, 26.13, 31.01, 31.05, 38, 40, 43, 44, 45.02, 45.03, 45.05, 45.07, 45.09, 45.10, 49, 50, 51.02, 51.04, 51.06, 51.07, 51.08, 51.09, 51.10, 51.15, 51.16, 51.17, 51.19, 51.20, 51.22, 51.23, 51.24, 51.25, 51.27, 51.31, 51.33, 52.03, 52.06, 52.09, 52.10, 52.11, 52.12, 52.15, 52.16, 52.20, 54, 60

*Eritrea **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Eswatini

- 01, 03, 04, 09.01, 09.04, 09.07, 09.09, 10, 11, 13, 14, 19.09, 22, 26, 27, 31, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49.01, 49.02, 50.04, 51, 52, 60

Ethiopia

- 01, 03, 04, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Fiji **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Gambia, The

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54

Ghana

- 01, 03, 04, 09, 10, 11, 13, 14, 16, 19.01, 19.05, 24, 25, 26, 27, 31, 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Guatemala

- 01, 03, 04, 05, 09.01, 09.04, 09.07, 09.10, 10, 11, 13, 14, 16, 19.01, 19.05, 22, 23, 24, 25, 26, 27, 40, 41, 42, 43, 44, 45, 48, 49, 51, 52.02, 52.03, 52.04, 52.06, 52.08, 52.09, 52.10, 52.11, 52.12, 52.13, 52.15, 52.16, 52.20, 60

Haiti

- 01, 03, 04, 09, 10, 11, 13, 14, 19, 22, 23, 24, 26, 27, 31, 40, 41, 42, 43, 44, 45

*Honduras **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Jamaica **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Kenya **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Kosovo

- 01.01, 01.06, 03.01, 03.02, 03.05, 04, 05, 09, 10, 11, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Lebanon **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Liberia **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Malawi

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14.01, 14.03, 14.05, 14.07, 14.08,

14.09, 14.10, 14.14, 14.18, 14.19, 14.20, 14.21, 14.25, 14.33, 14.35, 14.38, 14.39, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Mali

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*Mauritania **

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Mozambique

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Nepal

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*Nicaragua **

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Niger

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Nigeria

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Palestinian Authority (West Bank and Gaza)

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Philippines, The

- 01, 03, 04.03, 05, 09.01, 09.09, 09.10, 10, 11, 13.02, 13.06, 13.09, 13.10, 13.11, 13.12, 13.13, 14, 16, 19, 23, 25, 26, 27, 31, 39, 40, 41, 42, 43, 44.07, 45, 49, 51.01, 51.02, 51.04, 51.06, 51.07, 51.08, 51.09, 51.10, 51.12, 51.15, 51.17, 51.19, 51.22, 51.23, 51.24, 51.25, 51.27, 51.31, 51.33, 52.04, 52.06, 52.10, 52.11, 52.13, 52.14, 52.17, 52.20, 54, 60

Rwanda

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 31, 38, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Senegal

- 01, 03, 04, 09, 10, 11, 13, 14, 16, 22, 23, 24, 25, 26, 27, 38, 40, 41, 42, 43, 44, 45, 47, 48, 49, 50, 51, 52, 54, 60

Tajikistan

- 01, 04, 10, 11, 14

Tanzania

- 01, 03, 04.02, 09.01, 09.04, 11, 13, 14, 16, 25, 26, 27, 31.01, 40, 41, 42, 43, 44, 45, 46, 47, 51, 52.02, 52.03, 52.08, 52.09, 52.10, 52.11, 52.20, 60

*Timor-Leste **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Togo

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*Tonga **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

Venezuela, RB

- 01, 03, 04.03, 05, 09.01, 09.07, 10, 11, 13, 14, 16, 19.01, 19.05, 23, 24, 25, 26, 27, 31.01, 31.05, 38, 40, 41, 42, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Yemen, Rep.**

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

*Zambia **

- 01, 03, 04, 05, 09, 10, 11, 12, 13, 14, 16, 19, 22, 23, 24, 25, 26, 27, 31, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 54, 60

* All listed skills apply to this country.

Julie M. Stufft,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2024–28718 Filed 12–6–24; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0253]

Entry-Level Driver Training; Albert Farley Jr.; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Albert Farley Jr. has requested an exemption from the theory and behind-the-wheel (BTW) instructor requirements contained in the entry-level driver training (ELDT) regulations for himself as a prospective training instructor. Mr. Farley Jr. seeks an exemption from the requirement that instructors have at least two years of driving experience of the same or higher class and/or the same endorsement level as the commercial motor vehicle (CMV) to be operated to satisfy the instructor requirements under the ELDT regulations. FMCSA requests public comment on the applicant's request for exemption.

DATES: Comments must be received on or before January 8, 2025.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2024–0253 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2024–0253) for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: If you do not have access to the internet, you may view the docket by visiting Docket Operations on the ground floor of the DOT West Building,

1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL–14 FDMS, which can be reviewed under the ''Department Wide System of Records Notices'' at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 366–2722; *richard.clemente@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2024–0253), indicate the specific section of this document to which the comment applies, and provide a reason for your suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number ''FMCSA–2024–0253'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses submitted by the applicant. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely maintain a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reasons for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Applicant's Request

Albert Farley, Jr. requests an exemption from the two-year road time requirement for a Class A CDL in 49 CFR 380.301. Although Mr. Farley's application references 49 CFR 380.301, section 380.301 applies to Longer Combination Vehicle (LCV) instructor requirements. FMCSA contacted Mr. Farley and confirmed that he is a Class A CDL holder who instructs Class A and B CDL students and does not seek to be an LCV instructor. FMCSA clarified that Mr. Farley requests an exemption from the requirement in the ELDT regulations in 49 CFR 380.605 that theory and BTW instructors have at least two years of driving experience of the same or higher class and/or the same endorsement level as the CMV to be operated.

Mr. Farley requests the exemption due to the growing demand for Class A CDL operators in his county, as agricultural hauling and logging are two primary industries that rely heavily on these drivers. He further asserts that there is an urgent need for CDL instructors as there are only three driver training schools that offer such training. The applicant adds that over the past 32 years, he has gained valuable experience as a bus driver, and in the last two years he has taken on the role of instructor to address the bus driver shortage by becoming a Class 1 CDL—Bus Driver Education Instructor. The applicant further states that fulfilling the two-year road requirement in the ELDT rules would pose a financial strain and create a void in his current workplace. Mr. Farley's application includes three letters of support emphasizing Mr. Farley's work experience and the need for more Class A instructors.

A copy of Albert Farley Jr.'s application for exemption and the letters in support of his application are available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Albert Farley, Jr.'s application for an exemption from the requirements in 49 CFR 380.605 from the definition of a Theory and Behind-the-wheel (BTW) instructor, which would allow Mr. Farley to become a class A CDL instructor without two years of interstate driving on his class A CDL license. All comments received before

the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–28764 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0125]

Commercial Driver's License; 3 North LLC; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; denial of application for exemption.

SUMMARY: FMCSA announces its decision to deny 3 North LLC's request for a 5-year exemption to enable 3 of its commercial driver's license (CDL) holders under the age of 21, with a ''K'' restriction for intrastate-only operations, to drive commercial motor vehicles (CMVs) in intrastate operations in a State other than their State of domicile. FMCSA analyzed the application and public comments and determined that the exemption would not likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

FOR FURTHER INFORMATION CONTACT: Ms. Bernadette Walker, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 385–2415; *bernadette.walker@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Services, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view comments, go to *www.regulations.gov,* insert the docket number ''FMCSA–2024–0125'' in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click ''Browse Comments.''

To view documents mentioned in this notice as being available in thein the docket, go to *www.regulations.gov,* insert docket number ''FMCSA–2024–0125'' in the keyword box, click ''Search,'' and choose the document to review.

If you do not have access to the internet, you may view the docket by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the safety analyses submitted by the applicant.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). If granted, the exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulation(s)/Requirements

Drivers of CMVs, as defined in 390.5T, operating in interstate commerce, must be at least 21 years of age (§ 391.11(b)(1)). CDL holders who are younger than age 21 may drive in intrastate commerce only in the driver's State of domicile. FMCSA's CDL regulations in 49 CFR 383.153(a)(10)(vii) require that CDLs issued to drivers limited to intrastate commerce be marked with a ''K'' restriction.

Applicant's Request

3 North LLC's application for an exemption was described in detail in the **Federal Register** published on June 11, 2024 (89 FR 49263) and will not be repeated here as the facts have not changed.

IV. Public Comments

In the **Federal Register** Notice announcing the receipt of 3 North LLC's application, FMCSA requested public comments by July 11. FMCSA subsequently extended the comment period until July 25, 2024 (89 FR 56473) because the exemption application was not available for public review in the docket until June 24, 2024.

The Agency received six comments, one supporting the application, three opposing, and two neither supporting nor opposing it. The Hooper Cooperation stated in support, ''There are many exceptions in the FMCSRs that attempt to balance the need for public safety with the common value of the service being performed by the CMV driver, including one relieving hours of service requirements for utility service vehicles. One would think similar consideration could be made for the 'K' restricted CDL holder provided they operate only in a route-defined intrastate capacity when working on projects outside of their home state.''

Three commenters opposed the exemption. The Truck Safety Coalition, Citizens for Reliable and Safe Highways, and Parents Against Tired Truckers jointly stated, ''This exemption request is unsafe and defies all available evidence for teen driving safety.'' They said about the applicant's request, ''No data is cited regarding the vehicle density of the alleged remote roads. No reason is given why the company cannot simply hire drivers with a CDL age 21 or older. No additional precautions are proposed for these under-21 drivers to minimize risk to themselves or others on the road or at the job site. No effort is made to ensure they achieve an equivalent or greater level of safety with a high-risk cohort of drivers.'' The American Association of Motor Vehicle Administrators (AAMVA) stated that States use the intrastate in a variety of different circumstances, commenting, ''the application of the K restriction as limited to intrastate operations is specifically meant to ensure that the driver, who has not met federal regulatory obligations, is prevented from moving to another jurisdiction and exchanging a restricted driver's license for another restricted license. If the license transfer process does not include

a reason for issuance, drivers may now be allowed to operate in environments for which they may not be qualified.'' AWM Associates, LLC stated, ''FMCSA should not be interfering with state laws regarding transfer of CDLs.''

Dennis Murphy made the following suggestion: ''3 North LLC could accomplish its goals of having 18–20-year-old CDL holders operate in another State by enrolling in the Safe Driver Apprenticeship Program without requiring any exemptions. This would ensure that the 18–20-year-old CDL holders who are operating in another State than they hold a license in are held to the same standards as any other 18–20-year-old CDL holder who wishes to operate in a different state than they hold a license in.'' CL, an individual, stated, ''If an exemption is granted, the exempted individuals should be required to obtain a medical certificate. This exemption must be tied to the three (3) individuals and should not be transferable once those individuals turn 21.''

V. FMCSA Safety Analysis and Decision

FMCSA evaluated 3 North LLC's application and the public comments and denies the exemption request. Based on the information provided by the applicant and commenters, the Agency is unable to determine that the applicant would likely achieve a level of safety equivalent to, or greater than, the level obtained by complying with the regulation. FMCSA agrees with AAMVA that allowing drivers with a ''K'' restriction to operate in States other than their State of domicile could disrupt and confuse each State's use of the ''K'' restriction and could allow drivers to operate in environments for which they may not be qualified. Accordingly, the Agency would need persuasive evidence that such operations would likely achieve an equivalent level of safety before interfering with the ''K'' restriction. Furthermore, FMCSA agrees that the more appropriate path for motor carriers interested in using individuals under the age of 21 is the Agency's Safe Driver Apprenticeship Program (*https://www.fmcsa.dot.gov/sdap*).

For the reasons stated above, 3 North LLC's exemption application is denied.

Vincent G. White,

Deputy Administrator.

[FR Doc. 2024–28850 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No.: DOT–OST–2024–0130]

Public Interest Waiver of the Application of Certain Domestic Preference Requirements and Policies for Transit-Oriented Development Housing Projects

ACTION: Notice; request for comment.

SUMMARY: In order to expeditiously deliver projects and provide meaningful infrastructure results while ensuring the appropriate application of domestic content standards, the U.S. Department of Transportation (DOT) is proposing a waiver of the domestic preference requirements to transit-oriented development (TOD) projects that receive credit assistance through the Build America Bureau (the Bureau) under the Transportation Infrastructure Finance and Innovation Act (TIFIA) and Railroad Rehabilitation and Improvement Financing (RRIF) credit programs.

DATES: Comments must be received by December 24, 2024.

ADDRESSES: Comments on this notice may be submitted to the U.S. Government electronic docket site at *https://www.regulations.gov,* Docket: DOT–OST–2024–0130.

Note: All submissions received, including any personal information therein, will be posted without change or alteration to *https://www.regulations.gov.* For more information, you may review DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Duane Callender, US Department of Transportation, Build America Bureau, at 202–366–2300 or *Duane.Callender@dot.gov.* For legal questions, please contact, Jessica Pettrone, DOT Office of the General Counsel, at 202–366–8560 or *jessica.pettrone@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

DOT has a longstanding policy of requiring all projects, including TOD projects, receiving TIFIA and RRIF credit assistance to comply with domestic steel, iron, and manufactured products content requirements, collectively known as ''Buy America'' requirements,[1] even where not covered by a specific Buy America statute. DOT has consistently required for-profit borrowers to comply with Buy America requirements on projects receiving credit assistance since TIFIA's inception in 1998 and since 2010 for RRIF, whether or not appropriated funds were used for the cost of the credit assistance. Accordingly, because Buy America is applied to all projects receiving TIFIA or RRIF credit assistance, DOT, in an effort to ensure transparency and maintain consistency in the application of Buy America standards for all recipients (one rule for all projects and borrowers), proposes to apply this waiver to both projects with for-profit borrowers that do not use any appropriated funds for the cost of the loan, to which Buy America requirements are applied as a matter of policy, as well as to projects with non-Federal entity borrowers (whether or not such loans use appropriated funds), to which Buy America requirements apply as a matter of law. DOT proposes a waiver of the Buy America manufactured products requirement for TIFIA and RRIF TOD projects that include any housing elements (TOD Housing Projects) and that enter into creditworthiness review on or before December 31, 2025.

On November 15, 2021, President Biden signed the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act (IIJA). Public Law 117–58. BIL reauthorized Federal surface transportation programs and invested billions in transformational projects that are creating good-paying jobs, growing the economy, and making our transportation system safer and more resilient. TOD projects are eligible for both TIFIA (23 U.S.C. 601(a)(12)(E)) and RRIF (49 U.S.C. 22402(b)(1)(F)) financing, subject to all other eligibility criteria, and compliance with all applicable Federal requirements and creditworthiness standards.[2]

Transportation and land use reforms are central strategies to achieving many of the Biden-Harris administration goals, including reaching net-zero greenhouse gas emissions by 2050; addressing the housing supply and affordability crises throughout the country; and advancing equity, fair

[1] As described in more detail below, after the enactment of the Infrastructure Investment and Jobs Act in 2021 (Pub. L. 117–58), Buy America requirements now include domestic construction material requirements.

[2] Eligible TOD projects can take many forms, including joint development; public infrastructure; and economic development, including commercial and residential development. One of the key parameters of the programs, among others, is that TOD projects must be within walking distance of a qualifying transit or passenger rail station. *See https://www.transportation.gov/buildamerica/TOD.*

housing, and environmental justice.[3] Providing long-term, low-interest direct loans through the TIFIA and RRIF credit programs to TOD projects is one of the primary tools available to DOT to help achieve this mission.

Over the last three years, DOT has taken several concrete steps to date to facilitate TOD financing under the TIFIA and RRIF credit programs. DOT has published TOD guidance [4] and a policy statement [5] and authorized TOD projects' eligibility to borrow up to the maximum allowed under TIFIA to promote the creation of more walkable, mixed-use spaces near transit that support vibrant, sustainable, and equitable communities.[6] Additionally, the Bureau has worked on outreach to developers and created several tools including the TOD Eligibility Map [7] and has conducted webinars to help educate potential borrowers about the opportunities and requirements of the programs.

The BIL also includes the Build America, Buy America Act (BABA) at div. G, sec. 70901–52. BABA greatly strengthens Made in America standards by expanding the coverage and application of Buy America preferences in Federal financial assistance programs for infrastructure. The Act requires that the head of each covered Federal agency shall ensure that ''none of the funds made available for a Federal financial assistance program for infrastructure . . . may be obligated for a project unless all of the iron, steel, manufactured products, and construction materials used in the project are produced in the United States.'' BIL sec. 70914(a).

BABA applies to Federal financial assistance, which term includes ''all expenditures by a Federal agency to a non-Federal entity for an infrastructure project.'' BIL sec. 70912(4)(B). ''Non-Federal entity,'' as defined in 2 CFR 200.1, does not include for-profit entities. Therefore, BABA by its terms does not apply to Federal financial assistance to for-profit entities.[8] However, in accordance with the Office of Management and Budget (OMB)'s Guidance Memorandum M–24–02, *Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure,* Federal agencies may consider applying domestic preference requirements to for-profit entities, consistent with their legal authorities. DOT has a longstanding policy of requiring all projects, including TOD projects, receiving TIFIA or RRIF credit assistance to comply with domestic steel, iron, and manufactured products content requirements, collectively known as ''Buy America'' requirements,[9] even where not covered by a specific Buy America statute, including chapter 83 of title 41, United States Code (Buy American), because no appropriated funds are used for the cost of the loan. DOT has consistently required for-profit borrowers to comply with Buy America requirements on projects receiving credit assistance since TIFIA's inception in 1998 and since 2010 for RRIF, whether or not appropriated funds were used for the cost of the credit assistance. Accordingly, because Buy America is applied to all projects receiving TIFIA or RRIF credit assistance, DOT, in an effort to ensure transparency and maintain consistency in the application of Buy America standards for all recipients (one rule for all projects and borrowers), will apply this waiver to both projects with for-profit borrowers that do not use any appropriated funds for the cost of the loan, to which Buy America requirements are applied as a matter of policy, as well as to projects with non-Federal entity borrowers (whether or not such loans use appropriated funds), to which Buy America requirements apply as a matter of law. DOT is proposing a waiver of the Buy America manufactured products requirement for TOD Housing Projects that enter into creditworthiness review on or before December 31, 2025.

TOD projects are a class of eligible capital projects under the TIFIA and RRIF credit programs administered by the Bureau. The Bureau recently provided guidance on Federal requirements for TOD projects receiving TIFIA or RRIF credit assistance.[10] Pursuant to that guidance, the Bureau reiterated the DOT's longstanding policy of requiring all projects, including TOD projects, receiving TIFIA and RRIF credit assistance to comply with domestic steel, iron, and manufactured products content requirements, collectively known as ''Buy America'' requirements, even where not covered by a specific Buy America statute, including Buy American requirements because no appropriated funds are used for the cost of the loan.

Waiver

DOT is proposing to issue a public interest waiver of the Buy America requirements for manufactured products that apply to Bureau-financed TOD Housing Projects that enter into creditworthiness review on or before December 31, 2025. For these projects, DOT would continue to apply domestic steel, iron, and construction materials content requirements.

To ensure transparency and maintain consistency in the application of Buy America standards for all recipients (one rule for all projects and borrowers), this waiver will apply to both TOD Housing Projects with for-profit borrowers and those with non-Federal entity borrowers.

To continue to support the goals of Buy America policies, DOT will work closely with TOD Housing Project borrowers to better understand and document the sources of materials and products used in such projects. This research will assist DOT in refining its domestic preference requirements policy for TOD projects entering enter the Bureau's creditworthiness review phase after January 1, 2026, and to further support both the delivery of housing and domestic manufacturing.

Under OMB Memorandum M–24–02, agencies are expected to assess ''whether a significant portion of any cost advantage of a foreign-sourced product is the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products'' as appropriate before granting a public interest waiver. DOT's analysis has concluded that this assessment is not applicable to this waiver.

DOT will consider all comments received in the initial 15-day comment

[3] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/16/president-biden-announces-new-actions-to-ease-the-burden-of-housing-costs/.*

[4] *https://www.transportation.gov/buildamerica/TOD.*

[5] *https://www.transportation.gov/buildamerica/sites/buildamerica.dot.gov/files/2023-10/TOD%20Policy%20Statement.pdf*

[6] *https://www.transportation.gov/buildamerica/TIFIA49.*

[7] *https://www.transportation.gov/buildamerica/about/resources-mode/interactive-map-tifia-and-rrif-tod-eligibility.*

[8] *See* OMB Memorandum M–22–11 *Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure* (April 18, 2022), p. 2 (''for-profit organizations are not considered non-Federal entities''); OMB Memorandum M–24–02 *Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure* (October 25, 2023), p. 4 (restating the guidance on for-profit entities from M–22–11); and 88 FR 57750, 57774 (October 23, 2023) (''Thus—although OMB does not require them to do so—Federal agencies are allowed, under the existing structure of part 200, to apply part 200, including the domestic preferences at § 200.322, to for-profit entities'').

[9] As noted above, after the enactment of BABA, Buy America requirements now include domestic construction material requirements per BIL sec. 70914(a).

[10] *https://www.transportation.gov/buildamerica/about/resources-mode/tod-project-federal-requirements-guidance.*

period during our consideration of the proposed waiver. Comments received after this period, but before notice of our finding is published in the **Federal Register**, will be considered to the extent practicable.

Issued in Washington, DC.

Polly E. Trottenberg,

Deputy Secretary.

[FR Doc. 2024–28820 Filed 12–6–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Information Collection and Request for Public Comment

ACTION: Notice and request for public comment.

SUMMARY: The U.S. Department of the Treasury, as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act (PRA) of 1995. Currently, the Community Development Financial Institutions Fund (CDFI Fund), U.S. Department of the Treasury, is soliciting comments concerning information collections utilized by the CDFI Bond Guarantee Program (BG Program). Information on the BG Program can be found on the CDFI Fund's website at *https://www.cdfifund.gov/programs-training/programs/cdfi-bond*.

DATES: Written comments must be received on or before February 7, 2025 to be assured of consideration.

ADDRESSES: You may submit comments concerning the BG Program information collections via the Federal e-Rulemaking Portal at *www.regulations.gov*. Follow the instructions on the website for the submission of comments. In general, all comments will be available for inspection at *www.regulations.gov*. Comments, including attachments and other supporting materials, are part of the public record. Do not submit any information in your comments or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Susan Suckfiel, BG Program Manager, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington DC 20220, (202) 653–0421 (not a toll-free number) or by email to *bgp@cdfi.treas.gov*. Information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's website at *http://www.cdfifund.gov*.

SUPPLEMENTARY INFORMATION:

Titles: BG Program Information Collections—(1) Qualified Issuer Application, (2) Guarantee Application, (3) Secondary Loan Requirements Certification, (4) Financial Condition Monitoring Report, (5) Pledged Loan Monitoring Report, (6) Tertiary Loan Monitoring Report, (7) Annual Assessment Report, and (8) Secondary Loan Commitment Form.

OMB Number: 1559–0044.

Abstract: The purpose of the Community Development Financial Institutions (CDFI) Bond Guarantee Program (BG Program) is to support CDFI lending by providing Guarantees for Bonds issued by Qualified Issuers as part of a Bond Issue for Eligible Community or Economic Development Purposes. The BG Program provides CDFIs with a source of long-term capital and further the mission of the CDFI Fund to increase economic opportunity and promote community development investments for underserved populations and distressed communities in the United States. The CDFI Fund achieves its mission by promoting access to capital and local economic growth by investing in, supporting, and training Community Development Financial Institutions (CDFIs). The operation of the BG Program is supported by the collection of information across various forms, collectively the BG Program Information Collections: (1) Qualified Issuer Application, (2) Guarantee Application, (3) Secondary Loan Requirements Certification, (4) Financial Condition Monitoring Report, (5) Pledged Loan Monitoring Report, (6) Tertiary Loan Monitoring Report, (7) Annual Assessment Report, and (8) Secondary Loan Commitment Form. There are no significant content changes to the forms; however, minor, non-substantive changes may have been made to certain forms in order to improve the clarity and/or accuracy of the data collections.

Copies of the forms constituting the BG Program Information Collection may be found on the CDFI Fund's website at *https://www.cdfifund.gov*.

Current Actions: Extension without change of currently approved collection.

Type of Review: Regular.

Affected Public: Approved Eligible CDFIs and Qualified Issuers (QI).

TABLE 1—ALL FORMS—ESTIMATED REPORTING BURDEN

Form	Number of respondents	Number of responses per respondent	Number of annual responses	Hours per response	Number of hours annually
Bond Guarantee Program Application Materials (Qualified Issuer Application and Guarantee Application)	20	1	20	80	1,600
Financial Condition Monitoring (FCM) Report	40	4	160	1.5	240
Pledged Loan Monitoring (PLM) Report	40	12	480	1.5	720
Tertiary Loan Monitoring (TLM) Report	15	12	180	1.5	270
Annual Assessment	40	1	40	2	80
Secondary Loan Commitment Form and Certification Form	40	1	40	3	120
Total	.....	.....	920	.....	3,030

Request for Comments: Comments submitted in response to this Notice will be summarized and/or included in the request for Office of Management and Budget approval. Comments concerning the BG Program Information Collection are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on

respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collections of information displays a valid OMB control number.

Authority: 12 CFR part 1808.

Pravina Raghavan,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2024–28833 Filed 12–6–24; 8:45 am]

BILLING CODE 4810–05–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Application and Renewal Fees Imposed on Surety Companies and Reinsuring Companies; Increase in Fees Imposed; Correction

AGENCY: Bureau of the Fiscal Service, Treasury.

ACTION: Notice of fees imposed on surety companies and reinsuring companies; Correction.

SUMMARY: The Department of the Treasury, Bureau of the Fiscal Service, published a document in the Federal Register of December 2, 2024, adding renewal fees for Complementary and Alien Reinsurers as well as Admitted Reinsurer—Reinsurance Market companies and increasing the existing fees it imposes on and collects from surety companies and reinsuring companies, effective January 1, 2025. The document contained typographical errors effecting the dollar values.

FOR FURTHER INFORMATION CONTACT: Melvin Saunders, at (304) 480–5108 or *melvin.saunders@fiscal.treasury.gov*; or Bobbi McDonald, at (304) 480–7098 or *bobbi.mcdonald@fiscal.treasury.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 2, 2024, in FR Doc. 2024-28231, on page 95911, in ''The new fee rate schedule'' section should read as follows:

(1) Examination of a company's application for a Certificate of Authority as an acceptable surety or as an acceptable reinsuring company on Federal bonds: $13,600.

* * * * *

(3) Examination of a company's application for recognition as an Admitted Reinsurer: $5,000.

* * * * *

(6) Examination of a company's application for recognition as an Alien Reinsurer: $5,000.

* * * * *

(8) Examination of a company's application for recognition as a Complementary Reinsurer: $5,000.

* * * * *

Dated: December 4, 2024.

Lela Anderson,

Attorney-Advisor.

[FR Doc. 2024–28806 Filed 12–6–24; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0892]

Agency Information Collection Activity Under OMB Review: Request for Reimbursement of Preparatory (PREP) Course for Licensing or Certification Test

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Comments and recommendations for the proposed information collection should be sent by January 8, 2025.

ADDRESSES: To submit comments and recommendations for the proposed information collection, please type the following link into your browser: *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0892.''

FOR FURTHER INFORMATION CONTACT:

VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov*.

SUPPLEMENTARY INFORMATION:

Title: Request for Reimbursement of Preparatory (PREP) Course for Licensing or Certification Test, VA Form 22–10272.

OMB Control Number: 2900–0892, *https://www.reginfo.gov/public/do/PRASearch.*

Type of Review: Revision of a currently approved collection.

Abstract: The information collected on the VA Form 22–10272 will be utilized to permit beneficiaries to apply for reimbursement of approved preparatory courses taken to assist with preparing for a Licensing or Certification Test. VA will use data from this information collection to ensure eligible Post 9/11 GI Bill (chapter 33) and Survivors' and Dependents' Educational Assistance (DEA or chapter 35) can receive payment for attending and completing the approved preparatory course. Without the utilization of this form, eligible beneficiaries will not be able to apply for the reimbursement they may be rightly entitled to pursuant to 38 U.S.C. 3315B.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 80631–80632, October 3, 2024.

Affected Public: Individuals and Households.

Estimated Annual Burden: 10 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Occasionally.

Estimated Number of Respondents: 41.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–28827 Filed 12–6–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity Under OMB Review: Veterans Group Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will

submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Comments and recommendations for the proposed information collection should be sent by January 8, 2025.

ADDRESSES: To submit comments and recommendations for the proposed information collection, please type the following link into your browser: *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–NEW.''

FOR FURTHER INFORMATION CONTACT: *VA PRA information:* Maribel Aponte, (202) 461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION:

Title: Veterans Group Life Insurance, VA Form SGLV 8714.

OMB Control Number: 2900–NEW. *https://www.reginfo.gov/public/do/PRASearch.*

Type of Review: New collection.

Abstract: This form will be used by the Department of Veterans Affairs Insurance Center (VAIC) to enable a third party to act on behalf of the insured Veteran/beneficiary. Many of our customers are of advanced age or suffer from limiting disabilities and need assistance from a third party to conduct their affairs. The information collected provides an optional service and is not required to receive insurance benefits.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 80017, October 1, 2024.

Affected Public: Individuals or Households.

Estimated Annual Burden: 12,500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 25,000.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–28828 Filed 12–6–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0679]

Agency Information Collection Activity: Certification of Change or Correction of Name Government Life Insurance

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before February 7, 2025.

ADDRESSES: Comments must be submitted through *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202–461–8900, *nancy.kessinger@va.gov*.

VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Certification of Change or Correction of Name Government Life Insurance—VA Form 29–586.

OMB Control Number: 2900–0679. *https://www.reginfo.gov/public/do/PRASearch* (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Extension of a currently approved collection.

Abstract: The form is used by the insured as a certification of change or correction of name. The information on the form is required by law, U.S.C. 1904 and 1942.

Affected Public: Individuals and households.

Estimated Annual Burden: 20 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 120.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–28826 Filed 12–6–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0178]

Agency Information Collection Activity Under OMB Review: Monthly Certification of On-The-Job and Apprenticeship Training

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice by clicking on the following link *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0178.''

FOR FURTHER INFORMATION CONTACT: *VA PRA information:* Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION:

Title: Monthly Certification of On-The-Job and Apprenticeship Training, VA Form 22–6553d-1; 22–6553d.

OMB Control Number: 2900–0178, *https://www.reginfo.gov/public/do/PRASearch.*

Type of Review: Revision of a currently approved collection.

Abstract: With the use of VA Forms 22–6553d-1; 22–6553d, benefits are authorized monthly based on the number of hours worked in a training capacity by the trainee as verified by the training establishment. Unscheduled terminations result in the termination of benefits. If hours are reduced to less than a full-time work schedule, a reduction of benefits will occur. Public Law 115–89 ''Veterans Apprenticeship and Labor Opportunity Reform Act'' (VALOR Act) was signed into law on November 21, 2017. Section 3 of this law amended 38 U.S.C. 3680(c) to eliminate the trainee's certification requirement. As a result, this form is only completed, signed, and certified by the training establishment to report the trainee's number of hours worked and/or to report the trainee's date of termination. The form no longer requires the signature of the trainee. The form is then sent to the Regional Processing Office (RPO) for processing.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 80307–80308, October 2, 2024.

Affected Public: Training Establishments.

Estimated Annual Burden: 39,340 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: 12 Annually per Respondent.

Estimated Number of Respondents: 19,670.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–28829 Filed 12–6–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Monday,

No. 236 December 9, 2024

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 410, et al.

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 410, 411, 414, 423, 424, 425, 427, 428, and 491

[CMS–1807–F and CMS–4201–F5]

RIN 0938–AV33 and 0938–AU96

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for, the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; updates to the Medicare Diabetes Prevention Program expanded model; payment for dental services inextricably linked to specific covered medical services; updates to drugs and biological products paid under Part B including immunosuppressive drugs and clotting factors; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or a Medicare Advantage Prescription Drug (MA–PD) plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act); update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to Clinical Laboratory Fee Schedule regulations; updates to the diabetes payment structure and PHE flexibilities; expansion of colorectal cancer screening and Hepatitis B vaccine coverage and payment; establishing payment for drugs covered as additional preventive services; Medicare Parts A and B Overpayment Provisions of the Affordable Care Act and Medicare Parts C and D Overpayment Provisions of the Affordable Care Act.

DATES: These regulations are effective on January 1, 2025.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786–6312, Morgan Kitzmiller, (410) 786–1623, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, (814) 769–0143, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to potentially misvalued services under the PFS.

Mikayla Murphy, (667) 414–0093, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Tamika Brock, (312) 886–7904, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to teaching physician billing for services involving residents in teaching settings.

Sarah Leipnik, (410) 786–3933, Mikayla Murphy, (667) 414–0093, Regina Walker-Wren, (410) 786–9160, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment for caregiver training services and addressing health-related social needs (community health integration, principal illness navigation, and social determinants of health risk assessment).

Erick Carrera, (410) 786–8949, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to office/outpatient evaluation and management visit inherent complexity add-on.

Sarah Irie, (410) 786–1348, Emily Parris (667) 414–0418, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment for advanced primary care management service.

Sarah Leipnik, (410) 786–3933, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to global surgery payment accuracy.

Pamela West, (410) 786–2302, for issues related to supervision of outpatient therapy services in private practices, certification of therapy plans of care, and KX modifier threshold.

Lindsey Baldwin, (410) 786–1694, Regina Walker-Wren, (410) 786–9160, Erick Carrera, (410) 786–8949, Mikayla Murphy, (667) 414–0093, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to advancing access to behavioral health services.

Michelle Cruse, (443) 478–6390, Erick Carrera, (410) 786–8949, Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to dental services inextricably linked to other covered medical services.

Zehra Hussain, (214) 767–4463, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Adam Brooks, (202) 205–0671, Rachel Radzyner, (410) 786–8215, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to complex drug administration.

Glenn McGuirk, (410) 786–5723, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov*, for issues related to FQHC payments.

Heidi Oumarou, (410) 786–7942, for issues related to the FQHC market basket.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, for issues related to RHC payments.

Kianna Banks (410) 786–3498 and Cara Meyer (667) 290–9856, for issues related to RHCs and FQHCs and Conditions for Certification or Coverage.

Colleen Barbero (667) 290–8794, for issues related to Medicare Diabetes Prevention Program.

Ariana Pitcher, (667) 290–8840, or *OTP_Medicare@cms.hhs.gov*, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and benchmarking methodology.

Richard (Chase) Kendall, (410) 786–1000, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to reopening ACO payment determinations, and mitigating the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations.

Lucy Bertocci, (410) 786–3776, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program prepaid shared savings, advance investment payments, beneficiary notice and eligibility requirements.

Rachel Radzyner, (410) 786–8215, for issues related to payment for preventative services, including preventive vaccine administration and drugs covered as additional preventive services.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Genevieve Kehoe, *Ambulatoryspecialtycare@cms.hhs.gov*, or 1–844–711–2664 (Option 4) for issues related to the Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care.

Kimberly Long, (410) 786–5702, for issues related to expanding colorectal cancer screening.

Rachel Katonak, (410) 786–8564, for issues related to expanding Hepatitis B vaccine coverage.

Mei Zhang, (410) 786–7837, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act).

Katie Parker, (410) 786–0537, for issues related to Parts A and B overpayment provisions of the Affordable Care Act.

Alissa Stoneking, (410)786–1120, for issues related to Parts C and D overpayment provisions of the Affordable Care Act.

Amy Gruber, (410) 786–1542, for issues related to low titer O+ whole blood transfusion therapy during ground ambulance transport.

Renee O'Neill, (410) 786–8821, for inquiries related to Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Danielle Drayer, (516) 965–6630, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2025 PFS final rule, refer to item CMS–1807–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This final rule revises payment policies under the Medicare PFS and makes other policy changes, including the implementation of certain provisions of the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118–22, November 16, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117–328, September 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this final rule includes provisions regarding other Medicare payment policies described in sections III. and IV.

This rulemaking also codifies policies previously established in guidance for the Medicare Prescription Drug Inflation Rebate Program at new parts 427 and 428, including clarifications to certain existing policies, consistent with sections 1847A(i) and 1860D–14B of the Social Security Act (the Act). This rulemaking establishes new policies for the Medicare Prescription Drug Inflation Rebate Program, including removal of units of drugs subject to discarded drug refunds from the Part B rebate amounts, the process for reconciliation of a Part B or Part D rebate amount to incorporate certain revised information, and procedures for imposing civil money penalties on manufacturers that do not pay Part B or Part D inflation rebate amounts within a specified period of time.

This rulemaking updates the Rural Health Clinic (RHC) and Federally Qualified Health Clinic (FQHC) Conditions for Certification and Conditions for Coverage (CfCs), respectively, by clarifying the requirements and intent of the program regarding the provision of services. These changes also aim to ensure RHCs are provided flexibility in the services they offer, including specialty and laboratory services.

This rulemaking also further advances Medicare's overall value-based care strategy of growth, alignment, and equity through the Medicare Shared Savings Program (Shared Savings Program) and the Quality Payment Program. The structure of these programs enables us to develop a set of tools for measuring and encouraging improvements in care, which may support a shift to clinician payment over time into Advanced Alternative Payment Models (APMs) and accountable care arrangements which reduce care fragmentation and unnecessary costs for patients and the health system.

This rulemaking amends our regulations regarding the standard for an ''identified overpayment'' under Medicare Parts A, B, C, and D to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given to those terms in the Federal False Claims Act. 87 FR 79559. This rulemaking also finalizes proposals regarding timeframes for reporting and returning Parts A and B overpayments that we made in the CY 2025 PFS proposed rule.

B. Summary of the Key Provisions

Section 1848 of the Act requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In

addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this final rule, we establish RVUs for CY 2025 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, Medicare and Medicaid provider and supplier enrollment policies, and other policies regarding programs administered by CMS.

Specifically, this final rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management (E/M) Visits (section II.F.)
- Enhanced Care Management (section II.G.)
- Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds (section II.H.)
- Advancing Access to Behavioral Health Services (section II.I.)
- Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Other Covered Services (section II.J.)
- Payment for Skin Substitutes (section II.K.)
- Strategies for Improving Global Surgery Payment Accuracy (section II.L.)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs) (section III.C.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)
- Medicare Diabetes Prevention Program (MDPP) (section III.E.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152) (section III.H.)
- Medicare Prescription Drug Inflation Rebate Program (section III.I.)
- Request for Information: Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care (section III.J.)
- Modifications to Coverage of Colorectal Cancer Screening (section III.K.)
- Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section III.L.)
- Expand Hepatitis B Vaccine Coverage (section III.M.)
- Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport (section III.N.)
- Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (section III.O.)
- Medicare Parts C and D Overpayment Provisions of the Affordable Care Act (section III.P.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Regulatory Impact Analysis (section VI.)

C. Summary of Costs and Benefits

We have determined that this final rule is economically significant. We estimate the CY 2025 PFS conversion factor to be 32.3465 which reflects a 0.02 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the removal of the temporary 2.93 percent payment increase for services furnished from March 9, 2024, through December 31, 2024, as provided in the CAA, 2024. For a detailed discussion of the economic impacts, see section VI., Regulatory Impact Analysis, of this final rule.

II. Provisions of the Final Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We referred readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical

equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we referred readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2025 PFS final rule PE/HR'' on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2025, we have incorporated the available utilization data for two new specialties, Marriage and Family Therapist (MFT) and Mental Health Counselor (MHC), which we recognized effective January 1, 2024, in accordance with section 4121 of the CAA, 2023. We proposed to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Marriage and Family Therapist (MFT) from Licensed Clinical Social Workers; and
- Mental Health Counselor (MHC) from Licensed Clinical Social Workers

These updates are reflected in the ''CY 2025 PFS final rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Comment: One commenter stated that they supported the proposal to include utilization data for MFTs and MHCs in calculating practice expense Relative Value Units. The commenter stated that accurate RVUs ensure that MFTs and MHCs receive appropriate reimbursement, covering essential overhead costs and sustaining their practices, which supports the financial viability of mental health practices and also promotes equitable access to care for all patients, regardless of the complexity of their conditions.

Response: We appreciate the support for our proposal from the commenter.

After consideration of the comments, we are finalizing our proposed PE/HR crosswalks for the Marriage and Family Therapist and Mental Health Counselor specialties.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and

the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the three most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of

claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We did not make any proposals associated with the list of expected specialty assignments for low volume services, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for codes that meet these criteria for CY 2024. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the significant adverse impact on MP RVUs that results from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of approximately 75 low volume HCPCS codes with recommended expected specialty assignments.

Response: After reviewing the information provided by the commenters to determine whether the specialty assignments they recommended were appropriate for the services in question, based on determining if the recommended specialty matches the dominant specialty in the claims data, we are finalizing the additions to the list of expected specialty assignments for low volume services identified in Table 1. We agreed with the commenters that, based on claims data, CPT codes 33231 and 33240 should be crosswalked to the Cardiac Electrophysiology specialty and that CPT codes 33900–33904 and 93574–93575 should be crosswalked to the Interventional Cardiology specialty. We also agree with commenters that CPT codes 56633 and 58240 should be crosswalked to the Gynecological Oncology specialty. However, we do not have PE/HR data for these specialties as they were not part of the PPIS when it was conducted in 2007; therefore, we are crosswalking these CPT codes to the closest available specialties (Cardiology and Obstetrics/Gynecology, respectively), as listed on Table 1.

We disagreed with the commenters on a series of additional suggested assigned specialties. In each case, there was another specialty which was reported more than twice as often in the claims data as the specialty suggested by commenters and in some cases reported as much as twenty times as often. Therefore, we are crosswalking CPT code 22505 to the Neurosurgery specialty, CPT code 25670 to the Orthopedic Surgery specialty, CPT code 28116 to the Podiatry specialty, CPT code 35231 to the Otolaryngology specialty, CPT code 36585 to the General Surgery specialty, CPT code 36810 to the Pulmonary Disease specialty, and CPT code 60522 to the Thoracic Surgery specialty (which was additionally suggested by one commenter) as these were the dominant specialties in the claims data. These crosswalks are included in Table 1.

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Table 1: New Additions to the Expected Specialty Assignment List

HCPCS	Short Descriptor	Expected Specialty Assignment
15600	Delay flap trunk	Plastic And Reconstructive Surgery
15920	Removal of tail bone ulcer	General Surgery
15941	Remove hip pressure sore	Plastic And Reconstructive Surgery
21422	Treat mouth roof fracture	Maxillofacial Surgery
22505*	Manipulation of spine	Neurosurgery
22808	Arthrd ant dfrm 2-3 vrt sgm	Orthopedic Surgery
23180	Remove collar bone lesion	Orthopedic Surgery
23455	Repair shoulder capsule	Orthopedic Surgery
23680	Optx sho dislc neck fx fixj	Orthopedic Surgery
25670*	Treat wrist dislocation	Orthopedic Surgery
26508	Release thumb contracture	Hand Surgery
27065	Remove hip bone les super	Orthopedic Surgery
27170	Repair/graft femur head/neck	Orthopedic Surgery
27418	Repair degenerated kneecap	Orthopedic Surgery
27420	Revision of unstable kneecap	Orthopedic Surgery
27442	Revision of knee joint	Orthopedic Surgery
27756	Treatment of tibia fracture	Orthopedic Surgery
28116*	Revision of foot	Podiatry
29837	Elbow arthroscopy/surgery	Orthopedic Surgery
29861	Hip arthro w/fb removal	Orthopedic Surgery
32036	Thoracostomy w/flap drainage	Thoracic Surgery
33231*	Insrt pulse gen w/mult leads	Cardiology
33240*	Insrt pulse gen w/singl lead	Cardiology
33366	Trcath replace aortic valve	Cardiac Surgery
33415	Revision subvalvular tissue	Thoracic Surgery
33900*	Perq p-art revsc 1 nm nt uni	Cardiology
33901*	Perq p-art revsc 1 nm nt bi	Cardiology
33902*	Perq p-art revsc 1 abnor uni	Cardiology
33903*	Perq p-art revsc 1 abnor bi	Cardiology
33904*	Perq p-art revsc each addl	Cardiology
34704	Evasc rpr a-unilac ndgft rpt	Vascular Surgery
35001	Repair defect of artery	Vascular Surgery
35013	Repair artery rupture arm	Vascular Surgery
35231*	Repair blood vessel lesion	Otolaryngology
35331	Rechanneling of artery	Vascular Surgery
35400	Angioscopy	Vascular Surgery
35525	Art byp grft brachial-brchl	Vascular Surgery
35565	Art byp grft iliofemoral	Vascular Surgery
35601	Art byp common ipsi carotid	Vascular Surgery
35647	Art byp aortofemoral	Vascular Surgery
36585*	Replace picvad cath	General Surgery
36810*	Insertion of cannula	Pulmonary Disease
39540	Repair of diaphragm hernia	General Surgery
43122	Partial removal of esophagus	Thoracic Surgery
43194	Esophagoscp rig trnso rem fb	Otolaryngology
43257	Egd w/thrml txmnt gerd	Gastroenterology
43290	Egd flx trnsorl dplmnt balo	Gastroenterology
43291	Egd flx trnsorl rmvl balo	Gastroenterology
43520	Incision of pyloric muscle	General Surgery
43605	Biopsy of stomach	General Surgery

HCPCS	Short Descriptor	Expected Specialty Assignment
44605	Repair of bowel lesion	General Surgery
47480	Incision of gallbladder	General Surgery
49215	Excise sacral spine tumor	General Surgery
50365	Transplantation of kidney	General Surgery
51992	Laparo sling operation	Obstetrics/Gynecology
54057	Laser surg penis lesion(s)	Urology
55842	Extensive prostate surgery	Urology
56633*	Extensive vulva surgery	Obstetrics/Gynecology
58240*	Removal of pelvis contents	Obstetrics/Gynecology
59151	Treat ectopic pregnancy	Obstetrics/Gynecology
60522*	Removal of thymus gland	Thoracic Surgery
61619	Repair dura	Neurosurgery
61682	Intracranial vessel surgery	Neurosurgery
61737	Litt icr mlt trj mlt/cplx ls	Neurosurgery
63741	Install spinal shunt	Neurosurgery
63744	Revision of spinal shunt	Neurosurgery
67225	Eye photodynamic ther add-on	Ophthalmology
67413	Explore/treat eye socket	Ophthalmology
69728	Rmv ntr oi imp sk tc>=100	Otolaryngology
69729	Impl oi implt sk tc esp>=100	Otolaryngology
69730	Rplc oi implt sk tc esp>=100	Otolaryngology
74263	Ct colonography screening	Gastroenterology
78216	Liver & spleen image/flow	Diagnostic Radiology
78445	Vascular flow imaging	Diagnostic Radiology
93574*	Njx cath slct pulm vn angrph	Cardiology
93575*	Njx cath slct p angrph mapca	Cardiology
95863	Muscle test 3 limbs	Neurology
G9157	Transesoph doppl cardiac mon	Anesthesiology

* Recommended specialty assignment crosswalked; see above.

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After consideration of the public comments, we are finalizing the additions to the list of expected specialty assignments for low volume services as detailed in Table 1. The full list of expected specialty assignments is included in the CY 2025 public use files, which are available on the CMS website under downloads for the CY 2025 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(Note: For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by

adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we referred readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table 2.

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TABLE 2: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in creating the file consistent with the current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services,

the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

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We also adjust volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We noted that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act required that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We applied the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

We note that for CY 2025, we proposed mandatory use of the 54 and 55 modifiers when practitioners furnishing global surgery procedures share in patient care and intend only to furnish preoperative/intraoperative or postoperative portions of the total global procedure. If finalized, this proposal will likely increase the number of claims subject to the adjustment described in the discussion above. We discuss this proposal in section II.L. of this final rule.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally, 150,000 minutes.

usage = variable, see discussion below in this proposed rule.

price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than two years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2025.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

In the past, we have stated that we believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). In the past, we have proposed (and subsequently finalized) to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and CF to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. As the MEI cost shares are updated, we would typically propose to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the 2017-based MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

In the CY 2014 PFS proposed rule (78 FR 43287 through 43288) and final rule (78 FR 74236 through 74237), we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18). The CY 2014 proposed and final adjustments were consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components,

including the adjustments described in the CY 1999 PFS final rule (63 FR 58829), CY 2004 PFS final rule (68 FR 63246 and 63247), and CY 2011 PFS final rule (75 FR 73275).

In the CY 2023 PFS final rule (87 FR 69688 through 69711), we finalized to rebase and revise the MEI to reflect more current market conditions faced by physicians in furnishing physicians' services (referred to as the ''2017-based MEI''). We also finalized a delay of the adjustments to the PE pools in steps 3 and 10 and the recalibration of the relativity adjustment in step 18 until the public had an opportunity to comment on the rebased and revised 2017-based MEI (87 FR 69414 through 69416). Because we finalized significant methodological and data source changes to the MEI in the CY 2023 PFS final rule and significant time has elapsed since the last rebasing and revision of the MEI in CY 2014, we believed that delaying the implementation of the finalized 2017-based MEI was consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. We refer readers to the discussion of our comment solicitation in the CY 2023 PFS final rule (87 FR 69429 through 69432), where we reviewed our ongoing efforts to update data inputs for PE to aid stability, transparency, efficiency, and data adequacy. We also solicited comment in the CY 2023 PFS proposed rule on when and how to best incorporate the 2017-based MEI into PFS ratesetting, and whether it would be appropriate to consider a transition to full implementation for potential future rulemaking. We presented the impacts of implementing the 2017-based MEI in PFS ratesetting through a 4-year transition and through full immediate implementation, that is, with no transition period in the CY 2023 PFS proposed rule. We also solicited comment on other implementation strategies for potential future rulemaking in the CY 2023 PFS proposed rule. In the CY 2023 PFS final rule, we discussed that many commenters supported our proposed delayed implementation, and many commenters expressed concerns with the redistributive impacts of the implementation of the 2017-based MEI in PFS ratesetting. Many commenters also noted the AMA's intent to collect practice cost data from physician practices, which could be used to derive cost share weights for the MEI and RVU shares.

In the CY 2025 PFS proposed rule, we stated that in light of the AMA's current data collection efforts and because the methodological and data source changes to the MEI finalized in the CY 2023 PFS final rule would have significant impacts on PFS payments, similar to our discussion of this topic in the CY 2024 PFS rulemaking cycle (88 FR 78829 through 78831), we continue to believe that delaying the implementation of the finalized 2017-based MEI cost share weights for the RVUs is consistent with our efforts to balance payment stability and predictability with incorporating new data through more routine updates. For these reasons, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2024. As we noted in the CY 2024 PFS final rule, many commenters on the CY 2024 PFS proposed rule supported our continued delayed implementation of the 2017-based MEI in PFS ratesetting (88 FR 78830). Most of these commenters urged us to pause consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices have concluded, although a few commenters recommended that we implement the MEI for PFS ratesetting as soon as possible. We stated that we agree with the commenters that it would be prudent, and avoid potential duplication of effort, to wait to consider other data sources for the MEI while the AMA's data collection activities are ongoing. We stated that as we discussed in the CY 2024 PFS final rule, we continue to monitor the data available related to physician services' input expenses, but we are not proposing to update the data underlying the MEI cost weights at this time. Given our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through more routine updates to the MEI, we did not propose to incorporate the 2017-based MEI in PFS ratesetting for CY 2025. We invited comments on this approach, as well as any information on the timing of the AMA's practice cost data collection efforts and other sources of data we could consider for updating the MEI. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our continued delayed implementation of the 2017-based MEI in PFS ratesetting. Most of these commenters urged CMS to delay consideration of other sources for the MEI until the AMA's efforts to collect practice cost data from physician practices have concluded. The AMA RUC commented that they concluded survey efforts on August 31, 2024, and are working to analyze the data. Some commenters requested a more frequent update of the PPIS every three to five years given the dramatic redistributive impacts of implementing updated data after many years. Some commenters requested a separate MEI for behavioral health to adequately and appropriately value outpatient mental health and substance use services. Another commenter disagreed with more frequent PPIS efforts because they can be burdensome, particularly for small, independent practices in underserved areas where time must be taken away from direct patient care to complete the survey. The commenter stated that larger health systems and practices are more equipped to respond to these surveys which leads to biased and unreliable survey results. The commenter urged CMS to consider contingencies or alternatives to the PPIS to address the lack of data availability or response rates for some specialties. One commenter requested that CMS seek alternative, more current data sources to rebase and revise the MEI if the AMA PPIS data proves insufficient, stating that the 2017-based MEI derived predominantly from the 2017 US Census Bureau's Service Annual Survey (SAS) are outdated and should not be used for updates.

A few commenters urged CMS to implement the 2017-based MEI for PFS ratesetting as soon as possible. One commenter stated that the SAS Census Bureau data should be used to determine the MEI in the future instead of the AMA's PPIS data because it is reliable, regularly updated, and objectively collected.

Response: We appreciate commenters' feedback, specifically as it relates to updating PFS ratesetting, and will consider the commenters' feedback in future rulemaking.

Comment: One commenter stated that CMS finalized the 2017-based MEI based primarily on a subset of data from the 2017 US Census Bureau's SAS. The commenter stated that assumptions made for the updated weights did not include physicians who are employed by hospitals and large health systems. The commenter stated that data from facility-based physicians should be included since MEI weights also cover physician compensation and professional liability insurance.

Response: We refer the commenter to the discussion of methodologies and a response to this concern in the CY 2024 PFS final rule (88 FR 78830 and 78831).

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are

included in the CY 2025 direct PE input public use files, which are available on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. We directed readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, one commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We directed readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a ''PE worksheet'' that details the

recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. As in previous calendar years, to facilitate rulemaking for CY 2025, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor, StrategyGen, which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we referred readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2025, we proposed to update the price of 17 supplies and one equipment item in response to the public submission of invoices following the publication of the CY 2024 PFS final rule. The 18 supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 20, CY 2025 Invoices Received for Existing Direct PE Inputs.

Comment: Several commenters stated that they commended CMS for recognizing the importance and cost of Long-Term Electrocardiography Monitoring (LT–ECG) Services, reflected in the updated pricing for supply item SD339. The commenters stated that the updated pricing is critical for ensuring patient access to LT–ECG services under CPT codes 93241, 93243, 93245, and 93247, while also providing essential payment stability for providers.

Response: We appreciate the support from the commenters for our proposed SD339 supply pricing.

Comment: A commenter stated that they supported the proposed pricing increases for the EP112 equipment and the SL474, SL478, SL479, SL480, SL482, and SL492 supplies. The commenter stated that they supported the proposed changes to the pricing for these items and urges CMS to finalize them as proposed. A separate commenter stated that they supported the proposed change to the pricing of the SL474 supply as they believe it improves the accuracy of pricing for practice expense items within the overall fee schedule.

Response: We appreciate the support from the commenters for our proposed supply and equipment pricing.

Comment: A commenter stated that they fully supported CMS's proposal to create three new supply codes in the PE database (SD370, SD371, and SD372) to facilitate appropriate pricing by the MACs for Temporary Female Intraurethral Valve-Pump services. The commenter stated that they agreed that short of establishing national pricing for CPT codes 0596T and 0597T, creating supply codes with accurate pricing for the devices should facilitate rate setting by the MACs that appropriately accounts for the device costs. The commenter urged CMS to finalize as proposed the creation of these supply codes and the proposed prices that correspond to each.

Response: We appreciate the support from the commenter for our proposed supply pricing of the SD370–SD372 items.

An interested party submitted 30 invoices to update pricing for the human amniotic membrane allograft mounted on a non-absorbable self-retaining ring (SD248) supply. We previously updated the price of this supply in the CY 2024 final rule (88 FR 78901) based on averaging together the price of the Prokera Slim, Prokera Classic, and Prokera Plus devices. The interested party submitted new invoices for all three of these devices which averaged to a new price of $1149.00 which we proposed for the SD248 supply. We solicited additional comments from interested parties regarding the price of the SD248 supply as well as any information as far as whether one of these three devices (the Prokera Slim, Prokera Classic, and Prokera Plus) would be more typical than the other two for use as a supply in CPT code 65778.

Comment: Many commenters stated that they supported the proposed payment increase for CPT 65778 based on the proposed pricing of the SD248 supply. Commenters described the clinical benefits of the SD248 supply and how it has been instrumental in helping patients with medical conditions that would not respond to conventional medical treatment.

Response: We appreciate the support from the commenters for our proposed pricing of the SD248 supply.

In the case of the indocyanine green (25ml uou) (SL083) supply, we noticed that there was a clear bimodal distribution of prices on the eight submitted invoices, clustered around $91.00 and $141.67, respectively, with no pricing in between $100 and $140. We proposed the updated total average price of $125.11 based on the eight submitted invoices for the SL083 supply, however, we solicited comments on why there was such divergence in the pricing on the submitted invoices, as well as whether these may represent pricing for two different supplies.

Comment: Several commenters thanked CMS for updating the price of the indocyanine green (25ml uou) (SL083) supply in the proposed rule and recommended that this price be finalized. Commenters stated that the differences in pricing for the SL084 supply contained on the submitted invoices demonstrated an increase that occurred during the second half of 2023 rather than a price differential between two distinct products; commenters stated that practices paid an average of

$87 earlier in 2023 and by 2024 the price had increased to $141, with some paying as much as $156.

Response: We appreciate the support from the commenters for our proposed supply pricing of the SL083 supply, as well as the additional information regarding its pricing.

Regarding the Reaction buffer 10X (Ventana 950–300) (SL478) supply, we proposed to update the price from $0.037 to $0.045, which is less than the $0.075 contained on the invoice submitted by interested parties. We were able to find this product readily available for purchase online at a quantity of 10 liters for $453 or a price of $0.045. We do not believe that it would be typical for providers to pay a higher price based on smaller unit quantities; therefore, we proposed to update the price of the SL478 supply but only to $0.045, which is the price to purchase this supply online, as stated above.

Interested parties also alerted CMS to a technical correction for pricing the Atomizer tips (disposable) (SL464) supply. We previously finalized a price of $2.66 for the SL464 supply, which was included in the table of Invoices Received for Existing Direct PE Inputs in the CY 2018 final rule (82 FR 53162). However, due to a technical error, the updated pricing for the SL464 supply was never implemented. We proposed to make this correction for CY 2025; the corrected price of $2.66 for the SL464 supply is included in Table 20.

Comment: A commenter stated that the proposed payment rates for HCPCS codes G2082 and G2083 did not include the updated supply pricing for esketamine described by the SH109 and SH110 supply codes, based on wholesale acquisition cost (WAC) data submitted by the commenter to CMS on May 31, 2024. The commenter stated that lack of consistent WAC supply pricing updates has contributed to payment instability for these services and puts beneficiary access at risk. The commenter stated that their goal was to align on a clear process to ensure consistency and predictability in the approach to updating the annual payment amounts for the SH109 and SH110 supplies and urged CMS to incorporate the updated WAC pricing data for these supplies in the PFS final rule.

Response: We did not propose to update the price of the SH109 and SH110 esketamine supplies in the proposed rule. However, as part of our process to act on public requests to update equipment and supply prices, we have reviewed the WAC pricing data submitted by the commenters. Based on this information, we are finalizing an increase in the pricing of the SH109 supply from $735.63 to $772.41 and an increase in the pricing of the SH110 supply from $1103.44 to $1158.62.

With regards to the process for submitting annual pricing updates for these supply items, we remind the commenter that to be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and will consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

We did not propose to update the price of another ten supplies, which were the subject of public submission of invoices. Our reasons for not proposing updates to these prices are detailed below, and we solicited additional information from interested parties for assistance in pricing these supplies:

- *Liposorber supplies: Tubing set (SC083), Plasma LDL adsorption column (SD186), and Plasma separator (SD188):* We received invoices for these three Liposorber supplies from an interested party. However, it was unclear from the invoice submissions what the unit quantity size is for each product. We require additional information regarding the unit size of each supply included on these invoices to establish updated pricing, and therefore, we did not propose updates to the prices for these supplies. We solicited additional comments regarding the pricing of these supplies and whether the pricing has increased so dramatically, as it seems unlikely that prices have tripled in the 5 years since we most recently updated the pricing for these supplies.

Comment: A commenter stated that they continue to believe that CPT code 36516 suffers from a large reimbursement gap between the facility and non-facility/physician office setting because CMS is using outdated pricing data for essential liposorber supplies. The commenter therefore submitted additional paid invoices for three liposorber supply items: the tubing set (SC083), Plasma LDL adsorption column (SD186), and plasma separator (SD188). The commenter stated that these invoices clearly identified the unit quantity and provided a breakdown of the costs to show the individual (per-supply item price) as well as case price (6 items per case per different supply item).

Response: We appreciate the additional invoice submissions from the commenter and the clarification on the supply quantities for the associated supply items. Based on this additional pricing data, we are finalizing price increases to $87.52 for the SC083 supply, to $1419.04 to the SD186 supply, and to $149.70 for the SD188 supply, in each case based on an average of the six submitted invoices.

Comment: A commenter stated that Liposorber supplies are unique in that they require special shipping, handling, storing, and insurance requirements. The commenter stated that, for instance, the Plasma LDL adsorption Column (SD186) and the Plasma Separator (SD188) are sensitive to atmospheric conditions and must be packaged, shipped, and stored at mandated temperatures, as well as avoid exposure to cold, direct sunlight, high humidity, or excessive vibrations. The commenter stated that the high cost and fragility of these supplies requires the practice to purchase additional insurance coverage, and these additional shipping and handling costs are not reflected in the invoiced purchase price but add considerable expense to the provision of apheresis services.

Response: We remind the commenter that shipping and storage costs are not included in the price of supplies and equipment under our PE methodology. This is because these costs are covered under the indirect portion of the PE; it is not the case that these costs are not being paid, but rather that they are addressed under a different part of the PE methodology.

- *Congo Red kits (SA110):* We received three invoices from interested parties requesting an increase in the price of the SA110 supply from $6.80 to $18.78. However, we were able to find Congo Red staining kits readily available online at a price of 100 for $410 or $4.10 per kit. The unit size of these kits was also unclear, which made price comparisons with the submitted invoices difficult. Based on the three invoices and the online price of 100 for $410 or $4.10 per kit, we do not believe there is enough pricing data to support an increase in the price of the SA110 supply from $6.80 to $18.78, and we did not propose an increase in the price of this supply.
- *Gauze, non-sterile 4in x 4in (SG051):* We received one invoice from interested parties requesting an increase

in the price of the SG051 supply from $0.03 to $0.04. However, the submitted invoice price appeared to be for surgical gauze, not non-sterile gauze. We were able to find the 4x4 non-sterile gauze readily available online at less than the invoice price. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SG051 supply from $0.03 to $0.04, and we did not propose an increase in the price of this supply.

- *Permanent marking pen (SL477):* We received one invoice from interested parties requesting an increase in the price of the SL477 supply from $2.81 to $4.62. However, we found black marking pens, such as Sharpies, widely available at unit prices around $2.00 when purchased in larger quantities. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL477 supply from $2.81 to $4.62, and we did not propose an increase in the price of this supply.
- *Hematoxylin II (Ventana 790–2208) (SL483):* We received four invoices from interested parties requesting an increase in the price of the SL483 supply from $0.780 to $2.722. However, we were able to find hematoxylin II stains readily available online at cheaper prices, such as $52.00 for 500 ml ($0.104 per ml). Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL483 supply from $0.780 to $2.722, and we did not propose an increase in the price of this supply.
- *Bluing reagent (Ventana 760–2037) (SL484):* We received three invoices from interested parties requesting an increase in the price of the SL484 supply from $4.247 to $6.130. While researching the pricing of the SL484 supply, we were unable to determine the unit quantity size on invoices, which made it difficult to evaluate if the requested price accurately reflected market pricing. As best we could tell, the requested price increase to $6.130 was more expensive than comparable online bluing reagents available for purchase. Based on this information, we do not believe there is enough pricing data to support an increase in the price of the SL484 supply from $4.247 to $6.130, and we did not propose an increase in the price of this supply.
- *EZ Prep (10X) (Ventana 950–102) (SL481) and 250 Test Prep Kit # 78 (Ventana 786–3034) (SL486):* In each of these cases, we received invoices from interested parties requesting substantial increases in the price of the associated supplies, from $0.034 to $0.509 for the SL481 supply and from $0.309 to $2.134 for the SL486 supply. We do not believe that it is reasonable to expect that the typical market prices for these supplies have increased by 1400 percent and 600 percent, respectively, in the 5 years since we most recently updated the pricing for these supplies. The limited pricing information we could find online for each product also failed to support these drastic increases in pricing. Based on this information, we do not believe there is enough pricing data to support the requested increases for the SL481 and SL486 supplies, and we did not propose increases to the prices for these supplies.

(1) Invoice Submission

We reminded readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule and will consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

In recent years, we have noticed a growing number of invoice submissions for use in updating supply and equipment pricing. Although we continue to believe in the importance of using the most recent and accurate invoice data to reflect current market pricing, we do have some concerns that the increased use of these submissions may distort relativity across the fee schedule. Relying on voluntary invoice submissions to update pricing for a small subset of the total number of supply and equipment items in our database, while leaving the overwhelming majority of prices untouched, could be distorting pricing in favor of the most recent submissions. We believe that it may be more efficient, and more accurate, to update supply and equipment pricing in a more comprehensive fashion similar to the pricing update that took place from CY 2019 to CY 2022. For example, future updates to supply and equipment pricing could take place in tandem with updates to clinical labor pricing after the current clinical labor update concludes in CY 2025. We welcomed public comments on this general topic of more comprehensive updates to supply and equipment pricing, and we may consider comments we receive to inform future rulemaking.

Comment: Many commenters supported the concept of more regular and comprehensive updates to supply and equipment pricing. Commenters stated their support for a deliberate, systematic approach to supply, equipment, and clinical labor updates and agreed that it would be prudent to update pricing consistently, such as every 5 years. Many commenters stated that such a process would provide transparency in the timing of these updates, give greater granularity into the data sources that serve as the basis of input pricing changes, and maintain the current process that allows stakeholders to submit invoices in advance of rulemaking. Several commenters requested the implementation of a 4-year phase-in transition for any future pricing updates, as gradually phasing in cost changes helps to prevent abrupt and potentially harmful effects on specific providers or services. One commenter stated that establishing a cycle of updates every four years was not advisable, as updates that frequent could amplify the impact of short-term market fluctuations, in addition to increasing the administrative burden for both CMS and health care providers.

Response: We appreciate the feedback from the commenters regarding potential future updates to supply and equipment pricing, which we will consider for use in potential future rulemaking.

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rulemaking. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we proposed to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup. We proposed to update the pricing of the ''pack, cleaning and disinfecting, endoscope'' (SA042) supply from $19.43 to $31.29, to update the pricing of the ''pack, drapes, cystoscopy'' (SA045) supply from $17.33 to $14.99, to update the pricing of the ''pack, ocular photodynamic therapy'' (SA049) supply from $16.35 to $26.35, to update the pricing of the ''pack, urology cystoscopy visit'' (SA058) supply from $113.70 to $37.63, and to update the pricing of the ''pack, ophthalmology visit (w-dilation)'' (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we also proposed to delete the ''pack, drapes, laparotomy (chest-abdomen)'' (SA046) supply entirely. The updated prices for these supply packs are listed in the valuation of specific codes section of the preamble under Table 20, CY 2025 Invoices Received for Existing Direct PE Inputs.

In accordance with the RUC workgroup's recommendations, we also proposed to create 8 new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We proposed to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55% (eg, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The new supply pack component items are listed in the valuation of specific codes section of the preamble under Table 21, CY 2025 New Invoices.

We also proposed the following additional supply substitutions based on the recommendations of the RUC workgroup. We proposed to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16 in x 29 in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We proposed to remove the deleted SA046 supply pack and replace it with two supplies—the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18 in x 26 in (SB019)—for CPT codes 19000 and 60300. We proposed to remove the deleted SA046 supply pack and replace it with 2 supplies—the drape, towel, sterile 18 in x 26 in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply—for CPT codes 22510, 22511, 22513, and 22514. We proposed to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we also proposed not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however, this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

Comment: Several commenters stated their appreciation that CMS proposed to implement the supply pack pricing update and associated revisions as recommended by the RUC's workgroup.

Response: We appreciate the support for our proposal from the commenters.

Comment: Several commenters supported the proposed supply pack pricing update as recommended by the RUC workgroup, however they indicated concern over the proposed decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. Commenters stated that the proposed pricing reduction in the SA058 supply could result in drastic payment rate cuts for physicians performing cystoscopy services in the office setting. Commenters requested that CMS either delay the pricing update or phase-in the supply pack changes over a four-year period like it has done for other PE changes with significant redistributive effects, allowing independent urology practices to better prepare for the negative financial impact this change will have. One commenter requested that pricing reductions should be implemented over a 7- to 10-year period.

Response: We appreciate the feedback from the commenters regarding the proposed changes in pricing for these supply packs, particularly the decrease in pricing for the urology cystoscopy visit pack (SA058). After considering the comments, we agree that the use of a phased-in transition period would be appropriate to allow practitioners to adjust to the updated pricing of these supplies. During our previous supply and equipment pricing update in the CY 2019 PFS final rule, we finalized a policy to phase in any updated pricing that we established during the 4-year transition period for very commonly used supplies and equipment, such as sterile gloves (SB024) or exam tables (EF023), even if invoices were provided as part of the formal review of a code family (83 FR 59475). Based on this previously established policy, we are finalizing the use of a pricing transition for three supply packs:

TABLE 5: Supply Pack Pricing Transition

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

Following the same pattern as our previous supply/equipment and clinical labor pricing updates, we are finalizing the implementation of this pricing transition over 4 years such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2025, one-third of the difference between the CY 2025 price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028 (86 FR 65025). For the other proposed supply packs, the cystoscopy drapes pack (SA045) is only included in 7 HCPCS codes and the ocular photodynamic therapy pack (SA049) is only included in a single HCPCS code which do not meet these criteria established in previous rulemaking. We are therefore finalizing each of them at their updated pricing for CY 2025 as proposed in the proposed rule. We believe that the use of this pricing transition will minimize any potential disruptive effects during the 4-year transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply packs.

Comment: Several commenters stated that although five incomplete packs would have their pricing updated in the proposed rule, mathematical errors still remained for a number of additional supply packs. Commenters stated that only 3 of the 18 affirmed packs were priced correctly to match their components and provided tables showing the pricing of an additional 15 packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. Commenters requested that CMS initiate a correction of the packs pricing such that the sum of the individual components match the price of the corresponding pack.

Response: We appreciate the additional information provided by the commenters regarding the pricing of these supply packs. We have compiled this information provided by the commenters for the 15 affected supply packs into Table 6.

TABLE 6: Supply Pack Pricing Requested By Commenters

HCPCS Codes	Item Name	CMS Code	Current Price	New Price	% Change
111 codes	pack, basic injection	SA041	$10.45	$17.28	65%
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$1.98	-61%
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$1.35	-50%
239 codes	pack, pelvic exam	SA051	$20.16	$2.81	-86%
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$9.90	106%
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$11.54	111%
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$10.34	124%
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$18.18	149%
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$16.05	159%
120 codes	pack, drapes, ortho, large	SA080	$37.30	$25.38	-32%
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%
119 codes	pack, protective, ortho, large	SA083	$10.86	$14.75	36%
27 codes	pack, protective, ortho, small	SA084	$5.99	$8.15	36%

While we share the concerns of the commenters regarding the need for accuracy in the pricing of these supply packs, we have reservations about their potential for pricing disruptions. Ten of these supply packs are included in the direct PE inputs for at least 100 HCPCS codes, and three of the packs are included in more than 1000 HCPCS codes. Many of these pricing updates would lead to drastic changes in pricing for these supply packs which are included in hundreds of HCPCS codes, such as the SA051 pelvic exam pack decreasing in price from $20.16 to $2.81 (−86 percent) and the SA048 minimum multi-specialty visit pack decreasing in price from $5.02 to $1.98 (−61 percent). We are particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment.

Therefore, we are not finalizing pricing updates for these additional 15 supply packs as requested by commenters. We anticipate returning to this subject in future rulemaking to allow any changes in associated pricing for HCPCS codes to appear in the proposed rule and provide an opportunity for the public to comment. Should these supply pack pricing updates be proposed in future rulemaking, we anticipate that we may propose the same pricing transition described above due to the number of potentially affected HCPCS codes. We are finalizing all of the other supply pack pricing changes as proposed, with the exception of the 4-year pricing transition for three supply packs as described above.

The RUC workgroup also reviewed the issue of skin adhesives and identified several generic alternatives to using the skin adhesive (Dermabond) (SG007) supply. The workgroup stated that there are multiple skin adhesive products, at different price points, available that work similarly to Dermabond and requested that generic alternatives be used overall in place of brand names in the CMS direct PE database. The workgroup made a series of suggestions for CMS to create new medical supply item codes to encompass the generic formulations of cyanoacrylate skin adhesive in multidose form and single use sterile application.

We appreciated the recommendations from the RUC workgroup and concur that generic alternatives should be used in place of brand names, where appropriate, in the CMS direct PE database. However, we had no pricing information or submitted invoices for the 4 generic formulations of cyanoacrylate skin adhesive requested by the RUC workgroup (2-Octyl-cyanoacrylate, n-Butyl-2-cyanoacrylate, Combined n-Butyl and 2-Octylcyanoacrylate, and Ethyl-2-cyanoacrylate). Since these 4 potential new supplies had no pricing information and are not currently included as direct PE inputs for any HCPCS codes, we did not add them to our direct PE database for the CY 2025 proposed rule due to lack of available information.

Comment: Several commenters, including the RUC, stated that they solicited invoices for Dermabond and its generic alternatives. The commenters stated that they were able to find and submit invoices for the Dermabond (SG007) supply but were unable to find invoices for the generic skin adhesives. Commenters stated that they continued to believe that generic versions overall are a better alternative than the use of brand names in the CMS direct PE database and encouraged CMS to explore other sources of information regarding generic skin adhesives.

Response: We appreciate the feedback from commenters regarding these skin adhesives and the submission of invoices associated with the SG007 supply. We agree with the commenters that the use of generic alternatives is preferred in place of brand names when naming new supply and equipment items for use in the CMS direct PE database. However, many of the supply and equipment items such as the SG007 supply have existed in the CMS files for decades at this point. We believe that it would be more disruptive and potentially confusing to attempt to rename items like the SG007 supply given how the current Dermabond name has been in common use for PFS ratesetting for at least 20 years. We are not finalizing a change to the name of this supply, and since we received no pricing information or submitted invoices for the four generic formulations of cyanoacrylate skin adhesive, we are not finalizing any changes to their status as well.

With regards to the submitted invoices for the SG007 supply, the six invoices refer to different Dermabond products and their unit quantity size is unclear. The current SG007 supply simply has the unit size of ''item'' and we were unable to determine how the submitted invoices relate in terms of pricing to the current supply. We are therefore not finalizing an update to the price of the SG007 supply at this time.

c. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types, and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Beginning in CY 2019, we updated the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 was the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Interested parties raised concerns that the long delay since clinical labor pricing was last updated created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, several interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Some interested parties also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. They argued that since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There was considerable interest among interested parties in updating the clinical labor rates, and

when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), interested parties supported the idea.

Therefore, we proposed to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update (86 FR 39118 through 39123). We believed updating the clinical labor pricing was important to maintain relativity with the recent supply and equipment pricing updates. We proposed to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for our CY 2022 clinical labor proposal.

We recognized that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com.*) We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. We ultimately finalized the use of median BLS wage data instead of mean BLS wage data in response to comments in the CY 2022 PFS final rule. To account for the employers' cost of providing fringe benefits, such as sick leave, we finalized a benefits multiplier of 1.296 based on a BLS release from June 17, 2021 (USDL–21–1094). As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected a median hourly wage rate of $12.98, which we multiplied by the 1.296 benefits modifier and then divided by 60 minutes to arrive at the finalized per-minute rate of $0.28.

After considering the comments on our CY 2022 proposals, we agreed with commenters that the use of a multi-year transition would help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected interested parties, and promoting payment stability from year-to-year. We believed it would be appropriate to use a 4-year transition, as we have for several other broad-based updates or methodological changes. While we recognized that using a 4-year transition to implement the update means that we will continue to rely in part on outdated data for clinical labor pricing until the change is fully completed in CY 2025, we agreed with the commenters that these significant updates to PE valuation should be implemented in the same way, and for the same reasons, as for other major updates to pricing such as the recent supply and equipment update. Therefore, we finalized the clinical labor pricing update implementation over 4 years to transition from current prices to the final updated prices in CY 2025. We finalized the implementation of this pricing transition over 4 years, such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2022, one-third of the difference between the CY 2022 price and the final price is implemented for CY 2023, and one-half of the difference between the CY 2023 price and the final price is implemented for CY 2024, with the new direct PE prices fully implemented for CY 2025. (86 FR 65025) An example of the transition from the current to the fully-implemented new pricing that we finalized in the CY 2022 PFS final rule is provided in Table 7.

TABLE 7: Example of Clinical Labor Pricing Transition

Current Price	$1.00	
Final Price	$2.00	
Year 1 (CY 2022) Price	$1.25	1/4 difference between $1.00 and $2.00
Year 2 (CY 2023) Price	$1.50	1/3 difference between $1.25 and $2.00
Year 3 (CY 2024) Price	$1.75	1/2 difference between $1.50 and $2.00
Final (CY 2025) Price	$2.00	

(1) CY 2023 Clinical Labor Pricing Updates

For CY 2023, we received information from one interested party regarding the pricing of the Histotechnologist (L037B) clinical labor type. The interested party provided data from the 2019 Wage Survey of Medical Laboratories which supported an increase in the per-minute rate from the $0.55 finalized in the CY 2022 PFS final rule to $0.64. This rate of $0.64 for the L037B clinical labor type is a close match to the online salary data that we had for the Histotechnologist and matches the $0.64 rate that we initially proposed for L037B in the CY 2022 PFS proposed rule. Based on the wage data provided by the commenter, we proposed this $0.64 rate for the L037B clinical labor type for CY 2023; we also proposed a slight increase in the pricing for the Lab Tech/Histotechnologist (L035A) clinical labor type from $0.55 to $0.60 as it is a blend of the wage rate for the Lab Technician (L033A) and Histotechnologist clinical labor types. We also proposed the same increase to $0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 PFS final rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type (86 FR 65032).

Based on comments received on the CY 2023 proposed rule, we finalized a change in the descriptive text of the L041A clinical labor type from ''Angio Technician'' to ''Vascular Interventional Technologist''. We also finalized an update in the pricing of three clinical labor types: from $0.60 to $0.84 for the Vascular Interventional Technologist (L041A), from $0.63 to $0.79 for the Mammography Technologist (L043A), and from $0.76 to $0.78 for the CT Technologist (L046A) based on submitted wage data from the 2022 Radiologic Technologist Wage and Salary Survey (87 FR 69422 through 69425).

(2) CY 2024 Clinical Labor Pricing Updates

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2024 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2024 was based on the clinical labor pricing that we finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 of the update. Based on comments received on the CY 2024 proposed rule, we finalized an update in the clinical labor pricing of the cytotechnologist (L045A) clinical labor type from $0.76 to $0.85 based on submitted data from the 2021 American Society of Clinical Pathologists (ASCP) Wage Survey of Medical Laboratories (88 FR 78838).

(3) CY 2025 Clinical Labor Pricing Update Proposals

We did not receive new wage data or other additional information for use in clinical labor pricing from interested parties prior to the publication of the CY 2025 PFS proposed rule. Therefore, our proposed clinical labor pricing for CY 2025 in Table 8 is based on the clinical labor pricing that we finalized in the CY 2024 PFS final rule, incremented an additional step for the final Year 4 of the update:

TABLE 8: CY 2025 Clinical Labor Pricing

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Y4 Rate Per Minute	Total % Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.28	22%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.36	38%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.46	53%
L032B	EEG Technician	BLS 29-2098	0.32	0.44	38%
L033A	Lab Technician	BLS 29-2010	0.33	0.55	67%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.39	18%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.60	70%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.44	19%
L037B	Histotechnologist	BLS 29-2010	0.37	0.64	73%
L037C	Orthoptist	BLS 29-1141	0.37	0.76	105%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.54	46%
L037E	Child Life Specialist	BLS 21-1021	0.37	0.49	32%
L038A	COMT/COT/RN/CST	BLS 29-2057, BLS 29-2055, L051A, BLS 19-4010	0.38	0.52	37%
L038B	Cardiovascular Technician	BLS 29-2031	0.38	0.60	58%
L038C	Medical Photographer	BLS 29-2050	0.38	0.38	0%
L039A	Certified Retinal Angiographer	BLS 29-9000	0.39	0.52	33%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.61	56%
L039C	Psychometrist	BLS 21-1029	0.39	0.64	62%
L041A	Vascular Interventional Technologist	ASRT Wage Data	0.41	0.84	104%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.63	54%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.63	54%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.63	50%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.64	52%
L043A	Mammography Technologist	ASRT Wage Data	0.43	0.79	84%
L045A	Cytotechnologist	BLS 29-9092	0.45	0.85	89%
L045B	Electron Microscopy Technologist	BLS 29-1124	0.45	0.89	98%
L045C	CORF social worker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.70	56%
L046A	CT Technologist*	ASRT Wage Data	0.46	0.78	70%
L047A	MRI Technologist	BLS 29-2035	0.47	0.76	62%
L047B	REEGT (Electroencephalographic Tech)	BLS 29-2035	0.47	0.76	62%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.70	49%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.70	49%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.81	32%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.77	54%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.77	54%
L050C	Radiation Therapist	BLS 29-1124	0.50	0.89	78%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	0.89	78%
L051A	RN	BLS 29-1141	0.51	0.76	49%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.77	51%
L051C	RN/CORF	L051A	0.51	0.76	49%
L052A	Audiologist	BLS 29-1181	0.52	0.81	56%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.79	49%
L054A	Vascular Technologist	BLS 19-1040	0.54	0.91	69%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.82	49%
L056A	RN/OCN	BLS 29-2033	0.79	0.81	3%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.85	50%

Labor Code	Labor Description	Source	CY 2021 Rate Per Minute	Final Y4 Rate Per Minute	Total % Change
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0%
L063A	Medical Dosimetrist	BLS 19-1040	0.63	0.91	44%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.52	41%
L152A	Medical Physicist	AAPM Wage Data	1.52	2.14	41%

As was the case for the market-based supply and equipment pricing update, the clinical labor rates remained open for public comment during the 60-day comment period for the CY 2025 PFS proposed rule. We stated that we expect to set the updated clinical labor rates for CY 2025 in this final rule. We updated the pricing of some clinical labor types in the CY 2022, CY 2023, and CY 2024 PFS final rules in response to information provided by commenters. For the full discussion of the clinical labor pricing update, we directed readers to the CY 2022 PFS final rule (86 FR 65020 through 65037).

Comment: Several commenters urged CMS to freeze the final year of implementation of the clinical labor policy in CY 2025 to avoid further redistributions and instability in the PFS. Commenters asked CMS to hold harmless the specialties that were most affected by the clinical labor pricing update and not move forward with the final year of the phase-in. One commenter disagreed with the finalized BLS 2021 benefit multiplier of 1.296 and stated that CMS should use the originally proposed 1.366 benefits multiplier instead.

Response: We finalized the use of a 4-year transition in the CY 2022 PFS final rule to help smooth out the changes in payment resulting from the clinical labor pricing update, avoiding potentially disruptive changes in payment for affected stakeholders, and promoting payment stability from year-to-year. As we stated in the CY 2022 PFS final rule, under section 1848 of the Act, we are required to base payment for services under the PFS on relative resource costs. To accomplish that, it is necessary periodically to update the information on which we base relative values. We believe, and commenters overwhelmingly agreed, that the BLS wage data is the best source to use for clinical labor pricing, and commenters did not identify alternative sources of data that could be used to update pricing. Although we recognize that payment for some services will be reduced as a result of the pricing update due to the BN requirements of the PFS, we do not believe that this is a reason to refrain from updating clinical labor pricing to reflect changes in resource costs over time as suggested by some commenters. The PFS is a resource-based relative value payment system that necessarily relies on accuracy in the pricing of resource inputs; continuing to use clinical labor cost data that are nearly two decades old would maintain distortions in relativity that undervalue many services which involve a higher proportion of clinical labor. As noted above, we also finalized the implementation of the pricing update through a 4-year transition to help address the concerns of the commenters about stabilizing RVUs and reducing large fluctuations in year-to-year payments. We direct readers to this prior discussion in the CY 2022 PFS final rule at 86 FR 65025.

Comment: Several commenters stated that the ongoing clinical labor pricing update was having the effect of driving patient care from the non-facility to the facility setting. The commenters stated that access to care for beneficiaries is increasingly constrained for many essential services and listed a series of procedures most impacted, such as hemorrhagic and ischemic strokes, maternal health, PAD, dialysis access, limb salvage services, and CPT code 93229 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional*).

Response: We previously addressed these concerns about site of service and patient access to care when we finalized the clinical labor pricing update; we direct readers to this prior discussion in the CY 2022 PFS final rule at 86 FR 65025.

Comment: A commenter stated that, to promote predictability and stability in physician payments and mitigate the financial impacts of significant fluctuations in physician payments that might accompany the clinical labor pricing update, CMS should consider using a threshold to limit the level of reductions in payments for specific services that would occur in a single year. The commenter stated that CMS consider implementing a cap on payment cuts to individual codes in a single year.

Response: We agree with the commenter on the importance of avoiding potentially disruptive changes in payment for affected interested parties and the need to promote payment stability from year-to-year. This is why we finalized the use of a multi-year transition for the clinical labor update in the CY 2022 PFS final rule to help smooth out the changes in payment resulting from the updated data (86 FR 65024). We also note for the commenter that section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. For additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70929).

Comment: A commenter thanked CMS for raising the clinical labor rate paid to nurses, however the commenter stated that this was only one step and nurses are consistently undervalued across all settings. The commenter stated that nursing care should be valued more highly than it is today and that nursing care is still undervalued in today's healthcare system. The commenter stated that RNs are mentioned in ten separate rows on the clinical labor pricing table, with the rate per minute for nurses varying from $0.52 per minute to $0.81 per minute, which brings uncertainty to the fee schedule as the value of the nurse fluctuates depending on the situation.

Response: We note for the commenter that the proposed CY 2025 clinical labor rate for the RN (L051A) type is $0.76,

which is based upon Bureau of Labor Statistics wage data as outlined in our methodology above. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing, and we did not receive any alternate wage data from commenters to suggest alternate RN pricing. With regards to the multiple listing of RNs on the table, there are a number of ''blended'' clinical labor types which often include RNs as one of the staffing types being averaged together. Blended clinical labor types have been a historical part of PFS services since we adopted the current PE methodology. We have done our best to identify which staffing types, including RNs, are included in these blends along with how they are averaged together to arrive at the final clinical labor pricing. We also note for the commenter that the pricing for the RN (L051A) clinical labor type is drawn directly from BLS wage data and the inclusion of RNs in other ''blended'' clinical labor types has no effect on the pricing of the L051A category itself.

Comment: A commenter stated that CMS must reevaluate the pricing for the Behavioral Health Care Manager (L057B) clinical labor type. The commenter noted that CMS maintained the current clinical labor pricing for the Behavioral Health Care Manager clinical labor type rather than update it in the CY 2022 PFS final rule because, although the BLS data reflected a decreased clinical labor rate for the Behavioral Health Care Manager labor type, CMS did not believe that the typical wages had decreased for this clinical labor type given that every other clinical labor type had increased (86 FR 65022). The commenter stated that growth for Behavioral Health Care Managers has increased on a similar trajectory as other clinical labor types and has in fact outpaced wage growth for other types of behavioral health providers. The commenter stated that BLS data indicates that salaries for clinicians who work as Behavioral Health Care Managers have increased at a rate of approximately 5 percent per year between 2021 and 2023, outpacing the wage increases for other types of related practitioners, such as psychiatrists, nurse practitioners, and physician assistants, which increased at rates below 4 percent per year. The commenter stated that Behavioral Health Care Manager wages increased at a pace that is consistent with the increase in wages for other clinical labor types (such as registered nurses, licensed practical nurses, and medical assistants), increasing by 27.2 percent from 2017 to 2023, compared with a 30.2 percent increase among other clinical labor types during the same period. The commenter requested that rather than holding the clinical labor rate for Behavioral Health Care Managers steady, the rate should be increased at a rate similar to the costs associated with other clinical labor types.

Response: We appreciate the additional information provided by the commenter with regards to the Behavioral Health Care Manager (L057B) clinical labor type. However, we continue to believe that the proposed pricing for this clinical labor type remains accurate, as it was based directly on BLS wage data (BLS category 21–1018: Substance Abuse, Behavioral Disorder, and Mental Health Counselors) rather than relying on a crosswalk or third party information. Although we understand that it appears unfair that the L057B clinical labor type maintained the same pricing while all of the other clinical labor types increased in valuation, this was due to the fact that the L057B type had been valued much more recently than the other clinical labor types. The L057B clinical labor type was added to the PFS for the CY 2017 final rule and therefore was priced at $0.57 per minute based on then-current rates for genetic counselors (81 FR 80350). Almost all of the other clinical labor types were last valued based on 2002 wage data, which caused the L057B clinical labor type to be artificially inflated in pricing relative to the other clinical labor types. For example, before the current clinical labor pricing update, Behavioral Health Care Managers were priced at $0.57 per minute, higher than the $0.51 per minute valuation of the Registered Nurse (L051A) clinical labor type, which clearly did not reflect market-based salaries. The commenter included a table in their submission indicating that salaries for Registered Nurses are approximately 40 higher than salaries for Behavioral Health Care Managers, which matches our current proposed pricing for these clinical labor types ($0.76 and $0.57 respectively). We believe that the current clinical labor pricing update has brought valuation of the L057B clinical labor type into relativity with the other clinical labor types by virtue of valuing all of them at the same time.

After consideration of the comments, we did not receive any new wage data for use in clinical labor pricing. Therefore, we are finalizing the clinical labor prices as proposed in Table 8 without refinement.

d. Technical Corrections to Direct PE Input Database and Supporting Files

We received the following comments on technical corrections to the direct PE input database and supporting files:

Comment: Several commenters, including the RUC, requested that CMS separately identify and pay for high-cost disposable supplies. Commenters highlighted the outsized impact that high-cost disposable supplies have within the current practice expense RVU methodology, which not only accounts for a large amount of direct practice expense for these supplies but also allocates a large amount of indirect practice expense into the PE RVU for the procedure codes that include these supplies. Commenters stated that if high-cost supplies were paid separately with appropriate HCPCS codes, the disproportionate indirect expense would no longer be associated with that service, with the result that indirect PE RVUs would be redistributed throughout the specialty practice expense pool and the practice expense for all other services. Commenters requested that CMS separately identify and pay for high-cost disposable supplies priced more than $500 using appropriate Healthcare Common Procedure Coding System (HCPCS) codes. Commenters provided several examples from the proposed rule where they stated this policy would be appropriate, including new HCPCS code GMEM1, the potential for a new add-on service based on tympanostomy CPT code 69433, and the price of the SD248 supply (human amniotic membrane allograft mounted on a non-absorbable self-retaining ring). In each case, commenters stated that these issues would be better addressed through the creation of standalone Q codes separately paid from the PFS so those prices could be monitored and, when appropriate, updated annually.

Response: We have received a number of prior requests from interested parties, including the RUC, to implement these separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. We are therefore not finalizing the implementation of standalone Level II HCPCS codes for high cost disposable supplies at this time. For further discussion of this issue, we direct the

reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251).

We are aware of the issues with the current PE methodology caused by very expensive supply and equipment items, and this is a subject that we may consider for future rulemaking alongside other updates to the PE methodology. We appreciate the continued feedback from commenters as we consider potential approaches to this complicated topic.

Comment: A commenter echoed the request from other interested parties that CMS separately identify and pay for high-cost disposable supplies priced more than $500. This commenter stated that they believed these services should be paid outside of the PFS, since PFS budget neutrality rules compound the challenge of appropriately valuing high-cost technology inputs without underpaying for physician professional services. The commenter recommended that CMS designate such services as office based procedures under a new place of service designation and establish payment under the outpatient prospective payment system (OPPS)/ambulatory surgical center rulemaking instead of the PFS.

Response: We appreciate the feedback from the commenter on potential methods for implementing separate payment for high-cost disposable supplies. Although we have no current plans for such a policy, we will take under consideration for potential future rulemaking.

Comment: Several commenters asked for clarification regarding the proposed PE RVUs for HCPCS code G2251. Commenters stated that the proposed non-facility and facility PE RVUs for HCPCS code G2251 showed a significant reduction from 0.15 to 0.00 despite no mention of a policy proposal for this service. Commenters stated that they wanted to bring this valuation to the attention of CMS and sought clarification on whether this was a data entry error or an intentional change related to the proposed Advanced Primary Care Management (APCM) codes.

Response: We appreciate the commenters for bringing this issue to our attention, and we clarify that the published 0.00 PE RVUs for HCPCS code G2251 was an unintended technical error. When we investigated this issue, we found that it was due to a previously finalized crosswalk: we finalized a policy in the CY 2021 PFS final rule to value HCPCS code G2251 identically to HCPCS code G2012 (85 FR 84532). However, we also proposed to delete HCPCS code G2012 for CY 2025 which inadvertently resulted in HCPCS code G2251 crosswalking over a zero value for its PE RVUs. Since HCPCS code G2012 will no longer exist in CY 2025, we are finalizing the removal of this crosswalk for HCPCS code G2251 which should correct this error and restore its PE RVUs.

Comment: A commenter requested that CMS consider changing the assistant at surgery payment policy indicator to ''2'' for CPT codes 37211, 37212, 37242, and 37197 to allow for the use of assistant surgeons. The commenter stated that these transcatheter procedures involve the infusion of thrombolytic therapy, precise embolization of arteries, and foreign body retrieval, which have the potential to be extremely technical in nature and may require a highly functional team, including an assistant surgeon in select cases. The commenter stated that select cases that are particularly challenging may necessitate the skills of two operators to perform distinct parts of the navigation and procedure for the precise and safe delivery of thrombolytic therapy and vascular embolization devices, as well as the safe and effective retrieval of foreign bodies. The commenter stated that changes to these payment policy indicators will ensure patient procedural safety and bring policy alignment to these complex transcatheter procedures.

Response: The four CPT codes identified by the commenter each currently have an assistant at surgery payment policy of ''1'' under which an assistant at surgery may not be paid. After reviewing the four CPT codes identified by the commenter, we agree that an assistant at surgery may be medically necessary in some particularly challenging cases. However, we believe that it would be more accurate to finalize an assistant as surgery payment policy of ''0'' rather than the requested ''2'', which establishes that the payment restriction for an assistant at surgery applies to this procedure only if supporting documentation is submitted to establish medical necessity. We believe that this will ensure that an assistant at surgery will only be employed in the particularly challenging and medically necessary cases described by the commenter. Therefore we are finalizing an assistant at surgery payment policy indicator of ''0'' for CPT codes 37211, 37212, 37242, and 37197.

Comment: A commenter stated that the direct PE inputs for CPT code 65426 do not contain a supply item for human amniotic membrane allograft product (the SD247 supply). The commenter stated that as a result, the practice expense valuation does not account for the significant cost of this item when it is purchased and used. The commenter stated that while they are working with stakeholders to submit a potentially misvalued CPT code request for review in future rulemaking, they also wanted to note this issue and concern within the public comment period for this CY 2025 PFS rule.

Response: We appreciate the feedback from the commenter on this topic, and we would encourage them to continue pursuing the potentially misvalued code process if they believe that CPT code 65426 does not properly capture its typical direct PE inputs. We note the commenter did not present data indicating that the use of the expensive $835 SD247 supply is typical in CPT code 65426. We are not finalizing any changes to the code at this time.

5. Development of Strategies for Updates To Practice Expense Data Collection and Methodology

a. Background

The AMA PPIS was first introduced in 2007 as a means to collect comprehensive and reliable data on the direct and indirect PEs incurred by physicians (72 FR 66222). In considering the use of PPIS data, the goal was to improve the accuracy and consistency of PE RVUs used in the PFS. The data collection process included a stratified random sample of physicians across various specialties, and the survey was administered between August 2007 and March 2008. Data points from that period of time are integrated into PFS calculations today. In the CY 2009 PFS proposed rule (73 FR 38507 through 3850), we discussed the indirect PE methodology that used data from the AMA's survey that predated the PPIS. In CY 2010 PFS rulemaking, we announced our intent to incorporate the AMA PPIS data into the PFS ratesetting process, which would first affect the PE RVU. In the CY 2010 PFS proposed rule, we outlined a 4-year transition period, during which we would phase in the AMA PPIS data, replacing the existing PE data sources (74 FR 33554). We also explained that our proposals intended to update survey data only (74 FR 33530 through 33531). In our CY 2010 final rule, we finalized our proposal, with minor adjustments based on public comments (74 FR 61749 through 61750). We responded to the comments we received about the transition to using the PPIS to inform indirect PE allocations (74 FR 61750). In the responses, we acknowledged concerns about potential gaps in the

data, which could impact the allocation of indirect PE for certain physician specialties and suppliers, which are issues that remain important today. The CY 2010 PFS final rule explains that section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, November 29, 1999) (BBRA) directed the Secretary to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. BBRA required us to establish criteria for accepting supplemental survey data. Since the supplemental surveys were specific to individual specialties and not part of a comprehensive multispecialty survey, we had required that certain precision levels be met in order to ensure that the supplemental data was sufficiently valid, and acceptable for use in the development of the PE RVUs. At the time, our rationale included the assumption that because the PPIS is a contemporaneous, consistently collected, and comprehensive multispecialty survey, we do not believe similar precision requirements are necessary, and we did not propose to establish them for the use of the PPIS data (74 FR 61742). We noted potential gaps in the data, which could impact the allocation of indirect PE for certain physician and suppliers. The CY 2010 final rule adopted the proposal, with minor adjustments based on public comments, and explained that these minor adjustments were in part due to non-response bias that results when the characteristics of survey respondents differ in meaningful ways, such as in the mix of practices sizes, from the general population (74 FR 61749 through 61750).

Throughout the 4-year transition period, from CY 2010 to CY 2013, we gradually incorporated the AMA PPIS data into the PFS rates, replacing the previous data sources. The process involved addressing concerns and making adjustments as necessary, such as refining the PFS ratesetting methodology in consideration of interested party feedback. For background on the refinements that we considered after the transition began, we referred readers to discussions in the CY 2011 through 2014 final rules (75 FR 73178 through 73179; 76 FR 73033 through 73034; 77 FR 98892; 78 FR 74272 through 74276).

In the CY 2011 PFS proposed rule, we requested comments on the methodology for calculating indirect PE RVUs, explicitly seeking input on using survey data, allocation methods, and potential improvements (75 FR 40050). In our CY 2011 PFS final rule, we addressed comments regarding the methodology for indirect PE calculations, focusing on using survey data, allocation methods, and potential improvements (75 FR 73178 through 73179). We recognized some limitations of the current PFS ratesetting methodology but maintained that the approach was the most appropriate at the time. In the CY 2012 PFS final rule, we responded to comments related to indirect PE methodology, including concerns about allocating indirect PE to specific services and using the AMA PPIS data for certain specialties (76 FR 73033 through 73034). We indicated that CMS would continue to review and refine the methodology and work with interested parties to address their concerns. In the CY PFS 2014 final rule, we responded to comments about fully implementing the AMA PPIS data. By 2014, the AMA PPIS data had been fully integrated into the PFS, serving as the primary source for determining indirect PE inputs (78 FR 74235). We continued to review data and the PE methodology annually, considering interested party feedback and evaluating the need for updates or refinements to ensure the accuracy and relevance of PE RVUs (79 FR 67548). In the years following the full implementation of the AMA PPIS data, we further engaged with interested parties, thought leaders and subject matter experts to improve our PE inputs' accuracy and reliability. For further background, we referred readers to our discussions in final rules for CY 2016 through 2022 (80 FR 70892; 81 FR 80175; 82 FR 52980 through 52981; 83 FR 59455 through 59456; 84 FR 62572; 85 FR 84476 through 84478; 86 FR 62572).

In our CY 2023 PFS final rule, we issued an RFI to solicit public comment on strategies to update PE data collection and methodology (87 FR 69429 through 69432). We solicited comments on current and evolving trends in health care business arrangements, the use of technology, or similar topics that might affect or factor into PE calculations. We reminded readers that we have worked with interested parties and CMS contractors for years to study the landscape and identify possible strategies to reshape the PE portion of physician payments. The fundamental issues are clear but thought leaders and subject matter experts have advocated for more than one tenable approach to updating our PE methodology.

As described in previous rulemaking, we have continued interest in developing a roadmap for updates to our PE methodology that account for changes in the health care landscape. Of various considerations necessary to form a roadmap for updates, we reiterate that allocations of indirect PE continue to present a wide range of challenges and opportunities. As discussed in multiple cycles of previous rulemaking, our PE methodology relies on AMA PPIS data, which may represent the best aggregated available source of information at this time. However, we acknowledge the limitations and challenges interested parties have raised about using the current data for indirect PE allocations, which we have also examined in related ongoing research. We noted in our CY 2023 and CY 2024 rules that there are several competing concerns that CMS must take into account when considering updated data sources, which also should support and enable ongoing refinements to our PE methodology.

b. Preparation for Incorporating Refreshed Data and Request for Information on Timing To Effectuate Routine Updates

In the CY 2024 PFS proposed rule, we continued to encourage interested parties to provide feedback and suggestions to CMS that give an evidentiary basis to shape optimal PE data collection and methodological adjustments over time. Considering our ratesetting methodology and prior experiences implementing new data, we issued a follow-up from the CY 2023 comment solicitation for general information. We solicited comments from interested parties on strategies to incorporate information that could address known challenges we experienced in implementing the initial AMA PPIS data. Our current methodology relies on the AMA PPIS data, legislatively mandated supplemental data sources (for, example, we use supplemental survey data collected in 2003, as required by section 1848(c)(2)(H)(i) of the Act to set rates for oncology and hematology specialties), and in some cases crosswalks to allocate indirect PE as necessary for certain specialties and provider types. We also sought to understand whether, upon completion of the updated PPIS data collection effort by the AMA, contingencies or alternatives may be necessary and available to address the lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

In response to last year's RFI, most commenters stated that CMS should

defer significant changes until the AMA PPIS results become available. For further background, refer to 88 FR 78841 to 78843. In responding to our RFI, the AMA RUC provided a set of responses, which many other commenters repeated in their separate, individual comments. In summary, the AMA RUC letter submission from CY 2024 suggested that CMS should not consider further changes until PPIS data collection and analysis is complete. Overall, the AMA comments generally do not support any change to the methodology and stated that CMS should wait to consider any further changes until PPIS updates become available. Further, we noted that through its contractor, Mathematica, the AMA secured an endorsement for the PPIS updates from each State society, national medical specialty society, and others prior to fielding the survey (88 FR 78843). Refer to the AMA's summary of the PPIS, available at *https://www.ama-assn.org/system/files/physician-practice-information-survey-summary.pdf*. The AMA expects analysis, reporting, and documentation to complete by the end of CY 2024, and the AMA would share data with CMS when results become available.

As we stated in the proposed rule, we believe the AMA's approach may possibly mitigate nonresponse bias, which created challenges using previous PPIS data. However, we remain uncertain about whether endorsements prior to fielding the survey may inject other types of bias in the validity and reliability of the information collected. We believe it remains important to reflect on the challenges with our current methodology, and to continue to consider alternatives that improve the stability and accuracy of our overall PE methodology. We reiterate our discussion summarizing the responses to previous years' RFIs in each of the CY 2023 and CY 2024 final rules (refer to 87 FR 69429 through 69432 and 88 FR 78841 to 78843). We have started new work under contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. We will continue to study possible alternatives, and would include analysis of updated PPIS data, as part of our ongoing work. In the meantime, we requested general information from the public on ways that CMS may continue work to improve the stability and predictability of any future updates. Specifically, we requested feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs.

We stated that we believe that establishing a cycle of timing to update supply and equipment cost inputs every 4 years may be one means of advancing shared goals of stability and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and propose a phase-in period over the following 4 years. The phase-in approach maps to our experience with previous updates. Additionally, we stated that more frequent updates may have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

Further, we solicited feedback on possible mechanisms to establish a balance whereby our methodology would account for inflation and deflation in supply and equipment costs. We remain uncertain how economies of scale (meaning a general principle that cost per unit of production decreases as the scale of production increases) should or should not factor into future adjustments to our methodology. There remains a diversity of perspectives among interested parties about such effects. We sought information about specific mechanisms that may be appropriate, and in particular, approaches that would leverage verifiable and independent, third-party data that is not managed or controlled by active market participants.

Comment: Numerous commenters expressed concerns regarding CMS's current PE methodology, particularly highlighting its inadequacies in accommodating modern medical technologies and services, such as Software as a Medical Device (SaMD) and artificial intelligence (AI). These commenters stated that there is a need for CMS to revise its PE methodology to better reflect the actual costs of running medical practices today, which includes more frequent updates and the incorporation of direct costs for software and innovative technologies. Many also supported the AMA's ongoing Physician Practice Information Survey (PPIS) to ensure updated and accurate data informs PE calculations. Commenters urged CMS to collaborate closely with medical associations and incorporate broad stakeholder feedback without increasing reporting burdens, particularly for smaller practices.

Response: We thank commenters for their feedback and may consider this information for future rulemaking.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As outlined in section II.E. of this final rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RBRVS) Update Committee (RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of

consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period (76 FR 73026, 73058 through 73059), other individuals and groups submit nominations for review of potentially misvalued codes as well. Individuals and groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the same CY 2012 PFS final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 PFS final rule with comment period (77 FR 68892, 68896 through 68897), we built upon the work

we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes'' [1]). In the CY 2019 PFS proposed rule (73 FR 38589), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review of Work RVUs proposed rule (76 FR 32410, 32419), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2025 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67548, 67606 through 67608), we modified this process whereby the public and interested parties may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In each year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for potentially misvalued codes by February 10th and we display these nominations on our public website, where we include the submitter's name, their associated organization, and the submitted studies for full transparency. We sometimes receive submissions for specific, PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize below this year's submissions under the potentially misvalued code initiative. For CY 2025, we received 5 nominations concerning various codes. The nominations are as follows:

(1) CPT Codes 22210, 22212, 22214, 22216

An interested party nominated CPT codes 22210 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical*) (090 day global code), 22212 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic*) (090 day global code), 22214 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar*) (090 day global code), and 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)* (add-on ZZZ) as potentially misvalued for six reasons: (1) incorrect global period; (2) incorrect inpatient days; (3) incorrect intraservice work description; (4) overvalued intraservice times; (5) changed surgical practice; and (6) incorrect use of posterior osteotomy codes. The posterior osteotomy codes were last valued by the RUC in 1995. Currently, CPT code 22210 has a work RVU of 25.38, CPT code 22212 has a work RVU of 20.99, CPT code 22214 has a work RVU of 21.02, and CPT code 22216 has a work RVU of 6.03. CPT codes 22210, 22212, and 22214 have 7 inpatient days each, while CPT code 22216 has 0 inpatient days, and it is an add-on code.

First, the nominator stated that these posterior osteotomies are always performed as an optional addition to a spinal fusion and should be valued as add-on services and not as 90-day global services. We noted in the proposed rule that no references were provided to support the statement that the service is always performed as an optional addition to a spinal fusion. Second, the nominator explained that the average hospital stay for scoliosis fusion with osteotomy is 4 to 5 days according to the current literature,[2] [3] [4] in contrast with the currently included 7 inpatient days. We noted in the proposed rule that the

[1] The research team and panels of experts at the Harvard School of Public Health developed the original work RVUs for most CPT codes, in a cooperative agreement with the Department of Health and Human Services (HHS). Experts from both inside and outside the Federal Government obtained input from numerous physician specialty groups. This input was incorporated into the initial PFS, which was implemented on January 1, 1992.

[2] Halanski, Matthew Aaron, and Jeffrey A Cassidy. ''Do multilevel Ponte osteotomies in thoracic idiopathic scoliosis surgery improve curve correction and restore thoracic kyphosis?'' Journal of spinal disorders & techniques vol. 26,5 (2013): 252–5. *doi:10.1097/BSD.0b013e318241e3cf.*

[3] Floccari, Lorena V et al. ''Ponte osteotomies in a matched series of large AIS curves increase surgical risk without improving outcomes.'' Spine deformity vol. 9,5 (2021): 1411–1418. *doi:10.1007/s43390-021-00339-x.*

[4] Buckland, Aaron J et al. ''Ponte Osteotomies Increase the Risk of Neuromonitoring Alerts in Adolescent Idiopathic Scoliosis Correction Surgery.'' Spine vol. 44,3 (2019): E175–E180. *doi:10.1097/BRS.0000000000002784.*

majority of the medical literature submitted by the nominator presented outcome information on adolescent patients, which may be different from the Medicare population. Furthermore, the nominator stated that the intraservice work description for CPT code 22216 describes removal of the pedicle, which is not a typical part of a Ponte/Schwab II osteotomy. Among the posterior osteotomy codes, only CPT code 22216 had vignettes and we do not have information to decide whether the code descriptor is correct. We stated that we believed this issue would benefit from further review by the medical community and welcomed comments and considerations, including from the AMA CPT.

The nominator also asserted that intraservice times were too high, particularly for these osteotomy services furnished with scoliosis fusion procedures. The nominator explained that a typical scoliosis fusion would be billed with an intraservice time of up to 840 minutes for pediatric scoliosis fusion and 915 minutes for adult cases. However, referencing current literature, they observed that a typical scoliosis fusion in a child requires approximately 278 minutes (243–296 minutes),[5] [6] [7] which contrasts significantly with the durations indicated for the current codes. The nominator provided no studies to support a typical scoliosis fusion time in adults. Drawing from the literature, the nominators assert that intraservice times are overvalued for these services and propose that these times should be adjusted to align more closely with average and/or typical surgery times.

The nominator further asserted that this code family is potentially misvalued because surgical practice for these procedures has evolved since 1995. Approximately 30 years ago, osteotomies were infrequently performed and usually reserved for addressing completely ankylosed or fused spinal segments.[8] However, according to the nominator, contemporary surgical techniques often involve posterior osteotomies to release multiple stiff vertebral segments, thereby enhancing coronal correction and reducing thoracic hypokyphosis. In addition to changes in surgical techniques over time, there are notable shifts in the trends regarding the utilization of osteotomies. For instance, between 2007 and 2015, the use of posterior osteotomies in scoliosis cases nearly doubled, increasing from 17 percent to 35 percent.[9] Additionally, 73 percent of patients undergoing scoliosis surgery received posterior osteotomies.[4] This information supports the nominator's assertion that there have been notable changes in the surgical practice for these codes over time.

Lastly, the nominator highlighted what they believe is incorrect usage of posterior osteotomy codes. They noted instances where facet/soft tissue releases, such as Schwab type I osteotomies, are inaccurately reported with these codes. According to the nominator, isolated partial facetectomy and soft tissue release are already included in spinal fusion procedures and should not be separately billed with an osteotomy code. Additionally, CMS in reviewing data for these services identified potential bundling of services within this code family. For instance, CPT code 22210 is frequently billed alongside CPT code 22600 (*Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment*) (090-day global code), approximately 83 percent of the time. This indicates a common billing pattern, suggesting potential for coding revisions, including the consideration of consolidating individual services into bundled codes.

Overall, based on the six reasons provided by the nominator, along with the fact that these codes were last valued almost 30 years ago, and given the identified billing practices, we stated in the proposed rule that we concurred that CPT codes 22210, 22212, 22214, and 22216 were potentially misvalued. The nominator suggested two options to address this concern: (1) developing add-on codes to differentiate between the number of vertebral segments involved in the osteotomy procedure and whether it occurs in the cervical, thoracic, or lumbar regions; and (2) removing the current posterior osteotomy codes and incorporating osteotomies into new deformity fusion codes, both with and without osteotomy. We proposed to consider this code family as potentially misvalued and expressed appreciation for the detailed information submitted by the nominator with sufficient supporting evidence. We stated that we believed that this code family would benefit from a comprehensive review by the RUC, and we welcomed comments on a broader understanding of these codes. Additionally, we sought input on current standard billing practices. For example, information on whether the standard of practice has evolved over time, and if so, how it has evolved, could aid in identifying potential coding issues related to this matter.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters, including the AMA RUC, supported our proposal. The RUC stated that, since the osteotomy of the spine codes (CPT codes 22210, 22212, 22214, and 22216) were last reviewed in 1995, these codes may benefit from updated descriptions and consideration of bundling with related procedures. They suggested options such as developing add-on codes for segment-specific osteotomies or integrating these into new deformity fusion codes. They further stated they will place the nominated osteotomy codes (CPT codes 22210, 22212, 22214, and 22216) on the next Level of Interest (LOI) list for review at the January 2025 RUC meeting.

Response: We thank the commenters for their feedback.

Comment: A few commenters disagreed that the osteotomy of spine codes are potentially misvalued. The commenters stated that the procedures are primary interventions, not add-ons, and that the current global periods, inpatient days, and intraservice work descriptions accurately reflect the complexity of adult deformity surgery. They further stated that surgical techniques have not changed significantly and they believe that the codes are accurately valued and that altering them could disrupt coding practices and negatively impact patient care.

Response: While we acknowledge the comments asserting that CPT codes 22210, 22212, 22214 and 22216 are appropriately valued, we agree with the RUC that services such as those

[5] Samdani, Amer F et al. ''Do Ponte Osteotomies Enhance Correction in Adolescent Idiopathic Scoliosis? An Analysis of 191 Lenke 1A and 1B Curves.'' Spine deformity vol. 3,5 (2015): 483–488. *doi:10.1016/j.jspd.2015.03.002.*

[6] Pizones, Javier et al. ''Ponte osteotomies to treat major thoracic adolescent idiopathic scoliosis curves allow more effective corrective maneuvers.'' European spine journal:official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society vol. 24,7 (2015): 1540–6. *doi:10.1007/s00586-014-3749-1.*

[7] Feng, Jing et al. ''Clinical and radiological outcomes of the multilevel Ponte osteotomy with posterior selective segmental pedicle screw constructs to treat adolescent thoracic idiopathic scoliosis.'' Journal of orthopaedic surgery and research vol. 13,1 305. 29 Nov. 2018, *doi:10.1186/s13018-018-1001-0.*

[8] Ponte, Alberto et al. ''The True Ponte Osteotomy: By the One Who Developed It.'' Spine deformity vol. 6,1 (2018): 2–11. *doi:10.1016/j.jspd.2017.06.006.*

[9] Shaheen, Mohammed et al. ''Complication risks and costs associated with Ponte osteotomies in surgical treatment of adolescent idiopathic scoliosis: insights from a national database.'' Spine deformity vol. 10,6 (2022): 1339–1348. *doi:10.1007/s43390-022-00534-4.*

described by the nominator would benefit from review by the AMA RUC. Therefore, we are finalizing our proposal to finalize CPT codes 22210, 22212, 22214 and 22216 as potentially misvalued.

(2) CPT Code 27279

CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) (090 day global code) has been re-nominated as potentially misvalued based on the absence of separate direct PE inputs for this 090 day global code in the nonfacility setting. Currently, CPT code 27279 is only priced under the PFS in the facility setting, but the nominator requested that we establish separate direct PE inputs for this service to value the service when performed in the nonfacility/office setting (for example, in an office-based lab). The nominator stated that establishing payment for direct PE inputs in the nonfacility/office setting would increase access to this service for Medicare patients.

We did not nominate CPT code 27279 as potentially misvalued in the CY 2024 PFS final rule, mainly due to a lack of consensus in the medical community on whether these services may be safely and effectively furnished in the nonfacility/office setting. In this year's submission, the nominator provided three post-market surveillance publications and two independent reviews of minimally invasive sacroiliac (SI) joint fusion procedures to support their assertion that this 90-day surgical service could be safely and effectively furnished in the nonfacility/office setting. Based on the studies, the nominator stated that the current medical literature provides evidence supporting the conclusion that percutaneous or minimally invasive SI joint arthrodesis (CPT code 27279) carries a complication rate that is acceptably low, comparable to other spinal procedures commonly performed in the office-based lab (OBL). For instance, the risk of major complications during lateral trans iliac (LTI) SI joint fusion (CPT code 27279) is lower than the risks associated with other OBL procedures. These include the risk of iliac perforation during angioplasty, the risk of death, myocardial infarction (MI), and stroke during diagnostic cardiac catheterization. The nominator did not reference literature regarding the rates of major complications for other OBL procedures in their submission.

Based on the information submitted, we recognized the possibility that CPT code 27279 may be potentially misvalued, given the nominator's assertion that its complication rate is acceptably low based on the five studies they submitted. The results of the studies may suggest that CPT code 27279 can be safely performed in the office-based lab setting, as asserted by the nominator, with a relatively low complication rate. However, upon reviewing the submitted information, we also noted that these studies collectively report heterogeneous safety outcomes. The large variabilities in safety outcomes reported in the studies, coupled with several unreported outcomes, may indicate that we have little knowledge about the effect of the service on safety outcomes, prompting the need for further investigation. Therefore, we did not propose to consider this code as potentially misvalued, and we instead sought comments and additional studies from the broader medical community regarding whether this code should be priced under the PFS for the nonfacility/office setting.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that they opposed creating a nonfacility/office payment rate for CPT code 27279 due to patient safety concerns regarding this service being performed in the office setting. These commenters agreed with CMS on the lack of sufficient safety evidence for CPT code 27279 in nonfacility settings and recommended to maintain the current policy with respect to CPT code 27279 and not extend its use to nonfacility settings. They expressed that they were unaware that the service described by CPT code 27279 was being performed in nonfacility settings and stated their belief that it would be challenging for a medical practice to consistently meet the sanitary requirements necessary to safely perform this procedure on an ongoing basis. In addition, one commenter indicated that although this service is performed in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), both of those settings have rigorous conditions of participation that hold them to higher safety standards than physician offices. Regarding patient safety specifically, commenters shared CMS's concerns regarding the safety of delivering sacroiliac joint procedures in the office setting. The majority of the commenters recommended that CMS maintain its current policy and refrain from valuing CPT code 27279 in the non-facility setting and not adopt nonfacility PE values for CY 2025.

Response: We thank commenters for their feedback.

Comment: A few commenters supported establishing payment in the nonfacility/office setting for CPT code 27279. Commenters stated that the procedure described by CPT code 27279 can be safely performed in an office or nonfacility setting by referencing studies showing a low complication rate in OBL. They indicated that establishing direct PE inputs for the nonfacility setting would improve patient access to this service and supported obtaining direct PE inputs to increase patient access to care.

Response: We appreciate the comments and the additional information to support the establishment of nonfacility/office valuation for CPT code 27279. However, after review, the studies submitted by the nominator were not found to be persuasive. While we are seeking further information, commenters stated that they were not aware of any studies demonstrating the quality or safety of this procedure in a nonfacility setting. Based on Medicare claims data, CPT code 27279 is not regularly furnished in the nonfacility/office setting; the majority of utilization has occurred in the facility setting, with less than 1.0% in the nonfacility setting over the past 7 years. As with last year, the majority of commenters recommended that CMS maintain its current policy regarding CPT code 27279 and not extend its use to nonfacility settings. Since this service is not routinely furnished in a nonfacility setting, we believe that this procedure should only be paid in the facility settings at this time. Therefore, for CY 2025, we are finalizing our proposal not to nominate CPT code 27279 as potentially misvalued.

We continue to welcome the submission of new information regarding these services that was not part of our CY 2024 review of CPT code 27279. We would appreciate receiving any additional information, particularly published studies with sound methodology (for example, a systematic review or meta-analysis covering at least three databases) or new data.

(3) CPT Code 95800

An interested party re-nominated CPT code 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*) to update PEs that were last reviewed in 2017. This code was nominated as potentially misvalued

in the CY 2024 PFS proposed rule (88 FR 52283). For the CY 2024 final rule, we stated that we were unable to properly assess whether CPT code 95800 is potentially misvalued based on the evidence submitted with the original nominations and subsequent comments that CMS received (88 FR 78849 and 78850). This year, an interested party re-nominated CPT code 59800 noting two significant changes: (1) in the technologies available to perform home sleep apnea testing (HSAT) services; and (2) in clinical practice that leads to the typical procedure reported with the CPT code 95800. According to the nominator, the current practice utilizes disposable HSAT technology, such as the WatchPat One device, more often than the reusable equipment currently included in the procedure's direct PE inputs.

To account for these changes, the nominator requested the deletion of three direct PE input codes: (1) equipment code EQ335 (*WatchPAT 200 Unit with strap, cables, charger, booklet, and patient video*); (2) equipment code EQ336 (*Oximetry and Airflow Device*); and (3) supply code SD263 (*WatchPAT pneumo-opt sleep probes), which are WatchPAT probes used with the reusable WatchPAT unit. Instead, the nominator requested the addition of a supply code SD362 (the WatchPAT ONE device*), a disposable HSAT technology, as a replacement. According to our PE supply list, the combined price of the items that the nominator requested to delete (EQ335, EQ336, and SD263) is $4.71 + $4.55 + $73.32 = $82.58, which is $15.62 less than the price of the item that the nominator requested to add (SD362), priced at $98.20. The price of $98.20 was mentioned in the nomination letter without an accompanying specific invoice. Last year, the nominator submitted invoices, showing a price of $99.00 each (a case of 12 totaling $1,188.00) for the WatchPat One Device (SD362) (see Table 9).

TABLE 9: Listing of Nominator's Practice Expense items for addition or deletion to CPT code 95800

Current Equipment/Supply Code	Equipment/Supply Description	Nonfacility/ Office Equipment/Supply PE Cost	Recommended Equipment/ Supply Status
EQ335	WatchPAT 200 Unit with strap, cables, charger, booklet and patient video	$4.71	Delete
EQ336	Oximetry and Airflow Device	$4.55	Delete
SD263	WatchPAT pneumo-opt slp probes (reusable)	$73.32	Delete
SD362	WatchPAT ONE device (disposable)	$98.20	Add

The nominator asserted that testing trends have shifted away from traditional airflow-based tests, with a noticeable rise in peripheral arterial tone (PAT)-based (non-airflow) tests. The traditional airflow-based tests use the reusable supplies and equipment, whereas the PAT-based non-airflow tests use the disposable HSAT device. While describing these changes in trends, the nominator did not provide us with their internal data, thus we are unable to verify its validity. The nominator also stated that disposable HSAT devices were used for nearly 50 percent of CPT code 95800 services in 2023 and attributed the increased use of disposable devices to the COVID–19 public health emergency (PHE). Furthermore, the nominator projected that over 50 percent of CPT code 95800 services will be furnished using disposable devices in 2024 and 2025. Explaining the patterns and predictions, the nominator concluded that the pandemic significantly altered the delivery of HSAT services, with many sleep physicians transitioning to single-use, disposable sleep tests as an alternative to the reusable testing equipment that is shipped from patient-to-patient after post-use cleaning. The nominator believes that, going forward, the typical procedure described by CPT code 95800 in CY 2024 and beyond will be furnished using disposable HSAT devices rather than reusable equipment.

Since the COVID–19 PHE ended in 2023, we are still unclear as to whether the typical procedure reported with CPT code 95800 involves the use of a reusable or disposable HSAT device. Given that we only have access to the nominator's summary of their internal data to observe changes in usage trends, which may not be generalizable, we proposed to maintain the current direct PE supply and equipment inputs for CPT code 95800. While we did not propose to review CPT code 95800 as potentially misvalued for CY 2025, we sought public comments on this nomination. In particular, we sought comments on whether the typical procedure described by CPT code 95800 now involves the use of a disposable HSAT device rather than reusable equipment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to not nominate CPT code 95800 as potentially misvalued and advised us to continue monitoring this issue. The commenters reported a mix of disposable and reusable HSAT devices in use, noting that disposable devices have become more common since the COVID–19 PHE. The American Academy of Sleep Medicine (AASM) stated that HSAT data from AASM accredited sleep facilities indicated that, while there is an observed increase in the use of disposable HSAT devices, this does not suggest that members have converted to using them at this time. According to AASM, their survey data in 2022 indicated that the majority were still

using reusable HSAT devices. They generally believed there is insufficient information to determine whether disposable devices are more typical than reusable ones at this time, and therefore, they did not support the nomination of CPT code 95800 as potentially misvalued. They stated that further data collection would be needed to confirm whether the typical practice is now using disposable devices and suggested continued monitoring. Additionally, they opposed the removal of the Oximetry and Airflow device (EQ336), as it remains necessary for certain procedures.

Response: We thank commenters for their feedback.

Comment: The manufacturer and distributor of the WatchPAT disposable HSAT devices stated that a disposable HSAT offers the same accuracy and reliability as other WatchPAT products, but allows for quicker access to sleep data, particularly benefiting those in rural areas, enables physicians to better extend care, and reduces reinfection risks. Using their internal data, the device manufacturer stated that in 2023, 48 percent of WatchPAT tests used the disposable WatchPAT One device, reflecting a 4—8 percent annual increase since 2020; by the first half of 2024, this trend continued, with 53 percent of WatchPAT tests in the U.S. using the disposable HSAT device. Based on their utilization data and projections, the device manufacturer believed that there is strong evidence that the typical procedure in 2024 will involve the use of disposable rather than reusable HSAT equipment. The device manufacturer indicated that they do not have data on the number of Medicare patients using the disposable HSAT device, though they do not believe there is a significant difference in the use of reusable versus disposable equipment among Medicare or home sleep testing populations.

Response: We thank commenters for their summary of internal data and their feedback.

We acknowledge that the practice of medicine is evolving, and in clinically appropriate and effective circumstances, there may be support for transitioning from reusable to disposable HSAT equipment. We also recognize that the PE inputs for such services should be accurately determined to reflect typical clinical practice. However, after reviewing the public comments, we believe there is insufficient information at this time to demonstrate whether disposable or reusable HSAT devices are more commonly used than reusable HSAT equipment. Therefore, we are finalizing our proposal not to nominate CPT code 95800 as potentially misvalued.

However, we look forward to considering any additional information in the future as to whether disposable or reusable HSAT devices are more common. As suggested by the commenters, we believe more information is needed to confirm whether disposable devices are now the typical practice.

(4) CPT Codes 10021, 10004, 10005, 10006

An interested party nominated the CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), CPT code 10004 (*Fine needle aspiration biopsy, without imaging guidance; each additional lesion*), CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) as potentially misvalued. We noted in the proposed rule that this code family has been nominated several times in recent years. We discussed our review of these codes and our rationale for finalizing the current values extensively in the CY 2019 PFS final rule (83 FR 59517) and CY 2021 PFS final rule (85 FR 84602). Furthermore, this code family was nominated as potentially misvalued and discussed in the CY 2020 PFS final rule (84 FR 62625). For more information, we encourage the interested parties to refer to these prior PFS final rules.

The nominator specifically requested that we revisit our work RVU decisions for these codes, stating that the underpinnings of the reduction in work RVUs from the RUC-recommended values were flawed. The nominator suggested that CMS should adopt the RUC-recommended work RVUs. For CPT code 10021, the RUC recommended a work RVU of 1.20, but we adopted a lower value of 1.03. Similarly, for CPT code 10005, the RUC recommended a work RVU of 1.63, but we adopted 1.46. The nominator disagreed with these reductions from the RUC-recommended values by CMS, raising particular concerns about our choice for the RVU crosswalk for CPT code 36440 (*Push blood transfusion, patient 2 years or younger).* According to the nominator, the CPT code we chose is not comparable to fine needle aspiration (FNA) in any respect other than service time. The nominator raised several points, including that CPT code 36440 is rarely utilized and is almost never billed to Medicare because it pertains to a pediatric procedure conducted on neonates, while CPT code 10021 is never performed on neonates. They further asserted that the training and experience levels required to properly perform these procedures differ significantly; neonatal transfusions can be conducted by less experienced personnel, while performing a thyroid FNA demands more experience. Specifically, they argued that there is a notable difference in the work intensity between the two procedures. The thyroid is closely positioned to vital structures such as the carotid artery, jugular vein, lymphatic vessels, nerves, trachea, and esophagus. When sampling thyroid nodules, they are often in proximity to the carotid artery, jugular vein, or both. According to the nominator, even a slight deviation of 1–2 millimeters during the sampling procedure can result in accidental puncture of these critical blood vessels or other nearby structures. Factors such as respiratory movements, patient swallowing, or anxiety may cause the thyroid to move, further increasing the risk during the procedure. In contrast, neonatal phlebotomy does not require such measures. Also, the CPT code 36440 is designated as facility-only, meaning it does not include any clinical staff pre-service time and has no associated PE inputs. According to the nominator, FNA is a very complex and high-risk procedure that may require significant physician work and a higher level of clinical expertise to furnish the service, which is very different from CPT code 36440. We appreciated the survey (N=74) results that the nominator submitted to support their statements. The nominator-conducted survey, and their survey questions aimed to gather information on the practitioners' experiences, opinions, and practices related to FNA procedures. However, no other references such as peer reviewed medical literature or other nationally representative survey data were provided to reinforce their argument.

The nominator further stated that thyroid FNA should exclusively be performed as an outpatient procedure and does not require hospitalization. The nominator emphasized that the reduction in payment for the code family due to the reduction in work RVUs from the RUC-recommended values has led endocrinologists in office-based practices, those who are not affiliated with facilities, to discontinue furnishing this service. According to the nominator, as a consequence of this payment decrease, patients are now being referred to hospital-based radiology practices, despite the fact that thyroid FNA should ideally be conducted exclusively in nonfacility

outpatient settings. The nominator asserted that radiologists in hospital settings are often unfamiliar with the patient's medical history and risk factors for suspected thyroid cancer. The nominator further stated that radiologists' training in thyroid cancer primarily emphasizes imaging and procedures, rather than considering the patient's overall health perspective. This result may further lead to an increase in medically unnecessary procedures. Additionally, the nominator believes that the payment reduction for this code family has the potential to diminish the specialist workforce trained to perform these procedures, thereby presenting future challenges in patient care and access to specialized services.

Overall, we appreciate the comprehensive information and level of detail provided by the nominator. The nominator disagreed with the choice of crosswalk CPT code 36440 made by CMS, emphasizing the differences in provider training, procedure risk, and patient population. They stated the rarity of Medicare billing for this code. Additionally, they emphasized the importance of outpatient thyroid FNA being performed by endocrinologists. The shift to facility settings, prompted by reduced work RVUs, could raise Medicare costs. This, along with a potential decline in specialist workforce, may hinder patient access. However, in discussing this group of codes, we noted in the proposed rule that these codes have been recently reviewed multiple times through the annual PFS rulemaking process. We clarified once again that we disagree with the nominator that this code family is potentially misvalued. We acknowledged the possibility that there could be significant changes in the practice of delivering services described by these codes that were not fully reflected in the current work RVU. In such cases, it would be appropriate to refer the codes to the RUC to conduct a new survey to capture these changes accurately. However, we noted that these codes underwent thorough RUC survey and review processes during the October 2017 and January 2018 RUC meetings. Based on these considerations, we stated that we disagreed with the assertion that this code family is potentially misvalued. Nevertheless, we welcomed comments on whether these codes should be re-reviewed in light of the arguments made by the nominator.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal not to nominate CPT codes 10005, 10009, and 10021 as potentially misvalued and did not support a resurvey of the codes at this time, stating that these sets of codes have undergone several reviews in recent years.

Response: We thank the commenters for this feedback

Comment: The AMA RUC stated that these codes do not necessarily need to be re-evaluated and urged CMS to correct the mathematical error underlying the current work RVUs for CPT codes 10005, 10009, and 10021, and to accept the previous RUC-recommended work RVUs of 1.63 for CPT code 10005, 2.43 for CPT code 10009, and 1.20 for CPT code 10021. The RUC stated that the mathematical error occurred when CMS mistakenly double-counted the utilization of new codes that included bundled image guidance. The RUC believes that CMS misinterpreted the AMA's utilization crosswalk recommendations, emphasizing that the figures in the source utilization and utilization destination columns in Table 12 from the CY 2019 PFS final rule should be identical. Additionally, they stated that they provided the actual claims data from CY 2019 to evaluate the accuracy of CMS's RVU pool estimates during the CY 2019 rulemaking process. Lastly, a few commenters stated that they are not suggesting the entire code family is misvalued, but rather that only a subset of nominated FNA procedures is in question.

Response: The RUC continues to state that it believes there was an error in the utilization crosswalk for this code family during the CY 2019 review. In the CY 2019 PFS final rule, we refined the work RVUs of CPT codes 10021, 10005, and 10009 based on changes in surveyed work time and the relationships among the codes. For example, for CPT code 10021, we adjusted the work RVU from the RUC-recommended value of 1.20 to a finalized value of 1.03. This decision was driven by a decrease in the recommended intraservice time from 17 minutes to 15 minutes (a 12 percent reduction) and a decrease in total time from 48 minutes to 33 minutes (a 32 percent reduction). In contrast, the RUC-recommended work RVU only decreased from 1.27 to 1.20, representing a reduction of just over 5 percent. To better reflect these decreases in surveyed work time, we determined a work RVU of 1.03 was more accurate, using a crosswalk to CPT code 36440. It is important to note that the primary rationale for refining the work RVU did not reference the utilization crosswalk. Additionally, based on our previously explained rationale, we also note that the two columns—source utilization and utilization destination—do not need to be identical. Our review of these codes and our rationale for finalizing the current values are discussed in the CY 2019 PFS final rule (83 FR 59517 through 59521) and the CY 2021 PFS final rule (85 FR 84602 through 84604).

In continuing to repeat the same positions regarding the utilization crosswalk, however, the RUC has not provided any new information that was not already presented for the previous CMS reviews of these codes. In the event that there is a new RUC review of these services, as opposed to a restatement of the RUC's previous review, we would look forward to receiving any additional information or new data. We continue to welcome the submission of new information regarding these services that was not part of the previous CY 2019 and CY 2021 reviews of the code family.

Comment: Several commenters expressed concerns about the RVU reduction for the FNA codes, noting that since 2018, reduced reimbursement has led to an 18 percent decline in FNA procedures. They highlighted that this decrease disrupts continuity of care, causing delays in diagnosis and treatment, especially affecting patients in rural and low-income areas. Furthermore, they stated that the shift of FNA procedures from the office to facility setting has resulted in a 524 percent increase in Medicare costs and a rise in hospital-based services. Commenters also pointed out that Medicare claims from calendar year 2022 also indicate a shift in the type of clinician performing the procedure, with 52.3 percent of FNAs being performed by radiologists and only 17.6 percent by endocrinologists. They stated that radiologists often lack the capacity for the comprehensive follow-up care that would be provided by endocrinologists. Overall, they stated that the RVU reduction for the FNA codes would result in an increase in hospital-based facility fees and longer wait times for patients, would burden the healthcare system, and limit training opportunities for endocrinology fellows, potentially compromising future care quality and access.

Response: We appreciate the information provided by commenters regarding the impact of the current valuation on the setting of care where these services are provided. We welcome additional information on this issue; however, we continue to believe, as we have stated in past rulemaking,

that the FNA codes are accurately valued.

After consideration of the public comments, we continue to believe that the current valuation accurately reflects the typical work and direct PE inputs involved in furnishing FNA services. Therefore, for CY 2025, we are finalizing our proposal not to nominate CPT codes 10021, 10004, 10005, and 10006 as potentially misvalued.

(5) Tympanostomy Codes

CMS routinely interacts with interested parties, and in our most recent review, we have observed several new devices that could be beneficial for populations but are not currently included in our coding system. While there are variations in the described devices, they commonly share the following descriptions. This device uses an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum), and positioning and placing a ventilation tube across the tympanic membrane. The new device is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. This device allows the tympanostomy service to be furnished to patients without general anesthesia and the service could therefore be performed in the office setting.

Regarding the delivery of this service using innovative surgical technology, CMS stated in the proposed rule that we recognized that CPT code 69433 (*Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia*) (010-day global code) may serve as a sufficient base code, adequately describing the majority of the surgeon's work and facility resources. However, a practitioner may incur additional resources, due to the higher expected intraservice work driven by both time and intensity factors, especially when furnishing a service to a child, and the cost of the device when using these devices as part of the performed procedure. While the existing CPT code 69433 is not age-specific, both the vignette and the RVU associated with this procedure are established for adult patients who can respond to surgeon direction, and do not have risk of movement during the procedure. We stated that we believed that potentially establishing additional coding and payment for tympanostomy services may enable the provision of these services utilizing new technologies to a broader patient population who may benefit from innovative surgical technology. To improve the accuracy of the payment for these services, we solicited comments on several alternatives that we were considering for adoption in the CY 2025 PFS final rule or future rulemaking. First, we solicited comment on whether to establish a new G code that accounts for the work and PE for a procedure involving the positioning and placement of a ventilation tube across the tympanic membrane using an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum). We stated that we could assign contractor pricing to this potential G code for generalizable innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories. Alternatively, we solicited comment on whether we should establish an add-on payment for the service using inputs from CPT code 69433 as a crosswalk reference, plus direct costs from invoices for the surgical devices referenced above. We solicited comments regarding these potential approaches, particularly on whether there is additional information we should consider if we were to establish additional coding and payment for these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments, including from the RUC, stating that rather than developing new codes to describe tympanostomy tube delivery devices and/or systems, CMS should establish national pricing for Category III CPT code 0583T (*Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system and iontophoresis local anesthesia).* This code, implemented in 2020, includes a vignette describing its use for a child (the patient sitting on the parent or guardian's lap) and does not include general anesthesia. Commenters stated that national pricing for CPT code 0583T would allow procedures to be furnished without general anesthesia, saving families from taking time off work and avoiding the costs and risks associated with general anesthesia. One commenter stated that CPT code 31295 (*Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa*) is similar to the Category III CPT code 0583T procedure with respect to the intensity and invasiveness of the procedure, preparation time for the procedure, or total time to complete the procedure which is around 35–40 mins. Therefore, the commenter stated CMS can consider CPT code 31295 as the appropriate crosswalk reference. The RUC stated that it believes that this CPT code may be used to report this service as described and suggested that CMS should not create duplicate ways to report the same procedure.

Response: We thank comments for their feedback. We believe that CPT code 0583T does not adequately reflect the work and PEs for a procedure that uses innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories. Additionally, CPT code 0583T represents only one type of technology used for this service, whereas it is our understanding that there are multiple types of tympanostomy tube delivery devices and/or systems, and we do not want to limit payment for only one device. Therefore, we are not establishing a national price for Category III CPT code 0583T at this time. We appreciate the comments and feedback regarding the need for an appropriate rate for Category III CPT code 0583T and the potential for a crosswalk reference, however as discussed previously we will not be finalizing national pricing for CPT code 0583T.

Comment: Many commenters collectively supported the creation of additional coding to describe the resources associated with innovative tympanostomy tube delivery devices and/or systems. Commenters generally preferred that CMS establish a new G code, specifically an add-on G code with inputs based on CPT code 69433, for tympanostomy procedures, particularly using innovative surgical technology for patients at risk of movement during the procedure, such as pediatric patients. These commenters referenced the benefits of these minimally invasive, in-office procedures, which eliminate the risks associated with general anesthesia and offer quicker recovery, fewer infections, and improved access to care. They also stated that this innovative technology can be cost-effective, particularly for vulnerable and underserved populations with multiple health conditions. Additionally, the commenters stated that the ability to perform these procedures in an office setting, without the need for general anesthesia, significantly reduces associated risks and recovery time. Commenters stated that minimizing the use of general anesthesia is especially beneficial for pediatric patients, who are at a higher risk for anesthesia-related complications. However, while supporting the establishment of an add-

on G-code, a few commenters indicated that the current CPT code 69433 was designed for cooperative adults using standard instruments and therefore does not adequately reflect the resources and expertise involved.

Response: We appreciate the feedback from commenters and thank them for highlighting that these innovative tympanostomy procedures can be particularly beneficial for patients with additional health conditions, some of which may require multiple procedures and that CPT code 69433 may not fully account for the resources and expertise involved, or the tube delivery devices and/or systems.

We agree with commenters that these minimally invasive, in-office procedures can offer significant benefits, including reduced risks associated with general anesthesia, quicker recovery, fewer infections, and improved access to care. We also agree with commenters that the current coding is inadequate to reflect the different kinds of technologies used to conduct tympanostomies on children in the office setting, particularly those that do not require general anesthesia. Therefore, for CY 2025, we are finalizing the creation of a new add on G code, HCPCS code G0561 (*Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral (List separately in addition to 69433) (Do not use in conjunction with 0583T)*) to be billed with 69433 in order to describe the additional resource costs associated with using the innovative tympanostomy tube delivery devices and/or systems falling under emerging technology and services categories and are finalizing contractor pricing for CY 2025.

Lastly, we received several comments regarding CPT codes 21076–21089 which describe maxillofacial prosthodontic procedures (see Table 10). This code family was not discussed in the CY 2025 PFS proposed rule. Therefore, these comments are outside the scope of proposals included in the proposed rule, and we would not ordinarily summarize and respond to them in this final rule. However, we note that the commenters are welcome to submit these codes by February 10 of the coming year for consideration as potentially misvalued for the CY 2026 PFS proposed rule. See above for more information on how to submit a nomination for a potentially misvalued code.

TABLE 10: Listing of Maxillofacial Prosthetics

CPT codes	Description
21076	Impression and custom preparation; surgical obturator prosthesis
21077	Impression and custom preparation; orbital prosthesis
21079	Impression and custom preparation; interim obturator prosthesis
21080	Impression and custom preparation; definitive obturator prosthesis
21081	Impression and custom preparation; mandibular resection prosthesis
21082	Impression and custom preparation; palatal augmentation prosthesis
21083	Impression and custom preparation; palatal lift prosthesis
21084	Impression and custom preparation; speech aid prosthesis
21085	Impression and custom preparation; oral surgical splint
21086	Impression and custom preparation; auricular prosthesis
21087	Impression and custom preparation; nasal prosthesis
21088	Impression and custom preparation; facial prosthesis
21089	Unlisted maxillofacial prosthetic procedure

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502) and the CY 2024 PFS final rule (88 FR 78861 through 78866) and in 42 CFR 410.78 and 414.65. For a discussion of Telemedicine Evaluation and Management (E/M) Services, we refer readers to section II.E.4.18 of this final rule.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare Telehealth Services List in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Under the process we established beginning in CY 2003, we evaluated whether a service meets the following criteria:

- *Category 1:* Services similar to professional consultations, office visits, and office psychiatry services currently on the Medicare Telehealth Services List. In reviewing these requests, we looked for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site, and, if necessary, the telepresenter, a practitioner who was present with the beneficiary in the originating site. We also looked for similarities in the telecommunications system used to deliver the service, for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare Telehealth Services List. Our review of these requests included assessing

whether the service was accurately described by the corresponding code when furnished via telehealth and whether using a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should have included both a description of relevant clinical studies that demonstrated the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer-reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit did not include minor or incidental benefits. Some examples of other clinical benefits that we considered include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable signs or symptoms.
- Reduced recovery time.

In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare Telehealth Services List on a temporary basis following the end of the PHE for the COVID–19 pandemic. This new category described services that were added to the Medicare Telehealth Services List during the PHE, for which there was likely to be clinical benefit when furnished via telehealth, but there was not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis ultimately needed to meet the criteria under Category 1 or 2 in order to be permanently added to the *Medicare Telehealth* Services List. To add specific services on a Category 3 basis, we would conduct a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth.

In the CY 2024 PFS final rule (88 FR 78861 through 78866), we consolidated these three categories and implemented a revised 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List (5-step process), beginning for the CY 2025 Medicare Telehealth Services List. Rather than categorizing a service as ''Category 1'' or ''Category 2,'' each service is now assigned a ''permanent'' or ''provisional'' status. As described further below, a service is assigned a ''provisional'' status if there is not enough evidence to demonstrate that the service is of clinical benefit, but there is enough evidence to suggest that further study may demonstrate such benefit. The 5-step process review criteria are set forth in the CY 2024 PFS final rule (88 FR 78861 through 78866), listed at *https://www.cms.gov/medicare/coverage/telehealth/criteria-request,* and summarized below. Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other interested parties (83 FR 59491) and with the process set forth in prior calendar years, for CY 2025, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2024. Each request to add a service to the Medicare Telehealth Services List must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

Step 1. Determine whether the service is separately payable under the PFS.

When considering whether to add, remove, or change the status of a service on the Medicare Telehealth Services List, we first determine whether the service, as described by the individual HCPCS code, is separately payable under the PFS because, as further discussed in CY 2024 PFS final rule (88 FR 78861 through 78866), Medicare telehealth services are limited to those services for which separate Medicare payments can be made under the PFS. Before gathering evidence and preparing to submit a request to add a service to the Medicare Telehealth Services List, the submitter should therefore first check the payment status for a given service and ensure that the service (as identified by a HCPCS code), is a covered and separately payable service under the PFS (as identified by payment status indicators A, C, T, or R on our public use files).

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

If we determine at Step 1 that a service is separately payable under the PFS, we apply Step 2 under which we determine whether the service at issue is subject to the provisions of section 1834(m) of the Act. Section 1834(m) of the Act provides for payment to a physician (or other practitioner) for a service furnished via an interactive telecommunications system, notwithstanding that the furnishing practitioner and patient are not in the same location, at the same amount that would have been paid if the service was furnished without the telecommunications system. We have historically interpreted this to mean that only services that are ordinarily furnished with the furnishing practitioner and patient in the same location can be classified as a ''telehealth service'' for which payment can be made under section 1834(m) of the Act. Given that there may be a range of services delivered using certain telecommunications technology that, though they are separately payable under the PFS, do not fall within the definition of telehealth service set forth in section 1834(m) of the Act, the aim of Step 2 is therefore to determine whether the service at issue is, in whole or in part, inherently a face-to-face service. Services that fall outside the definition of telehealth service generally include services that do not require the presence of, or involve interaction with, the patient (for example, remote interpretation of diagnostic imaging tests, and certain care management services). Other examples include virtual check-ins, e-visits, and remote patient monitoring services which involve the use of telecommunications technology to facilitate interactions between the patient and practitioner, but do not serve as a substitute for an in-person encounter.

In determining whether a service is subject to the provisions of section 1834(m) of the Act, we therefore review during this Step 2 whether one or more of the elements of the service, as described by the particular HCPCS code at issue, ordinarily involve direct, face-to-face interaction between the patient

and practitioner such that the use of an interactive telecommunications system to deliver the service would be a substitute for an in-person visit.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

Step 3 is corollary to Step 2, and is used to determine whether one or more elements of a service are capable of being delivered via an interactive telecommunication system as defined in § 410.78(a)(3). In Step 3, we consider whether one or more face-to-face component(s) of the service, if furnished via audio-video communications technology, would be equivalent to the service being furnished in-person, and we seek information from requesters to demonstrate evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth, including, for example, in rural populations. The services are not equivalent when the clinical actions, or patient interaction, would not be of similar content as an in-person visit, or could not be completed.

Step 4. Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.

The purpose of Step 4 is to simplify and reduce the administrative burden of submission and review. For Step 4, we review whether the service elements of a code that we are considering for addition to, or removal from, the Medicare Telehealth Services List map to the service elements of a service that is already on the list and is assigned permanent status. Any code that satisfies this criterion would require no further analysis. If the service elements of a code maps to the service elements of a code that is already included on the Medicare Telehealth Services List and is assigned permanent basis, we will add the code to the Medicare Telehealth Services List and assign it permanent status. While we have not previously found that the service elements of a code we are considering for addition to the list map to the elements of a service that was previously added to the list and assigned permanent basis, we believe that it is appropriate to apply this step 4 analysis to compare the candidate service with any permanent code that is on the list on a permanent basis. When Step 4 is met, further evidence review is not necessary. We continue to Step 5 if Step 4 is not met.

Step 5. Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system.

Similar to Steps 3, 4, and 5 above, the purpose of step 5 is to simplify and reduce the administrative burden. Under Step 5, we review the evidence provided with a submission to determine the clinical benefit of a service. We then compare the clinical benefit of that service, when provided via telehealth, to the clinical benefit of the service if it were to be furnished in person. If there is enough evidence to suggest that further study may demonstrate that the service, when provided via telehealth, is of clinical benefit, CMS will assign the code a ''provisional'' status on the Medicare Telehealth Services List. Where the clinical benefit of a service, when provided via telehealth, is clearly analogous to the clinical benefit of the service when provided in person, CMS will assign the code ''permanent'' status on the Medicare Telehealth Services List, even if the code's service elements do not map to the service elements of a service that already has permanent status. We reminded readers that our evidentiary standard of demonstrated clinical benefit does not include minor or incidental benefits (81 FR 80194). We review the evidence submitted by interested parties, and other evidence that CMS has on hand. The evidence should indicate that the service can be safely delivered using two-way interactive audio-video communications technology. Clinical practice guidelines, peer-reviewed literature, and similar materials, should illustrate specifically how the methods and findings within the material establish a foundation of support that each element of the defined, individual service described by the existing face-to-face service code has been studied in the typical setting of care, typical population of beneficiaries, and typical clinical scenarios that practitioners would encounter when furnishing the service using only interactive, two-way audio-video communications technology to complete the visit or encounter with Medicare beneficiaries. General evidence may also answer the question of whether a certain beneficiary population requiring care for a specific illness or injury may benefit from receiving a service via telehealth versus receiving no service at all, but must establish that the service is a substitute for an equivalent in-person service. Evidence should demonstrate how all elements described by the individual service code can be met when two-way, interactive audio-video communications technology is used as a complete substitute for any face-to-face interaction required between the patient and practitioner that are described in the individual code descriptor. We further remind readers that submissions reflecting practitioner services furnished to Medicare beneficiaries are helpful in our considerations.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2025

We received several requests to permanently add various services to the Medicare Telehealth Services List, effective for CY 2025. The requested services are listed in Table 11.

TABLE 11: CY 2025 Requests for Permanent Addition to the Medicare Telehealth Services List

Category	HCPCS	Short Descriptor
Radiation Treatment Mgmt	77427	Radiation tx management x5
Psych Testing	96130	Psycl tst eval phys/qhp 1st
	96136	Psycl/nrpsyc tst phy/qhp 1st
	96137	Psycl/nrpsyc tst phy/qhp ea
Intensive Cardiac Rehab	G0422	Intens cardiac rehab w/exerc
	G0423	Intens cardiac rehab no exer
Developmental Testing	96112	Devel tst phys/qhp 1st hr
	96113	Devel tst phys/qhp ea addl
Health and Well Being Coaching	0591T	Hlth&wb coaching indiv 1st
	0592T	Hlth&wb coaching indiv f-up
	0593T	Hlth&wb coaching group
Outpatient Pulmonary Rehab	94625	Phy/qhp op pulm rhb w/o mntr
	94626	Phy/qhp op pulm rhb w/mntr
Cardiac Rehab	93797	Cardiac rehab
	93798	Cardiac rehab/monitor
Caregiver Training	97550	Caregiver traing 1st 30 min
	97551	Caregiver traing ea addl 15
Physical Therapy	97161	Physical therapy evaluation, low complexity
	97162	Physical therapy evaluation, moderate complexity
	97163	Physical therapy evaluation, high complexity
	97164	Physical therapy re-evaluation
	97110	Therapeutic exercises, each 15 mins
	97112	Neuromuscular re-education, each 15 mins
	97116	Gait training, each 15 mins
	97530	Therapeutic activities, each 15 mins
	97535	Self-care home management
OT Evaluation	97165	Ot eval low complex 30 min
	97166	Ot eval mod complex 45 min
	97167	Ot eval high complex 60 min
	97168	Ot re-eval est plan care
Speech, Language, and Voice Evaluation and Treatment	92507	Speech/hearing therapy
	92508	Speech/hearing therapy
	92521	Evaluation of speech fluency
	92522	Evaluate speech production
	92523	Speech sound lang comprehen
	92524	Behavral qualit analys voice
	96105	Assessment of aphasia
	92626	Eval aud funcj 1st hour
	92627	Eval aud funcj ea addl 15
	96125	Cognitive test by hc pro
	97129	Ther ivntj 1st 15 min
	97130	Ther ivntj ea addl 15 min
SGD Evaluation and Treatment	92607	Ex for speech device rx 1hr
	92608	Ex for speech device rx addl
	92609	Use of speech device service
Swallowing Evaluation and Treatment	92526	Oral function therapy
	92610	Evaluate swallowing function
Diagnostic Audiologic Testing	92550	Tympanometry & reflex thresh
	92552	Pure tone audiometry air
	92553	Audiometry air & bone

Category	HCPCS	Short Descriptor
	92555	Speech threshold audiometry
	92556	Speech audiometry complete
	92557	Comprehensive hearing test
	92563	Tone decay hearing test
	92565	Stenger test pure tone
	92567	Tympanometry
	92568	Acoustic refl threshold tst
	92570	Acoustic immitance testing
	92587	Evoked auditory test limited
	92588	Evoked auditory tst complete
	92625	Tinnitus assessment
	92626	Eval aud funcj 1st hour
	92627	Eval aud funcj ea addl 15
Diagnostic CI Testing	92601	Cochlear implt f/up exam <7
	92602	Reprogram cochlear implt <7
	92603	Cochlear implt f/up exam 7/>
	92604	Reprogram cochlear implt 7/>

Many of the services listed above were added to the Medicare Telehealth Services List on a temporary basis during the PHE for COVID–19, as discussed in the March 31st COVID–19 interim final rule with comment period (IFC) (85 FR 19235 through 19237) for the PHE for Covid–19, and we subsequently retained these services on a provisional basis. All of the submissions received this calendar year were requests to add services, including several of which are assigned provisional status on Medicare Telehealth Services List, to the Medicare Telehealth Services List on a permanent basis. For services currently assigned provisional status on the Medicare Telehealth Services List, we believe that, rather than selectively adjudicating only those services for which we received requests for potential permanent status, it would be appropriate to complete a comprehensive analysis of all provisional codes currently on the Medicare Telehealth Services List before determining which codes should be made permanent. Therefore, we are not making determinations on whether to recategorize provisional codes as permanent until such time as CMS can complete a comprehensive analysis of all such provisional codes which we expect to address in future rulemaking.

The following is a discussion of the requests received for addition of services to the Medicare Telehealth Services List:

(1) Continuous Glucose Monitoring

We received a request to add CPT code 95251 (*Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report*) to the Medicare Telehealth Services List and assign it permanent status. This code is not on the Medicare Telehealth Services List, nor had it been previously added and removed. The requester stated that the ability of the practitioner to interpret continuous glucose monitoring data and communicate changes in the diabetes care plan to their patients is enhanced by the availability of video visits, and the code should therefore be added to the Medicare Telehealth Services List.

This service does not meet the criteria described by Step 2 of the 5-step process: determination of whether the service is subject to the provisions of section 1834(m) of the Act. Under section 1834(m)(2)(A) of the Act, Medicare pays the same amount for a telehealth service as if the service is furnished in person (88 FR 78862). A service is subject to the provisions of section 1834(m) of the Act when at least some elements of the service, when delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all of those face-to-face elements of the service are furnished using an interactive telecommunications system as defined in § 410.78(a)(3) (88 FR 78863). In other words, as stated above, for a service to be considered a Medicare telehealth service subject to and payable under section 1834(m) of the Act, the service must be so analogous to in-person care such that the telehealth service, as defined in § 410.78, is essentially a substitute for a face-to-face encounter. We do not consider this service a Medicare telehealth service because it is not an inherently face-to-face service; the patient does not need to be present for the service to be furnished in its entirety. CPT code 95251 describes sensor placement and monitoring over a 72-hour period. We do not consider CPT code 95251 a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we proposed to not add this service to the Medicare Telehealth Services List.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: We received some comments requesting that we remove the criterion we use in Step 2 of our 5-step process to consider whether a services is analogous to an in-person service. The commenters stated that this service may be performed virtually alongside an E/M service furnished via Medicare telehealth. The commenters stated that a practitioner can provide this service in conjunction with a separately reportable telehealth service on the same day, and expressed concern that unless this code is added to the Medicare Telehealth Services List, there could be claims processing errors if the continuous glucose monitoring service is reported with Medicare telehealth POS codes.

Response: We believe that Step 2 of our 5-step process plays a critical role in ensuring that any service being considered to be added on the Medicare Telehealth Services List is sufficiently analogous to an in-person service in terms of both the clinical benefit provided and the way it is furnished. This criterion ensures that services delivered virtually offer the same, if not similar diagnostic and treatment value as in-person visits. Removing Step 2 would undermine this goal.

Furthermore, Section 1834(m) of the Act requires the Secretary to pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. As discussed in CY 2025 PFS proposed rule and this CY 2025 PFS final rule, this limits payment for Medicare telehealth services to those services that are, in whole or in part, inherently a face-to-face service.

We thank commenters for the additional information and concerns. We continue to believe that this service does not meet the requirements to be added to the Medicare Telehealth Services List because the service does not ordinarily involve the presence of, or interaction with, the patient.

After consideration of public comments, we are finalizing as proposed to not add this service on the Medicare Telehealth Services List.

(2) Cardiovascular and Pulmonary Rehabilitation

We received requests to permanently add cardiovascular *rehabilitation* services (CPT codes 93797 and 93798) and *pulmonary rehabilitation* services (CPT codes 94625 and 94626) to the Medicare Telehealth Services List. A requester cited studies that they say demonstrate that the availability of these services via telehealth enhances access and patient equity. Another requester cited evidence of improved outcomes for patients that had access to these services via telehealth.

These services are currently on the Medicare Telehealth Services List and are assigned provisional status. In the CY 2022 PFS final rule (86 FR 65054 through 65055), we explained that some services were added temporarily to the Medicare Telehealth Services List on an emergency basis to allow practitioners and beneficiaries to have access to medically necessary care while avoiding both risk for infection and further burdening healthcare settings during the PHE for COVID–19. As explained in the CY 2025 PFS proposed rule, rather than selectively adjudicating only those services for which we receive requests for potential permanent status, we intend to first complete a comprehensive analysis of all provisional codes currently on the Medicare Telehealth Services List before determining which codes should be made permanent. We therefore stated in the proposed rule that while we would consider the requestors' input in future rulemaking, we were not proposing to assign CPT codes 93797 and 93798 or CPT codes 94625 and 94626 permanent status on the Medicare Telehealth Services List and would instead maintain the services on the Medicare Telehealth Services List on a provisional basis for CY 2025.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported these services remaining on the Medicare Telehealth Services List, along with additional requests to revise their status of from provisional to permanent. In addition, we also received a resubmission of the original request to revise the status of these codes from provisional to permanent with no changes in the information provided.

Response: As we stated in the proposed rule, we are not considering whether to recategorize provisional codes as permanent in this rulemaking for CY 2025 because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking.

After consideration of public comments, we are finalizing as proposed to maintain these services on the Medicare Telehealth Services List on a provisional basis.

(3) Health and Well Being-Coaching

We received a request to add Health and Well-Being Coaching (CPT codes 0591T—0593T) to the Medicare Telehealth Services List with permanent status. These services are currently on the Medicare Telehealth Services List and are assigned a provisional status. We originally added these codes on a provisional basis in the CY 2024 PFS final rule (88 FR 78859 and 78860). One requester stated that health and well-being coaching, including content education, delivered in a telehealth modality is an evidence-based, cost-effective, sustainable, and common sense approach to facilitating lifestyle/behavioral intervention and treating the Medicare population with or at heightened risk for chronic diseases. As explained previously, we did not propose to revise the status of codes from provisional to permanent in the proposed rule because we intend to conduct a comprehensive review. Therefore, we did not propose to assign them to the Medicare Telehealth Services List with permanent status.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported these services remaining on the Medicare Telehealth Services List, along with additional requests to revise the status of codes from provisional to permanent. Some commenters recommended that we maintain the designation of these codes as provisional on the Medicare Telehealth Services List to allow for additional data and support to be collected for future requests to revise the status of codes from provisional to permanent.

Response: As we stated in the proposed rule, we are not considering in rulemaking for CY 2025 whether to recategorize provisional codes as permanent because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking.

After consideration of public comments, we are finalizing as proposed to maintain these services on the Medicare Telehealth Services List on a provisional basis.

(4) Psychological Testing and Developmental Testing

We received a request to add Psychological Testing and Developmental Testing (CPT codes 96112, 96113, 96130, 96136, and 96137) to the Medicare Telehealth Services List on a permanent basis. These services are currently on the Medicare Telehealth Services List and are assigned provisional status. In the March 31, 2020 interim final rule with comment period (IFC–1) (85 FR 19239), we originally added CPT codes 96130, 96136, and 96137 to the Medicare Telehealth Services List for the duration of the PHE for COVID–19, and in the CY 2021 PFS final rule (85 FR 85003), we stated we were retaining them on the list on a category 3 basis. In the CY 2023 PFS final rule (87 FR 69460), we added CPT codes 96112 and 96113 on a temporary basis.

As explained previously, we did not propose to revise the status of codes from provisional to permanent in the proposed rule because we intend to conduct a comprehensive review. Therefore, we did not propose to either remove these services from or to assign them permanent status on the Medicare Telehealth Services List.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported these services remaining on the Medicare Telehealth Services List, along with additional requests to revise the status of codes from provisional to permanent.

Response: We are not considering in this rulemaking for CY 2025 whether to recategorize provisional codes as permanent because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking.

After consideration of public comments, we are finalizing as proposed to maintain these services on the Medicare Telehealth Services List on a provisional basis.

(5) Therapy/Audiology/Speech Language Pathology

We received multiple requests to add the Therapy services described by CPT codes 97110, 97112, 97116, 97161 through 97164, 97530 and 97535, 97165 through 97168, and Audiology and Speech Language Pathology services CPT codes 92507, 92508, 92521 through 92524, 92526, 92607 through 92610, 96105 92626, 92627, 96125, 97129, 97130, 92607 through 92609 92550 through 92557, 92563, 92565 92567, 92568, 92570, 92587, 92588, 92601 through 92604, 92625 through 92627, and 92651 and 92652 to the Medicare Telehealth Services List on a permanent basis, stating that continuing telehealth flexibilities for these services could lead to reduced health care expenditures, increased patient access, and improved management of chronic disease and quality of life. These services are currently available on the Medicare Telehealth Services List and are assigned provisional status, and we refer readers to section II.D.1. for further discussion of these services. In the CY 2023 PFS final rule (87 FR 69451), we originally added CPT codes 90901, 97150, 97530, 97537, 97542, 97763, and 98960–98962 to the Medicare Telehealth Services List on a Category 3 basis. As explained previously, we did not propose to revise the status of codes from provisional to permanent in the proposed rule because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking. Therefore, we did not propose to assign them permanent status on the Medicare Telehealth Services List.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that these services be added to the Medicare Telehealth Services List on a permanent basis, citing concerns that, due to expiring PHE flexibilities, they believe the codes are scheduled to be removed from Medicare Telehealth Services List on December 31, 2024.

Response: As we stated in the proposed rule, we are not considering in this rulemaking for CY 2025 whether to recategorize provisional codes as permanent because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking. We clarify that we will retain these Therapy/Audiology/Speech Language Pathology codes on the Medicare Telehealth Services List with a provisional status after the expiration on December 31, 2024, of current statutory PHE-related telehealth policies that have expanded the scope of practitioners that could furnish and be paid for telehealth services.

After consideration of public comments, we are finalizing as proposed to maintain these services as provisional on the Medicare Telehealth Services List.

(6) Care Management

We received a request to permanently add General Behavioral Health Integration (CPT code 99484) and Principal Care Management (CPT codes 99424—99427) to the Medicare Telehealth Services List. These services are not on the Medicare Telehealth Services List, nor have they been previously added and removed. These services do not meet the criteria described by Step 2 of the 5-step process: determination of whether the service is subject to the provisions of section 1834(m) of the Act. As stated previously in this CY 2025 PFS final rule, section 1834(m) of the Act requires the Secretary to pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. As discussed in the CY 2025 PFS proposed rule and this CY 2025 PFS final rule, this limits payment for Medicare telehealth services to those services that are, in whole or in part, inherently a face-to-face service. Because these services are not inherently face-to-face services, and the patient need not be present for the services to be furnished in its entirety, we do not consider CPT codes 99484 and 99424—99427 to be telehealth services under section 1834(m) of the Act or our regulation at § 410.78. Therefore, we proposed to not add these services to the Medicare Telehealth Services List.

We did not receive public comments on this proposal and are finalizing as proposed.

(7) Posterior Tibial Nerve Stimulation for Voiding Dysfunction

We received a request to permanently add Posterior tibial neurostimulation (CPT code 64566) to the Medicare Telehealth Services List. This code is not on the Medicare Telehealth Services List, nor had it been previously added and removed. This service does not meet the criteria for addition described by Step 3 of the 5-step process, namely the review of the elements of the service as described by the HCPCS code and determining whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3). The requestor describes the services underlying CPT code 64566 as the continual or recurring treatments over a period of time consisting of the remote monitoring of device utilization and bladder diary for the generation of reports for review by the care provider. Based on our review, this description does not align with the elements of the service as described by CPT code 64566. CPT code 64566 describes a single treatment provided by a clinician who has direct contact with the patient and inserts an electrode into the skin overlying the posterior tibial nerve. Upon conclusion of the treatment, the clinician removes the electrode and examines and dresses the puncture wound. Providing these services would require in-person interaction. Therefore, we proposed to not add the service to the Medicare Telehealth Services List because we did not believe the service elements can be could in full using two-way audio-video telecommunications technology.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter recommended that we add this service to the Medicare Telehealth Services List on a permanent basis. This commenter provided similar information that was provided in the initial submission about a patch containing a microneedle array that the patient can apply themselves in support of their argument that the service can be furnished in full using two-way, audio/video telecommunications technology.

Response: We thank the commenter for the additional information. We continue to believe that this service does not meet the requirements to be added to the Medicare Telehealth Services List because the service elements cannot be met in full using two-way audio-video telecommunications technology. While

we appreciate the additional information regarding the patch, based on information provided by the RUC as to the typical resource costs associated with furnishing this procedure and input from our clinical advisors, there is not sufficient evidence to demonstrate, if the service was furnished using two-way audio-video telecommunications technology, that the clinician actions and patient interaction would be of similar content as an in-person visit. We will continue to evaluate whether Posterior Tibial Nerve Stimulation for Voiding Dysfunction, if using the patch discussed by the commenter, is capable of being delivered via an interactive telecommunication system and encourage interested parties to continue to engage with us regarding payment for this service. After consideration of public comments, we are finalizing as proposed to not add CPT code 64566 to the Medicare Telehealth Services List.

(8) Radiation Treatment Management

We received requests to permanently add Radiation Treatment Management (CPT code 77427) to the Medicare Telehealth Services List. The code is currently on the Medicare Telehealth Services List with provisional status. In the March 31, 2020 IFC (85 FR 9240), we originally added CPT code 77427 on the Medicare Telehealth Services List for the duration of the PHE for Covid-19. A requester stated that data collected during the PHE demonstrates that the telehealth option is as safe as the in-person equivalent. We also received a request that we remove this code from the Medicare Telehealth Services List, citing the importance of in-person physical examination to ensure quality of care and stating that a telehealth modality presents patient safety concerns such as those related to the ability of the practitioner to address side effects of radiation therapy. Given the safety concerns raised by members of the practitioner community, we believe this service may not be safely and effectively furnished, and therefore believe that such concerns merit removing this item from the telehealth list. Therefore, we proposed to remove this code from the Medicare Telehealth Services List, and we solicited comment on these quality of care concerns.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to remove Radiation Treatment Management from the Medicare Telehealth Services List. These commenters cited that the in-person visit portion of this code is important for high-quality care and patient safety. In addition, they provided information about the side effects of radiation treatment that can be impacted by comorbidities or other therapies or treatments.

Many commenters did not support our proposal to remove Radiation Treatment Management from the Medicare Telehealth Services List. These commenters stated that there have been no published safety incidents since this service has been able to be furnished via Medicare telehealth and that most of the side effects associated with radiation treatment delivery are minor dermatological issues that can be treated via audio-video technology. The commenters who did not support our proposal also provided information about the medical decision-making that is used when determining if a patient's side effects are appropriate to be resolved via a telehealth encounter or if an in-person visit would be more appropriate. Because the in-person visit portion of this code is conducted weekly, this decision can change based on whether the patient is experiencing side effects and other clinical considerations.

Response: We thank commenters for the extensive information provided both in support of and counter to our proposal for this service. After reviewing this information, we are compelled by the points raised by commenters regarding the lack of evidence of adverse patient safety outcomes and the importance of allowing clinical judgement in determining whether a patient can be seen via Medicare telehealth or whether the patient needs to be seen in-person. However, we recognize the ongoing patient safety concerns and welcome information regarding any adverse outcomes as it becomes available.

After consideration of public comments, we are not finalizing as proposed. Instead, we will retain Radiation Treatment Management (CPT code 77427) on the Medicare Telehealth Services List on a provisional basis.

(9) Home International Normalized Ratio (INR) Monitoring

We received a request to permanently add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List. This service is not on the Medicare Telehealth Services List, nor had it been previously added and removed. We proposed to add HCPCS code G0248 to the Medicare Telehealth Services List with provisional status because our clinical analyses of these services indicate that they can be furnished in full using two-way, audio and video technology, and information provided by requesters indicates that there may be clinical benefit; however, there is not yet sufficient evidence available to consider the services for permanent status. This service as described by the HCPCS code is a face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient's ability to perform testing and report results, and we believe each of these service elements the elements is capable of being furnished using an interactive telecommunications system. Adding this service on a provisional basis will allow additional time for the development of evidence of clinical benefit when this service is furnished via telehealth for CMS to consider when evaluating this service for potential permanent addition to the Medicare Telehealth Services List.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported adding these services to the Medicare Telehealth Services List on a provisional basis, and several recommended that we add these services to the Medicare Telehealth Services List on a permanent basis. Many commenters suggested that, as home INR services are primarily furnished by IDTFs, we should clarify that these suppliers are also able bill for Medicare Telehealth services. As these commenters explained in detail, the interaction with the patient described by this service is generally delivered by individuals considered to be clinical staff and not practitioners under the PFS and that studies have indicated positive outcomes when this clinical staff-provided service is delivered virtually, as it commonly has been since the first part of 2020.

Response: We thank commenters for their input. After reviewing the comments information provided by commenters regarding the entities who commonly bill for these services and the how they are currently delivered, we believe we need additional time to consider whether these services should be added to the formal list of Medicare telehealth services. Therefore, we are not finalizing addition to the Medicare telehealth list for CY 2025 and welcome input from interested parties which we may consider for future rulemaking. We note that we believe continued access to this service is important and not adding this service to the telehealth list at this

time does not mean that suppliers should change their current practices.

After consideration of public comments, we are not finalizing as proposed to add Home INR Monitoring (HCPCS code G0248) to the Medicare Telehealth Services List on a provisional basis.

(10) Caregiver Training

We received a request to permanently add Caregiver Training services, as described by CPT codes 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes*) and CPT code 97551 *(Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service))* to the Medicare Telehealth Services List. These codes do not currently appear on the Medicare Telehealth Services List nor had they previously been added or removed. We proposed to add these services to the Medicare Telehealth List with provisional status for CY 2025, in addition to the other currently payable caregiver training service codes (CPT codes 97550, 97551, 97552, 96202, 96203). . These codes describe new services that were added to the PFS beginning in 2024. Contingent upon finalizing the service code descriptions that we proposed in section II.E. of this final rule, we also proposed that HCPCS codes G0541–G0543 (GCTD1–3) and G0539–G0540 (GCTB1–2) be added to the Medicare Telehealth Services list for CY 2025 on a provisional basis. We believe that these codes are similar to other services already available on the Medicare Telehealth Services List, including education and training for patient self-management (CPT codes 98960–98962), self-care/home management training (CPT codes 97535), and caregiver-focused health risk assessment (CPT code 96161). Further, it appears that all elements of these services may be furnished when using two-way, audio-video interactive communications technology. Given the limited utilization of those codes for 2024, there are not studies supporting these codes' ability to be furnished remotely. Adding these services on a provisional basis will allow additional time for the development of evidence of clinical benefit when this service is furnished via telehealth for CMS to consider when evaluating these services for potential permanent addition to the Medicare Telehealth Services List.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported adding these services to the Medicare Telehealth Services List on a provisional basis. Some commenters recommended that we add these services to the Medicare Telehealth Services List on a permanent basis.

Response: We thank commenters for their support and may consider designating these services with permanent status on the Medicare Telehealth Services List in the future after additional data is provided in support of these services being furnished via telehealth.

After consideration of public comments, we are finalizing as proposed to add caregiver training services (CPT codes 97550, 97551, 97552, 96202, 96203 and HCPCS codes G0541–G0543 (GCTD1–3) and G0539–G0540 (GCTB1–2)) to the Medicare Telehealth Services list for CY 2025 on a provisional basis.

c. Other Services Proposed for Addition to the Medicare Telehealth Services List

(1) Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)

As outlined in Section II.E. of this final rule, we proposed national rates for HCPCS codes G0011 (Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15–30 minutes) and G0013 (Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence) pending the future finalization of the NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection. We believe these services are similar to services currently on the Medicare Telehealth Services list, specifically HCPCS codes G0445 (High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes) and CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional) as these codes are the codes from which HCPCS codes G0011 and G0013 were unbundled, respectively. As similarity to services currently on the Medicare Telehealth Services List is one of our criteria for permanent addition, we proposed to add HCPCS codes G0011 and G0013 to the Medicare Telehealth Services List with a permanent status.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this proposal, and we did not receive any comments that were not in support of our proposal.

Response: We thank commenters for their input. After consideration of public comments, we are finalizing as proposed to add HCPCS codes G0011 and G0013 to the Medicare Telehealth Services List with a permanent status on the Medicare Telehealth Services List, beginning in CY 2025.

(2) Other Consideration for Medicare Telehealth Services List

Comment: Many commenters requested that we add services to the Medicare Telehealth Services List for which we did not receive requests through the annual submissions for consideration for the CY 2025 rulemaking cycle and that we did not discuss in the CY 2025 PFS proposed rule.

Response: We consider requests to add or remove services from the Medicare Telehealth Services List through the process we established as required under section 1834(m)(4)(F)(ii). Requests can be submitted to the CMS Telehealth Review Process mailbox (*telehealth_review_process@cms.hhs.gov*) no later than February 10, 2025, to be considered for the CY 2026 cycle of annual notice and comment rulemaking. For more information on requesting additions to the Medicare Telehealth Services List, please see *https://www.cms.gov/medicare/coverage/telehealth/request-addition.*

Comment: Some commenters requested clarification that the services designated as ''provisional'' on the Medicare Telehealth Services List will remain on the list for CY 2025.

Response: As explained previously, we are not considering in this

rulemaking for CY 2025 whether to recategorize provisional codes as permanent because we intend to conduct a comprehensive analysis of all such provisional codes, which we expect to address in future rulemaking. Except as specifically stated otherwise in this section, services included on *the Medicare Telehealth Services List* with provisional status will remain on the list for CY 2025.

The services that we are adding to the Medicare Telehealth Services List are listed in Table 12.

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TABLE 12: Services Finalized for Addition to the Medicare Telehealth Services List for CY 2025

Category	HCPCS	Long Description	Finalized Status
PrEP for HIV	G0011	Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes	Permanent
	G0013	Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence	Permanent
Caregiver Training	97550	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes	Provisional
	97551	Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (list separately in addition to code for primary service)	Provisional
	97552	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [adls], instrumental adls [iadls], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face with multiple sets of caregivers	Provisional

Category	HCPCS	Long Description	Finalized Status
	96202	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes	Provisional
	96203	Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); each additional 15 minutes (List separately in addition to code for primary service)	Provisional
	G0541	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes	Provisional
	G0542	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541)	Provisional

Category	HCPCS	Long Description	Finalized Status
	G0543	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers	Provisional
	G0539	Caregiver training in behavior management/modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes	Provisional
	G0540	Caregiver training in behavior management/modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes	Provisional
Safety Planning Interventions	G0560	Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal or substance use-related crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts or risky substance use; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health or substance use disorder professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy)	Permanent

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We also point commenters to section II.I. of this final rule where we address requests from commenters to add HCPCS code G0560 to the Medicare Telehealth Services List. We are finalizing addition of HCPCS code G0560 to the Medicare Telehealth Services List.

d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often practitioners may furnish the service via Medicare telehealth. These include a limitation of one subsequent hospital care service furnished through telehealth every three days, added in the CY 2011 PFS final rule (75 FR 73317 through 73318), one subsequent nursing facility visit furnished through telehealth every 14 days, added in the CY 2011 PFS final rule (75 FR73318),

and one critical care consultation service furnished through telehealth per day, added in the CY 2017 final rule (81 FR 80198). In establishing these limits, we cited concerns regarding the potential acuity and complexity of these patients.

We temporarily removed these frequency restrictions during the PHE for COVID–19. In the March 31, 2020 COVID–19 interim final rule with comment period (IFC) (85 FR 19241), we stated that we did not believe the frequency limitations for certain subsequent inpatient visits, subsequent NF visits, and critical care consultations furnished via Medicare telehealth were appropriate or necessary for the duration of the PHE because this would have been a patient population who would have otherwise not had access to clinically appropriate in-person treatment. Although the frequency limitations resumed effect on May 12, 2023 (upon expiration of the PHE), through enforcement discretion during the remainder of CY 2023 and notice-and-comment rulemaking for CY 2024, Medicare telehealth frequency limitations have been suspended for CY 2024 (88 FR 78876 through 78878) for the following codes relating to Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services:

1. Subsequent Inpatient Visit CPT Codes:

- 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making when using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*);
- 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making when using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*); *and*
- 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making when using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*)

2. Subsequent Nursing Facility Visit CPT Codes:

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. when using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*);
- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making when using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*);
- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making when using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); and
- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. when using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*)

3. Critical Care Consultation Services: HCPCS Codes

- G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth.*); and
- G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth.*)

In the CY 2024 PFS final rule (88 FR 78877), we solicited comments from interested parties on how practitioners have been ensuring that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE. As discussed in that final rule, many commenters supported permanently removing these frequency limitations, stating that they are arbitrary and re-imposing the limitations would result in decreased access to care; that practitioners should be allowed to use their clinical judgment to determine the type of visit, how many visits, and the type of treatment that is the best fit for the patient so long as the standard of care is met; and that lifting these limitations during the PHE has been instructive and demonstrates the value of continuing such flexibilities. Many commenters urged us to permanently remove them. That said, some commenters did not support removing these frequency limitations citing patient acuity and safety, some commenters cited the importance of in-person care for patients in acute care settings. Some commenters stated that telehealth patient assessments and evaluations are never the same as in-person, hands on visits and should not be considered a viable replacement with no limitations for in-person care. We are continuing to consider what changes we should be making to how telehealth services are paid under Medicare in light of the way practice patterns may have changed following the PHE for COVID–19. Taking into account the information received from commenters in the CY 2024 PFS final rule, we believe it is reasonable to continue to pause certain pre-pandemic restrictions, such as the frequency limitations for the abovementioned codes for CY 2025. Removing such restrictions for CY 2025 would allow us to gather an additional year of data to determine how practice patterns are evolving and what changes, if any, to frequency limitations should be made on a permanent basis.

We do not believe pausing such frequency limitations for another year presents a level of safety risk requiring us to immediately reinstate the limitations. Our analysis of claims data indicates that the volume of services that would be affected by implementing these limitations is relatively low; in other words, these services are not being furnished via telehealth with such frequency that, if the frequency limits were in place, they would be met or exceeded very often or for many beneficiaries. Claims data from 2020–2023 suggest that less than five percent received one or more of these services as a telehealth service. Therefore, while claims data does not suggest that lifting these limitations during the PHE has led to an increase in utilization, we continue to be interested in information from interested parties on our concerns regarding the potential acuity and complexity of these patients and how such acuity and complexity should complexity should influence our implementation of frequency limitations.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals to continue to suspend application of telehealth frequency limits on subsequent

inpatient and nursing facility visits and critical care consultations through 2025. Commenters stated that they appreciated the continued flexibility while also acknowledging the concerns we expressed regarding the necessity of in-person care for patients in higher-acuity settings of care. Several commenters did suggest that we should permanently lift these restrictions, stating that this flexibility is helpful in addressing staffing shortages and that we should defer to individual clinical judgement when it comes to how frequently a patient requires in-person, non-telehealth care. A few commenters cautioned that we should not remove frequency limitations permanently, stating in-person care is essential to quality of life and care due to the complex nature and acuity of patients in these settings.

Response: We thank commenters for their input. We believe that continuing to suspend these frequency limitations on a temporary basis for CY 2025 will allow us more time to evaluate patient safety while preserving access in a way that is not disruptive to practice patterns that were established during and after the PHE. We appreciate the information regarding both patient safety concerns and concerns regarding supporting healthcare access. We expect to address these concerns in future rulemaking.

After consideration of public comments, we are finalizing as proposed to continue suspension of the telehealth frequency limits on subsequent inpatient and nursing facility visits and critical care consultations through CY 2025.

e. Audio-Only Communication Technology To Meet the Definition of ''Telecommunications System''

In our regulation at § 410.78(a)(3), we define ''interactive telecommunications system'' as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Through emergency regulations and waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we allowed the use of audio-only communications technology to furnish services described by the codes for audio-only telephone evaluation and management services and behavioral health counseling and educational services. Section 4113 of the CAA, 2023, extended the availability of telehealth services that can be furnished using audio-only technology and provided for the extension of other PHE-related flexibilities including removal of the geographic and location limitations under section 1834(m) of the Act through December 31, 2024.

In the CY 2022 PFS final rule (86 FR 65060), in part to recognize the changes made by section 123 of the CAA, 2021 that removed the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and the addition of the patient's home as a permissible originating site for these services, we revisited our regulatory definition of ''interactive telecommunications system'' beyond the circumstances of the PHE. Specifically, we finalized a policy to allow for audio-only services under certain circumstances and revised the regulation at § 410.78(a)(3) to permit the use of audio-only equipment for telehealth services furnished to established patients in their homes for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorders) if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology. We also established this policy in part because mental health services are different from most other services on the Medicare telehealth services list in that many of the services primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to the provision of the service.

However, with the successive statutory extensions of the telehealth flexibilities implemented in response to the PHE for COVID–19, most recently by the CAA, 2023, and our adoption of other extensions where we have had authority to do so, we have come to believe that it would be appropriate to allow interactive audio-only telecommunications technology when any telehealth service is furnished to a beneficiary in their home (when the patient's home is a permissible originating site) and when the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined previously, but the patient is not capable of, or does not consent to, the use of video technology. While practitioners should always use their clinical judgment as to whether the use of interactive audio-only technology is sufficient to furnish a Medicare telehealth service, we recognize that there is variable broadband access in patients' homes, and that even when technologically feasible, patients simply may not always wish to engage with their practitioner in their home using interactive audio and video. Under current statute, with the expiration of the PHE-related telehealth flexibilities on December 31, 2024, the patient's home is a permissible originating site only for services for the diagnosis, evaluation, or treatment of a mental health or substance use disorder, and for the monthly ESRD-related clinical assessments described in section 1881(b)(3)(B) of the Act.

We proposed in the CY 2025 PFS proposed rule to revise the regulation at § 410.78(a)(3) to state that an interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology. Additionally, a modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met. These are CPT modifier ''93'' and, for RHCs and FQHCs, Medicare modifier ''FQ'' (Medicare telehealth service was furnished using audio-only communication technology). Practitioners have the option to use the ''FQ'' or the ''93'' modifiers or both where appropriate and true, since they are identical in meaning.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal, stating that allowing audio-only communications technology to meet the definition of telecommunications system when a beneficiary is in their home and does not have access to, or does not wish to use, two-way, audio/video would improve access to care, particularly for rural and underserved populations.

Response: We thank commenters for their support.

Comment: A few commenters requested the removal of the requirement that the distant site practitioner be able to furnish Medicare telehealth services via two-way, audio/video technology. Commenters pointed out that there are circumstances where the practitioner might also be in a rural area or area without sufficient broadband infrastructure that might inhibit their capacity to furnish two-way, audio-video interactions. Other commenters recommended that we remove the requirement that audio-only only meet the definition of telecommunications system when the beneficiary is in their home, instead requesting that this flexibility be extended to all originating sites. We also received a few comments expressing reservation with the use of audio-only communication technology in furnishing Medicare telehealth services, stating that audio-only services are not analogous to in-person care and should not be a substitute for face-to-face encounters.

Response: We appreciate the commenters' views and concerns. As explained previously, Medicare telehealth services serve as a substitute for a service that is typically delivered through an in-person, face-to-face visit with the patient and practitioner. Medicare telehealth services are generally analogous to, and must include the elements of, the in-person service. We continue to believe that the use of two-way, real-time audio/video communications technology to furnish Medicare telehealth services is the closest approximation to an in-person service, and is an appropriate general expectation when furnishing a Medicare telehealth service. Therefore, we are maintaining the general definition of interactive telecommunications system in § 410.78(a)(3) for purposes of Medicare telehealth services to mean multimedia communications equipment that includes, at minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site physician or practitioner. We are also maintaining the requirement that distant site physicians and practitioners must have the technical capability to use an interactive telecommunications system that includes two-way, real-time, interactive audio and video communications at the time that an audio-only telehealth service is furnished.

We proposed in the CY 2025 PFS proposed rule to revise our definition of interactive telecommunications system in § 410.78(a)(3) to include two-way, real-time audio-only communication technology under certain circumstances for any telehealth service furnished to a beneficiary in their home (when the home is a permissible originating site for the telehealth service). We limited our proposal to permit Medicare telehealth services to be furnished using real-time audio-only technology only in the narrow circumstances that the service is furnished to a patient in their home, and the patient is either not capable or does not consent to use video technology. The purpose of our proposal was to recognize that, while real-time interactive audio-video remains the generally applicable standard, including for distant site practitioners who wish to furnish these services, there are special considerations for patients when a Medicare telehealth service is delivered in their home. For example, a patient may not have sufficient (or any) access to broadband to support the use of real-time video technology, may not have the technical proficiency or support in place to use video technology, or may have privacy concerns about using video technology for Medicare telehealth services in their home.

Patients may not wish to use video in their homes because they do not want the practitioner to view their private, personal living space. If the patient perceives the use of real-time video technology as intrusive, the requirement to use video technology without exception could discourage patients from accessing appropriate health care services through telehealth. We also recognize that a policy to address these special considerations can facilitate access to care that would be unlikely to otherwise occur, given the patient's technological limitations, abilities, or personal preferences. To reflect this limited exception to address the unique considerations of patients who may receive Medicare telehealth services in their homes, as stated in the CY 2025 PFS proposed rule, we proposed a policy that would permit a patient-driven choice to use audio-only technology to receive a Medicare telehealth service based on their technological capabilities and limitations, and their comfort level with the use of video technology in their home.

Separately, based on our review of the comments and our own independent analysis, we do not believe it would be appropriate at this time to permit two-way, real-time audio-only communication technology for telehealth services furnished at originating sites other than the patient's home. As we stated in the CY 2025 PFS proposed rule, all other originating sites are medical facilities that would generally have the infrastructure and broadband capacity to support two-way, audio/video communication technology. Additionally, patients would not have the same heightened expectation of privacy when video is used for a Medicare telehealth service in a medical facility as they would in their home.

We also note that practitioners should always use their clinical judgment in deciding to furnish services via telehealth, including in the patient's home, to ensure that appropriate care is being delivered; including scheduling in-person care as needed.

After consideration of public comments, we are finalizing as proposed to revise our regulations at § 410.78(a)(3) to permanently change the regulatory definition of an interactive telecommunications system to include two-way, real-time audio-only communication technology for any telehealth services furnished to beneficiaries in their homes if the distant site physician or practitioner is technically capable of using an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner, but the patient is not capable of, or does not consent to, the use of video technology. We clarify that no additional documentation, except for the appropriate modifier as mentioned above, are needed.

f. Distant Site Requirements

In the CY 2024 PFS final rule (88 FR 78873 through 78874) we discussed that many commenters expressed concerns regarding the expiring flexibility for telehealth practitioners to bill from their currently enrolled location instead of their home address when providing telehealth services from their home. CMS issued an FAQ, available at *https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf*, which extended the flexibility for telehealth practitioners to bill from their currently enrolled location instead of their home address when providing telehealth services from their home through December 31, 2023. Interested parties suggested that the expiration of this flexibility poses a potential and imminent threat to the safety and privacy of health professionals who work from home and furnish telehealth services. Commenters cited recent examples of workplace violence in health care facilities, where direct harm to nurses and other medical staff occurred. In addition to safety and privacy concerns, interested parties

explained that a significant number of practitioners would need to change their billing practices or add their home address to the Medicare enrollment file, coordinating with the appropriate Medicare Administrative Contractor in their jurisdiction, and this would present administrative burden. To address these concerns, commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners do not have to list their home addresses on enrollment forms.

In response, CMS finalized, through CY 2024, that we would continue to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

We have continued to hear from interested parties who have stressed the importance of continuing this flexibility for the safety and privacy of health care professionals. Given the shift in practice patterns toward models of care that include the practitioner's home as the distant site, we believe it would be appropriate to continue this flexibility as CMS considers various proposals that may better protect the safety and privacy of practitioners. Therefore, we proposed in the CY 2025 PFS proposed rule that through CY 2025 we would continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025. We also received comments requesting that we make this extension or a similar policy permanent. These commenters highlighted the need for a permanent solution for practitioners who do not have an in-person practice location. Other commenters requested clarification regarding whether the practitioner's home address could be across a state line from the location of the beneficiary provided that the practitioner is licensed in both states.

Response: We thank commenters for their input and may continue to consider the issues raised in future rulemaking. We remind interested parties that we defer to state law regarding licensure requirements for distant site Medicare telehealth practitioners. In addition, we note that a separate Medicare enrollment is required for each state in which the practitioner furnishes and intends to bill for covered Medicare services.

After consideration of public comments, we are finalizing as proposed that, through CY 2025, we continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing Medicare telehealth services from their home.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Direct Supervision Via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services, including diagnostic tests described under § 410.32 and services incident to a physician's (or other practitioner's) professional service described under § 410.26 (incident-to services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner. We define three levels of supervision in our regulation at § 410.32(b)(3): General Supervision, Direct Supervision, and Personal Supervision. Notwithstanding the temporary measures implemented in response to the PHE for COVID–19, direct supervision requires the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Again, notwithstanding the temporary measures implemented in response to the PHE for COVID–19, we have established this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability (please see the April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

Direct supervision is required for various types of services, including most incident-to services under § 410.26, many diagnostic tests under § 410.32, pulmonary rehabilitation services under § 410.47, cardiac rehabilitation and intensive cardiac rehabilitation services under § 410.49, and certain hospital outpatient services as provided under § 410.27(a)(1)(iv). In the March 31, 2020 COVID–19 IFC, we amended the definition of ''direct supervision'' for the duration of the PHE for COVID–19 (85 FR 19245 through 19246) at § 410.32(b)(3)(ii) to state that the necessary presence of the physician (or other practitioner) for direct supervision includes virtual presence through audio/video real-time communications technology. Instead of requiring the supervising physician's (or other practitioner's) physical presence, the amendment permitted a supervising physician (or other practitioner) to be considered ''immediately available'' through virtual presence using two-way, real-time audio/visual technology for diagnostic tests, incident-to services, pulmonary rehabilitation services, and cardiac and intensive cardiac rehabilitation services. We made similar amendments at § 410.27(a)(1)(iv) to specify that direct supervision for certain hospital outpatient services may include virtual presence through audio/video real-time communications. The CY 2021 PFS final rule (85 FR 84538 through 84540) and the CY 2024 PFS final rule (88 FR 78878) subsequently extended these policies through December 31, 2024. As stated in the CY 2024 PFS final rule, we extended this definition of direct supervision through December 31, 2024, in order to align the timeframe of the policy with other PHE-related telehealth policies that were extended most recently under the provisions of the CAA, 2023.

We note that in the CY 2021 PFS final rule (85 FR 84539) we clarified that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the service. We noted that this was the case during the PHE and would continue to be the case following the PHE. While flexibility to provide direct supervision through audio/video real-time communications technology was adopted to be responsive to critical needs during the PHE for COVID–19 to ensure beneficiary access to care, reduce exposure risk and to increase the capacity of practitioners and physicians to respond to COVID–19, we expressed concern that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond

the PHE for COVID–19, due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change; in-person supervision would be necessary for such services to allow for rapid on-site decision-making in the event of an adverse clinical situation. In addition to soliciting comment in the CY 2021 PFS proposed rule on whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use, we solicited comment in the CY 2024 PFS proposed rule on whether we should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024. Specifically, we stated that we were interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if direct supervision of certain types of services with virtual presence of the supervising practitioner is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. We were also interested in potential program integrity concerns that interested parties may have regarding this policy, such as overutilization or fraud and abuse.

(1) Proposal To Extend Definition of ''Direct Supervision'' To Include Audio-Video Communications Technology Through 2025

As discussed in the CY 2024 PFS final rule (88 FR 78878), in the absence of evidence that patient safety is compromised by virtual direct supervision, we are concerned about an abrupt transition to our pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner. We noted that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as incident-to services, and that physicians and/or other supervising practitioners, in certain instances, would need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. We acknowledge the utilization of this flexibility and recognize that many practitioners have stressed the importance of maintaining it, however we seek additional information regarding potential patient safety and quality of care concerns. This flexibility has been available and widely utilized since the beginning of the PHE, and we recognize that may enhance patient access. However, given the importance of certain services being furnished under direct supervision in ensuring quality of care and patient safety, and in particular the ability of the supervising practitioner to intervene if complications arise, we believe an incremental approach is warranted, particularly in instances where unexpected or adverse events may arise for procedures which may be riskier or more intense. In light of these potential safety and quality of care implications, and exercising an abundance of caution, we proposed in the CY 2025 PFS proposed rule to extend this flexibility for all services on a temporary basis only. Specifically, we proposed to revise the regulations at § 410.32(b)(3)(ii) to state that through December 31, 2025, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported extending this flexibility on a temporary basis for an additional year, although most requested that we make this flexibility permanent. A few commenters informed us of potential patient safety concerns and barriers to billing that we should consider before further extending or making this flexibility permanent. Some commenters opposed making this flexibility permanent due to concerns about increasing the amount of physician ''incident to'' billing for services provided by physician assistants and nurse practitioners, which would obscure the extent to which physician assistants and nurse practitioners are actually performing the services.

Response: We appreciate the support of commenters and look forward to reviewing the information provided as we consider the most appropriate way to balance patient safety concerns with the interest of supporting access that we may address in future rulemaking. After consideration of public comments, we are finalizing as proposed, to continue to define direct supervision to permit the presence and ''immediate availability'' of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025, and finalizing corresponding revisions to our regulations at § 410.32(b)(3)(ii).

(2) Proposal to Permanently Define ''Direct Supervision'' To Include Audio-Video Communications Technology for a Subset of Services

In the CY 2024 PFS proposed rule, we solicited comment on extending or permanently establishing the virtual presence flexibility for certain services valued under the PFS that are typically are performed in their entirety by auxiliary personnel as defined at § 410.26(a)(1). We stated such services would include incident-to services wholly furnished by auxiliary personnel or Level I office or other outpatient E/M visits for established patients. We also mentioned Level I Emergency Department (ED) visits in this list but have since concluded that ED services would not be wholly furnished by auxiliary personnel and, for that reason, have excluded them from the discussion in this final rule. Based on our review, these specific services present less of a patient safety concern than services for which there may be a need for immediate intervention of the supervising practitioner. As noted in the CY 2024 PFS proposed rule, allowing virtual presence for direct supervision of these services could balance patient safety concerns with the interest of supporting access and preserving workforce capacity for medical professionals while considering potential quality and program integrity concerns. After reviewing the various comments in response to this solicitation, additional feedback provided by interested parties, and conducting our own independent review, we believe these services are low risk by their nature, do not often demand in-person supervision, are typically furnished entirely by the supervised personnel, and allowing virtual presence for direct supervision of these services would balance patient safety concerns with the interest of supporting access and preserving workforce capacity.

We proposed in the CY 2025 PFS proposed rule to adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services described under § 410.26: (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary

personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5';[10] and (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*). As provided in the code descriptor for CPT code 99211, an office or other outpatient visit for the evaluation and management of an established patient does not require the presence of a physician or other practitioner and may be furnished incident to a physicians' service by a nonphysician employee of the physician under direct supervision. The service described by CPT code 99211 and the services that are identified with a PC/TC indicator of '5' as listed in the PFS Relative Value Files are services that are nearly always performed in entirety by auxiliary personnel. The vignette for CPT code 99211 describes the provision of supervision and guidance to the clinical staff as necessary. The code descriptor for this service specifies an E/M service that may not require the presence of a physician or other professional; and the current valuation, which is relatively low compared to other office and outpatient E/M services, suggests that this service would primarily be provided by auxiliary personnel.

We proposed an incremental approach whereby we would adopt without any time limitation the definition of direct supervision permitting virtual presence for services that are inherently lower risk: that is, services that do not ordinarily require the presence of the billing practitioner, do not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision, and are not services typically performed directly by the supervising practitioner.

For all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, we proposed, as described previously, to continue to define ''immediate availability'' to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

We proposed to revise the regulation at § 410.26(a)(2) to state that for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and services described by CPT code 99211 (office and other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported this policy and supported an incremental approach to making permanent the services that this definition applies to. Commenters provided additional services for us to consider adopting permanently as inherently low risk for purposes of the policy permitting direct supervision through virtual presence, such as diagnostic tests and behavioral health, dermatology, therapy, registered dietitian nutritionists, cardiac rehabilitation, and pulmonary rehabilitation services.

Response: We will consider adding to the services for which direct supervision can include virtual presence in future rulemaking.

After consideration of public comments, we are finalizing as proposed and revising our regulations at § 410.26(a)(2) to state that, for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and office and other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional. We note that, in instances where a service on the Medicare telehealth list, is available to beneficiaries in their homes, and also has the requirement of direct supervision, that under the applicable definition of direct supervision, the physician/practitioner is required to be available using both and audio and video. We note that does not necessarily mean that any interaction between the patient and the physician/practitioner supervising the service would require a video component.

(3) Teaching Physician Billing for Services Involving Residents With Virtual Presence

In the CY 2021 PFS final rule (85 FR 84577 through 84584), we established a policy that, after the end of the PHE for COVID–19, teaching physicians may meet the requirements to be present for the key or critical portions of services when furnished involving residents through audio/video real-time communications technology (virtual presence), but only for services furnished in residency training sites located outside of an Office of Management and Budget (OMB)-defined metropolitan statistical area (MSA). We made this location distinction consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas. We noted the ability to expand training opportunities for residents in rural settings. For all other locations, we expressed concerns that continuing to permit teaching physicians to bill for services furnished involving residents when they are virtually present, outside the conditions of the PHE for COVID–19, may not allow the teaching physician to have personal oversight and involvement over the management of the portion of the case for which the payment is sought, under section 1842(b)(7)(A)(i)(I) of the Act. In addition, we stated concerns about patient populations that may require a teaching physician's experience and skill to recognize specialized needs or testing and whether it is possible for the teaching physician to meet these clinical needs while having a virtual presence for the key portion of the service. We referred readers to the CY 2021 PFS final rule (85 FR 84577 through 84584) for a more detailed description of our specific concerns. At the end of the PHE for COVID–19, and as finalized in the CY 2021 PFS final rule, we intended for the teaching physician to have a physical presence during the key portion of the service

[10] For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, sections 30.2.2). For a full list of all PFS payment status indicators and descriptions, see the Medicare Claims Processing Manual (IOM Pub. 100–04, chapter 23, sections 30.2.2 and 50.6). Specific indicators by service are listed in the PFS Relative Value files at *https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*).

personally provided by residents in order to be paid for the service under the PFS, in locations that were within a MSA. This policy applied to all services, regardless of whether the patient was co-located with the resident or only present virtually (for example, the service was furnished as a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations). However, interested parties expressed concerns regarding the requirement that the teaching physician be physically present with the resident when a service is furnished virtually (as a Medicare telehealth service) within an MSA. Some interested parties stated that during the PHE for COVID–19, when residents provided telehealth services, and the teaching physician was virtually present, the same safe and high-quality oversight was provided as when the teaching physician and resident were physically co-located. In addition, these interested parties stated that during telehealth visits, the teaching physician was virtually present during the key and critical portions of the telehealth service, available immediately in real-time, and had access to the electronic health record. After review of the public comments, we finalized a policy that allowed the teaching physician to have a virtual presence in all teaching settings, only in clinical instances when the service was furnished virtually (for example, a 3-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As stated in the CY 2024 PFS final rule (88 FR 78880), we are concerned that an abrupt transition to our pre-PHE policy may present a barrier to access to many services. We also understand that teaching physicians have gained clinical experience providing services involving residents with virtual presence during the PHE for COVID–19 and could help us to identify circumstances where the teaching physician can routinely provide sufficient personal and identifiable services to the patient through their virtual presence during the key portion of the Medicare telehealth service. We sought comment and information to help us consider other clinical treatment situations where it may be appropriate to continue to permit the virtual presence of the teaching physician, while continuing to support patient safety, meeting the clinical needs for all patients, and ensuring burden reduction without creating risks to patient care or increasing opportunities for fraud. As summarized in the CY 2024 PFS final rule (88 FR 78881 through 78882), commenters encouraged us to establish this policy permanently and include in-person services to promote access to care, stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident. While we continue to consider clinical scenarios where it may be appropriate to permit the virtual presence of the teaching physician, we proposed in the CY 2025 PFS proposed rule to continue our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings through December 31, 2025, but only when the service is furnished virtually (for example, a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). This would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location through December 31, 2025. The teaching physician's virtual presence would continue to require real-time observation (not mere availability) and excludes audio-only technology. The documentation in the medical record would need to continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported extending the policy described in this proposal through CY 2025. However, several commenters continued to encourage us to establish this policy permanently for in-person and telehealth services, within or outside of an MSA. Commenters also reiterated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate, based on their assessment of the patient's needs and the competency level of the resident, noting that the Accreditation Council for Graduate Medical Education (ACGME) rules allow teaching physicians to concurrently monitor patient care through appropriate telecommunication technology when the teaching physician and/or patient is not physically present with the resident, in all geographic locations.

Response: We thank commenters for the additional information provided. We will consider the clinical instances when PFS payment is appropriate for teaching physicians furnishing services that involve residents, to ensure the teaching physician has personal oversight and involvement over the management of the portion of the case for which the payment is sought in future rulemaking.

After consideration of the public comments, we are finalizing the policy as proposed, to continue to allow teaching physicians to have a virtual presence in all teaching settings, but only for services furnished as a Medicare telehealth service. This will continue to permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought, through audio/video real-time communications technology, for all residency training locations through December 31, 2025.

(a) Request for Information for Teaching Physician Services Furnished Under the Primary Care Exception

The so-called primary care exception set forth at § 415.174 permits the teaching physician to bill for certain lower and mid-level complexity physicians' services furnished by residents in certain types of residency training settings even when the teaching physician is not present with the resident during the services as long as certain conditions are met, including that the services are furnished by residents with more than six months of training in the approved residency program; and that the teaching physician directs the care of no more than four residents at a time, remains immediately available and has no other responsibilities while directing the care, assumes management responsibility for beneficiaries seen by the residents, ensures that the services furnished are appropriate, and reviews certain elements of the services with each resident during or immediately after each visit. For a more detailed description of the list of services currently allowed under the primary care exception policy, we refer readers

to the CY 2021 PFS final rule (85 FR 84585 through 84590).

We have received feedback from interested parties requesting that we permanently expand the list of services that can be furnished under the primary care exception to include all levels of E/M services and additional preventive services. These interested parties have stated that the fact that high-value primary care and preventive services are not included in the scope of the primary care exception discourages their integration in residency training in these primary care settings, which has a negative impact on physician training, patient access, and longer-term outcomes. Additionally, these interested parties have suggested that including all levels of E/M services under the primary care exception could support primary care workforce development and improve patient continuity of care without compromising patient safety; furthermore, including additional preventive services within the primary care exception would increase the utilization of high-value services.

We believe the primary care exception was intended to broaden opportunities for teaching physicians to involve residents in furnishing services under circumstances that preserve the direction of the care by the teaching physician and promote safe, high-quality patient care. As such, we requested information to help us consider whether and how best to expand the array of services included under the primary care exception in future rulemaking. We were interested in hearing more about the types of services that could be allowed under the primary care exception, specifically preventive services, and whether the currently required six months of training in an approved program is sufficient for residents to furnish these types of services without the presence of a teaching physician. We sought comment to help us consider whether adding certain preventive services or higher level E/M services to the primary care exception will hinder the teaching physician from maintaining sufficient personal involvement in the care to warrant PFS payment for the services being furnished by up to four residents at any given time. Similarly, we requested information on whether the inclusion in the primary care exception of specific higher-level or preventive services will impede the teaching physician's ability to remain immediately available for up to four residents at any given time, while directing and managing the care furnished by these residents.

We received public comments in response to this request for information. The following is a summary of the comments we received and our response.

Comment: Many commenters stated they support permanently expanding the array of services included under the primary care exception, specifically to include certain preventive and/or higher level E/M services. Commenters continued to suggest that this expansion would support the primary care workforce development, improve patient continuity of care without compromising patient safety, and increase the utilization of some high-value services. Some commenters suggested that additional services should also be considered for inclusion under the primary care exception, specifically services that are related to patient continuity and integration of care, such as transitional care management, advance care planning, and chronic care management services. Other commenters requested that we consider expanding the primary care exception and definition of a ''teaching setting'' to include Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs) and Teaching Health Centers (THCs) that are reimbursed under Section 340H of the Public Health Service Act. Currently, the primary care exception does not apply to these centers, and commenters believe their inclusion would offer more training opportunities for residents and align payments for services provided at these centers with those furnished by residents under Medicare graduate medical education funding.

Response: We will consider the information provided for future rulemaking.

3. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001, through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI increase for CY 2025 was 3.6 percent and was based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we proposed to update the MEI increase for CY 2025 based on historical data through the second quarter of 2024. The final CY 2025 MEI update is 3.5 percent. Therefore, for CY 2025, the payment amount for HCPCS code Q3014 (*Telehealth originating site facility fee*) is $31.01. Table 13 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

4. Telehealth Place of Service Code

Comment: While not specifically addressing the proposed policies set forth in the CY 2025 PFS proposed rule, many commenters asked if claims for telehealth services billed with POS 10 (telehealth provided in patient's home) will be paid at the non-facility PFS rate for 2025.

Response: In the CY 2024 PFS final rule (88 FR 78874), we finalized that beginning in CY 2024, claims for telehealth services billed with POS 10 (telehealth provided in patient's home) will be paid at the non-facility PFS rate. This policy, as finalized, was not limited to CY 2024. Claims for telehealth services billed with POS 10 (telehealth provided in patient's home) will continue to be paid at the non-facility PFS rate for CY 2025 and beyond.

TABLE 13: The Medicare Telehealth Originating Site Facility Fee

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	NA	$ 20.00
2003	3.0	$ 20.60
2004	2.9	$ 21.20
2005	3.1	$ 21.86
2006	2.8	$ 22.47
2007	2.1	$ 22.94
2008	1.8	$ 23.35
2009	1.6	$ 23.72
2010	1.2	$ 24.00
2011	0.4	$ 24.10
2012	0.6	$ 24.24
2013	0.8	$ 24.43
2014	0.8	$ 24.63
2015	0.8	$ 24.83
2016	1.1	$ 25.10
2017	1.2	$ 25.40
2018	1.4	$ 25.76
2019	1.5	$ 26.15
2020	1.9	$ 26.65
2021	1.4	$ 27.02
2022	2.1	$ 27.59
2023	3.8	$ 28.64
2024	4.6	$ 29.96
2025*	3.5	$ 31.04

*Reflects the most recent estimate of the CY 2025 MEI percentage based on historical data through the second quarter of 2024.

5. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

For information related to outpatient physical therapy, occupational therapy, speech-language pathology, diabetes self-management training (DSMT) and medical nutritional therapy (MNT) services furnished by institutional staff in hospitals and other institutional settings to beneficiaries in their homes through communication technology, please refer to the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) final rule.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we

established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concerns over the years with our ongoing adjustment of work RVUs

based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2025 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with CMS' reference to older work time sources and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times and note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. Commenters recommended that CMS embrace the clinical input from practicing physicians when valid surveys were conducted and provide a clinical rationale when proposing crosswalks for valuation of services.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

We recognize that it would not be appropriate to develop work RVUs solely based on time, given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2025 PFS final rule, the following all share the same total work time of 30 minutes: CPT/HCPCS codes 76019 (*MR safety implant positioning and/or immobilization under supervision of physician or other qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room, with written report*), 98005 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded*), 98013 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded*), G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*), and G0545 (*Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent).* However, these codes had very different proposed work RVUs of 0.60, 1.30 (ProcStat ''I''), 1.20 (ProcStat ''I''), 0.45, and 0.89, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key references or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information).

With regard to the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback

from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. (83 FR 59515) We note that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 17 contains a list of codes and descriptors for which we proposed work RVUs for CY 2025; this includes all codes for which we received RUC recommendations by February 10, 2024. The proposed work RVUs, work time and other payment information for all CY 2025 payable codes are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 18 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this final rule, we also note that many of the refinements listed in Table 18 result in changes under the $0.35 threshold and will be unlikely to result in a change to the RVUs.

We note that the direct PE inputs for CY 2025 are displayed in the CY 2025 direct PE input files, available on the CMS website under the downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2025 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since

any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2025 we received invoices for several new supply and equipment items. Tables A–E8 and A–E9 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables A–E8 and A–E9 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that interested parties will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2025 are available on the CMS website under downloads for the CY 2025 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we referred readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The TC (including the TC portion of a global fee) of the service established for a year under the fee schedule without

application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for HOPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D), the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we referred readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2025, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2025, we proposed to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0868T (*High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and report*), 0876T (*Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)*), 74263 (*Computed tomographic (ct) colonography, screening, including image postprocessing*), 92137 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina including OCT angiography*), 93896 (*Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*), 93897 (*Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*), and 93898 (*Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)*). We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

In the CY 2024 PFS final rule (88 FR 78894), we noted that in response to the CY 2024 PFS proposed rule, commenters requested that CMS remove CPT code 92229 (*Imaging of retina for detection or monitoring of disease; point-of-care autonomous analysis and report, unilateral or bilateral*) from the OPPS cap list because it does not include an associated PC or physician interpretation and it is primarily utilized in the physician office setting. We solicited comment on the appropriateness of applying the OPPS cap to services such as this for which the interpretation component is not captured by work RVUs, and the service is not split into technical and professional components. We are more broadly evaluating how services involving assistive technologies are most accurately valued. We note that the OPPS rate for this service is currently higher than what would be paid in a physician office setting, and therefore the OPPS cap does not currently apply to CPT code 92229 as of 2024.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters requested that CMS remove CPT code 92229 from the OPPS cap list because it does not include an associated professional component (PC) or physician interpretation, and it is primarily utilized in the physician office setting. Despite CPT codes 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral),* 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral*), and 92229 all being in the same family of codes and representing the same imaging service, only differentiated by the modality of review and interpretation, commenters stated that CPT code 92229 falls outside the scope of the definition of ''imaging services'' under the DRA because it does not include a PC and TC split similar to the imaging technologies governed by section 5102(b) of the DRA. Commenters stated that ''the DRA is intended to apply to services typically performed in the hospitals, but CPT code 92229 is primarily done in the physician office setting,'' and therefore, commenters asserted that the code ''falls outside the intent of the law'' since CPT code 92229 is almost exclusively performed in physician office or clinic settings, not in hospital settings.

Response: We appreciate the commenters' feedback regarding CPT code 92229 and may consider the input for future rulemaking. We are always looking for ways to improve the accuracy of valuation and payment for services across settings. We note that the analogous CPT codes 92227 and 92228 are also typically performed in the physician office setting, at 92.1 percent and 81.5 percent, respectively, according to the RUC Database, similar to nearly every other ophthalmic code on the OPPS cap list. In response to the commenters' assertion about the DRA's application, we note that the amendments made to section 1848(b)(4) of the Act by section 5102(b)(1) of the DRA do not limit application of the OPPS cap to services typically performed in hospitals.

Comment: Some commenters expressed concern with the application of the OPPS cap to CPT code 74263 and stated that it would be a significant barrier to imaging centers providing this service because of the payment difference between the PFS payment amount and the OPPS payment amount, which has an estimated payment of $106.30. Commenters stated that if it were paid under the PFS without the cap, the technical component payment is estimated to be $566.22, and that the cap would likely diminish the benefit of our proposed expanded coverage for computed tomography colonography (CTC).

Some commenters requested that CMS exempt screening services such as CTC from the OPPS cap. Commenters stated that the DRA exempts screening and diagnostic mammography from the OPPS cap and that exemption likely demonstrates a concern specifically about the impact of the OPPS cap on screening and diagnostic services. Commenters stated that, given the prevalence of colon cancer and the

relatively new availability of colon cancer screening with CTC, it seems plausible and likely that if the OPPS cap were to be enacted today, Congress would have exempted additional screening services. Commenters also stated that, if an exemption is not statutorily allowed, CMS should assign a higher paying Ambulatory Payment Classification (APC), specifically APC 5524 Level 4 Imaging without Contrast that has a proposed 2025 OPPS payment amount of $544.85, which the commenters state is far more comparable to the resource-based 2024 PFS payment of $566.22.

Response: We appreciate the commenters' feedback regarding the application of the OPPS cap for CPT code 74263. We note that section 1848(b)(4)(B) of the Act specifically excludes diagnostic and screening mammography from the description of imaging services that are subject to the OPPS cap, and we do not have the statutory authority to exclude other services that are within the scope of the description of imaging services. We refer readers to the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) Final Rule that is expected to be published in the **Federal Register** for more information regarding the APC assignment for this code.

We did not receive public comments on the other proposed additions to the OPPS cap list for CY 2025. After consideration of public comments, we are finalizing the addition of the services listed above to the list of codes to which the OPPS cap applies, as proposed.

4. Valuation of Specific Codes for CY 2025

(1) Skin Cell Suspension Autograft (CPT Codes 15011, 15012, 15013, 15014, 15015, 15016, 15017, and 15018)

In September 2023, the CPT Editorial Panel approved the creation of eight new CPT codes to describe skin cell suspension autograft (SCSA) procedures. The code set includes a 000-day global base code (CPT code 15011 (*Harvest of skin for skin cell suspension autograft; first 25 sq cm or less*)) and an add-on code (CPT code 15012 (*Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)*)) describing the harvesting component of the procedure, an XXX global base code (CPT code 15013 (*Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin*) and an add-on code (CPT code 15014 (*Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)*)) describing the preparation component of the procedure, and two 090-day global base codes and two add-on codes for the application component to distinguish between body areas: trunk, arms, and legs with CPT codes 15015 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less*) and 15016 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)*); and face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, or multiple digits with CPT codes 15017 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less*) and 15018 (*Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)*).

We disagreed with the RUC-recommended work RVUs of 3.00, 2.00, 2.51, 2.00, 10.97, 2.50, 12.50, and 3.00 for CPT codes 15011 through 15018, respectively, and proposed contractor-pricing for these CPT codes due to concerns with the coding structure of the code family and the total physician time that results when these codes are billed multiple times on the same date of service for the typical patient.

We noted that our concerns with these CPT codes are expansive. Firstly, we noted that these CPT codes represent a segmentation of a single service that is performed sequentially on the same date of service. We solicited comment on whether the segmentation of the harvest, preparation, and application is necessary when these are sequential service parts of one episode of care and could be simplified by having just two codes that encompass all three service parts (harvest, preparation, and application), to differentiate the two different application areas. We also solicited comment on the base and add-on codes' incremental square centimeters, considering that the typical size treatment area described in the vignettes could result in the add-on codes being billed multiple times, particularly for the base application CPT code 15015 and add-on CPT code 15016. Based on the meeting notes from the September 2023 CPT Editorial Panel meeting, the specialty society initially structured their coding request to ''bundle'' the service components into fewer codes, but it is unclear to us why these codes were further segmented. We believed that the very large range of intraservice times from the 33 burn surgeons may have been exacerbated by the harvest, preparation, and application components of the service being segmented in this manner. Most notably, CPT code 15011, which describes the first 25 sq cm of harvest, base code, had an intraservice survey time range of 5 to 480 minutes, and CPT code 15017, which describes the first 480 sq cm of application to the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, had an intraservice survey time range of 10 to 360 minutes.

We noted that the survey median intraservice times for CPT codes 15011 through 15018 contradict numerous publicly available sources that describe much lower times for this service or specific service parts. Most notably, the manufacturer of the RECELL Autologous Cell Harvesting Device (RECELL® System) used in this service, indicates that a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin for the treatment of thermal burn wounds and full-thickness skin defects is ''prepared and applied at the point of care in as little as 30 minutes.'' [11] Additionally, Temple University Hospital published a news article on December 20, 2019, just 11 months after the U.S. Food and Drug Administration (FDA) approval of the RECELL® System for the treatment of acute thermal second and third-degree burns in adult patients in January 2019, stating that the entire process of skin sample collection, enzyme solution preparation, and suspension spraying/application ''can take as little as 30 minutes'' and ''treat a wound up to 80 times the size of the donor skin sample.'' [12] Additionally, an article

[11] *https://avitamedical.com/.*

[12] Temple Burn Center Using Spray-On SkinTM Cells Technology to Offer Patients a New, Less Invasive Option for the Treatment of Severe Burns. (2019, December 20). *https://medicine.temple.edu/*

published in Europe PubMed Central states that the procedure takes approximately 30 minutes and is performed by a burn surgeon trained in how to use RECELL® System, and does not require specialized laboratory staff.[13] Additionally, a 2007 study aimed at comparing the results from the RECELL® System and the classic skin grafting for epidermal replacement in deep partial thickness burns showed a total procedure time of 59±4 minutes for the RECELL® System group.[14]

More granularly, the FDA's Instructions for Use of the RECELL® Autologous Cell Harvesting Device state that ''if a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the Enzyme''.[15] Additionally, the National Institute for Health and Care Excellence (NICE) produced guidance on using the RECELL® System based on the consideration of evidence submitted and the views of expert advisers, and stated that the harvested skin is added to the proprietary enzyme solution in a processing unit and heated for 15 to 30 minutes to disaggregate the cells. The skin is then removed and scraped with a scalpel to develop a plume of cells. These cells are added to a buffer solution, aspirated and filtered to create a cell suspension that contains keratinocytes, melanocytes, fibroblasts and Langerhans cells.[16] We stated in the proposed rule that this correlates to the preparation component of the service described by CPT codes 15013 and 15014, for which the RUC recommended the survey median time of 33 and 28 minutes, respectively.

We stated in the proposed rule that we believe that the publicly available sources that make representations about the total service and preparation times contradict the RUC-recommended median times based on the survey of 33 burn surgeons. Moreover, when we considered how the add-on CPT codes 15012, 15014, 15016, and 15018 would be billed based on the typical patient described in the vignettes, we stated in the proposed rule that we believe the survey times are inflated compared to the publicly available sources, likely due to how the survey respondents considered the service given the segmentation of the code set. For example, the vignette for CPT code 15015 describing the application to the trunk, arms, and legs says ''A 35-year-old male sustained partial-thickness thermal burns on his trunk and arms measuring 3,600 sq cm. A skin cell suspension autograft is applied to 480 sq cm of the wound bed.'' Of the 33 burn surgeons surveyed, 96 percent found this vignette to be typical. Given the typical sq cm application area of 3,600 sq cm and the expansion ratio of harvested and prepared skin to treatment skin for application of 1:80, the typical episode of care would constitute 1 unit of both CPT codes 15011 and 15012 for harvesting, 1 unit of both CPT codes 15013 and 15014 for preparation, 1 unit of CPT code 15015 for the first 480 sq cm of application, and 7 units of CPT code 15016 for the remaining 3,120 sq cm of application area. When the RUC-recommended intraservice and total times (not including the post-operative visit time for CPT code 15015) for all the units billed on the same date of service as sequential service parts are summed, the intraservice time totals to 399 minutes and total time (not including the post-operative visit time included in the global period for CPT code 15015) totals to 529 minutes. The intraservice time total alone is nearly 6 and ⅔ hours.

We noted the RUC recommended that CPT codes 15011 through 15018 be placed on the New Technology list to be re-reviewed by the RUC for both work and PE for the September 2026 or January 2027 RUC meeting when 2025 Medicare utilization data is available, and at that time, the RUC would consider if other specialties were performing the service and if the service was performed in the non-facility setting. We look forward to re-reviewing these CPT codes when recommendations are re-submitted with more robust and inclusive survey data. In the meantime, we encourage the reconsideration of the family's coding structure by the CPT Editorial Panel given the challenging aspects of this service, including the fact that the current coding structure represents a severely segmented single episode of care with troublesome billing patterns for the typical patient, particularly for the add-on CPT code 15016 describing the additional 480 sq cm increments of application on the trunk, arms, and legs. This code is particularly concerning because the coding structure of the family requires 7 units of add-on CPT code 15016 to be billed for the typical patient. Similarly, the typical patient described in the vignettes for this family of codes would require 3 units of add-on CPT code 15018 due to the coding structure.

We also sought feedback on the recommended global period for CPT code 15013. The RUC recommended an XXX global period, which indicates that the global concept does not apply, but we believe a 000-day global period, indicating an endoscopic or minor procedure with related preoperative and postoperative relative values on the day of the procedure only in the fee schedule payment amount, may be more appropriate given the nature of the service (which is intertwined with the other codes in the series) and that the entire service cannot be completed without 15013. This would allow the entire service to run within a surgical global period.

We noted that we believe contractor-pricing is appropriate for CPT codes 15011 through 15018 until reconsideration of the coding structure and re-survey is complete, given the concerning aspects of the CPT codes. We noted that this service is currently billed for using contractor-priced CPT code 17999 (*Unlisted procedure, skin, mucous membrane and subcutaneous tissue*) and the eight new codes are expected to be a very low utilization.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to contractor price these codes until reconsideration of the coding structure and re-survey is complete. In their comment letter, the AMA RUC confirmed that these codes will be re-reviewed in 2027. One commenter provided additional information regarding CMS' concerns with the coding structure and encouraged CMS to finalize the AMA RUC's recommendations instead of contractor pricing for these codes as interim values, citing the uncertainty and payment variability that is possible with contractor pricing. The commenter stated that the manufacturer's information mentions the minimum amount of time (that is, ''as little as''),

news/temple-burn-center-using-spray-skin-cells-technology-offer-patients-new-less-invasive-option.

[13] Cooper-Jones B, Visintini S. A Noncultured Autologous Skin Cell Spray Graft for the Treatment of Burns. In: CADTH Issues in Emerging Health Technologies. Canadian Agency for Drugs and Technologies in Health, Ottawa (ON); 2016. PMID: 30855772.

[14] G. Gravante, M.C. Di Fede, A. Araco, M. Grimaldi, B. De Angelis, A. Arpino, V. Cervelli, A. Montone, A randomized trial comparing ReCell® system of epidermal cells delivery versus classic skin grafts for the treatment of deep partial thickness burns, Burns, Volume 33, Issue 8, 2007, Pages 966–972, ISSN 0305–4179, *https://doi.org/10.1016/j.burns.2007.04.011.*

[15] *https://www.fda.gov/media/169630/download.*

[16] National Institute for Health and Care Excellence. The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury. Medical technologies guidance [MTG21] [internet]. 2014. [Accessed 16 Nov 2017]. *https://www.nice.org.uk/guidance/mtg21/documents/the-recell-sprayon-skin-system-for-treating-skin-loss-scarring-and-depigmentation-after-burn-injury-medical-technology-consultation-document.*

and a maximum amount of time, potentially up to 60 minutes, to process a sample. The commenter stated that the time depends on skin thickness and how long it takes the enzyme to break it down and, depending on patient circumstances, the potential maximum amount of time to process a sample is no less relevant than the potential minimum amount of time.

Response: We thank commenters for the additional information they provided. However, we continue to have concerns about the coding structure and the valuations for the work and PE of these codes as described in the proposed rule. We recognize the commenter's citation of the manufacturer's information regarding minimum and maximum processing times but reiterate that this just one publicly available source of information and there are additional sources available. We also note that we value services based on the typical time for a service, not the minimum or maximum.

Based on the manufacturer's most recently updated Instructions for Use for a newly approved FDA device, RECELL GO®, processing typically takes ''around 35 minutes,'' [17] and we note that the new device will likely be considered by CPT and the AMA RUC during the codes' re-review. Additionally, another study published in the Annals of Surgery in September 2024 to determine the utility of Autologous Skin Cell Suspension (ASCS) in closing full-thickness (FT) defects from injury and infection showed mean size of ASCS application of 636 cm^2 with a range of 45 to 2212 cm^2, a mean surface area of the wounds grafted of 435 cm^2 with a range of 30 to 1608 cm^2, and a mean area of the donor site of 212 cm^2 with a range of 15 to 804 cm^2. The study also showed a mean surgical time of 71 minutes and total operating room time of 124 minutes using the RECELL® System.[18] Additionally, an interview of a physician about their clinical experience using RECELL® was recently published in the *Wound Care Learning Network* [19] that supports our concerns about the survey times. We note that this is only three additional sources that have become available since the proposed rule was published, therefore we continue to have concerns about the service times, segmentation of the coding, and billing patterns of the add-on codes based on the vignettes. After consideration of public comments, we are finalizing contractor pricing as proposed and look forward to reviewing these codes again after reconsideration of the coding structure and re-survey is complete. We encourage the consideration of the many publicly available sources of information when considering the base and add-on code structure of this family, and the time it takes to perform these services.

(2) Hand, Wrist, & Forearm Repair & Recon (CPT Codes 25310, 25447, 25448, and 26480)

In September 2022, the RUC referred CPT codes 26480 and 25447 to the CPT Editorial Panel for a code bundling solution. In May 2023, the CPT Editorial Panel approved a new bundled code (CPT code 25448) to report intercarpal or carpometacarpal joint suspension arthroplasty, including transfer or transplant of tendon, with interposition when performed while CPT code 25447 was revised to clarify that the code only included interposition of a tendon and not suspension. This family of codes was surveyed for the September 2023 RUC meeting.

We disagreed with the RUC-recommended work RVU of 9.50 for CPT code 25310 (*Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; each tendon*) and we instead proposed a work RVU of 9.00 based on the survey 25th percentile result. In reviewing CPT code 25310, we noted that the recommended intraservice time was unchanged at 60 minutes in the new survey; however, the RUC-recommended work RVU is increasing from the current 8.08 to 9.50. Although we did not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we stated that we believed that since the two components of work are time and intensity, increases in the recommended work RVU should typically be reflected in increases in the surveyed work time. We recognized that the total time for CPT code 25310 was increasing from 235 minutes to 263 minutes (an increase of 12 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, this again does not match the increase in the recommended work RVU, which is increasing from 8.08 to 9.50 (approximately 18 percent). We stated that it would be more accurate to propose the survey 25th percentile work RVU of 9.00 for CPT code 25310 which matches this increase in the total work time. We also noted that the intensity of CPT code 25310 was decreasing, not increasing, as recommended by the RUC which further suggested that a work RVU of 9.50 would not be appropriate for this code given the surveyed work times.

We disagreed with the RUC-recommended work RVU of 11.14 for CPT code 25447 (*Arthroplasty, intercarpal or carpometacarpal joints; interposition (eg, tendon)*) and we instead proposed a work RVU of 10.50 based on the survey 25th percentile result. In reviewing CPT code 25447, we noted that the recommended intraservice time was decreasing from 100 minutes to 75 minutes in the new survey; however, the RUC recommended maintaining the current work RVU of 11.14. Although we do not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in the surveyed work time should typically be reflected in decreases to the work RVU. We recognize that the total time for CPT code 25447 is slightly increasing from 278 minutes to 281 minutes (an increase of about 1 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, we believe that the sizable decrease in surveyed intraservice work time (a reduction of approximately 33 percent) better supports proposing the survey 25th percentile work RVU of 10.50 instead of maintaining the current work RVU of 11.14. We also disagreed with the RUC that the intensity of CPT code 25447 is unchanged due to increases in the post-operative work; we believe that the sizable decrease in surveyed intraservice work time indicates a modest decrease in intensity. We noted again that the intensity of CPT code 25310 is decreasing, not increasing, as recommended by the RUC which suggests that a similar pattern is likely taking place with clinically similar procedures elsewhere in the same code family.

We disagreed with the RUC-recommended work RVU of 13.90 for CPT code 25448 (*Arthroplasty, intercarpal or carpometacarpal joints; suspension, including transfer or transplant of tendon, with interposition, when performed*) and we instead proposed a work RVU of 11.85 based on the survey 25th percentile result. We

[17] *https://avitamedical.com/instructions-for-use/.*

[18] Hultman, C. Scott MD, MBA*; Adams, Ursula C. MD, MBA†; Rogers, Corianne D. MD*; Pillai, Minakshi MS†; Brown, Samantha T. PA–C*; McGroarty, Carrie Ann PA–C*; McMoon, Michelle PA–C, Ph.D.*; Uberti, M. Georgina MD‡. Benefits of Aerosolized, Point-of-care, Autologous Skin Cell Suspension (ASCS) for the Closure of Full-thickness Wounds From Thermal and Nonthermal Causes: Learning Curves From the First 50 Consecutive Cases at an Urban, Level 1 Trauma Center. Annals of Surgery 280(3):p 452–462, September 2024. | DOI: 10.1097/SLA.0000000000006387.

[19] *https://www.hmpgloballearningnetwork.com/site/woundcare/videos/recellr-spray-ontm-skin-cells-innovation-closure-full-thickness-wounds.*

noted that the RUC typically values new codes such as CPT code 25448 using this survey 25th percentile work RVU as opposed to the survey median work RVU that it recommended. The RUC's recommendations stated that CPT code 25448 should be valued higher than CPT code 25447 due to having higher intensity, a relationship which is preserved at our proposed work RVUs of 11.85 and 10.50 respectively. The RUC also stated in its recommendations that CPT code 25448 should be valued higher than reference CPT code 29828 (*Arthroscopy, shoulder, surgical; biceps tenodesis*) because it has more intraservice time and total work time. However, the RUC also stated elsewhere in its recommendations that the arthroscopy described by CPT code 29828 is more intense than the arthroplasty procedures described by this family of codes, which we believe supports CPT code 29828 having a higher work RVU despite its lower work times. Based on this information, we believe that proposing the survey 25th percentile work RVU of 11.85 is the most accurate valuation for CPT code 25448.

We disagreed with the RUC-recommended work RVU of 9.50 for CPT code 26480 (*Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon*) and we instead proposed a work RVU of 9.00 based on the survey 25th percentile result. In reviewing CPT code 26480, we noted that the recommended intraservice time was unchanged at 60 minutes in the new survey; however, the RUC-recommended work RVU is increasing from the current 6.90 to 9.50. Although we do not imply that changes in work time as reflected in survey values must equate to a one-to-one or linear change in the valuation of work RVUs, we believe that since the two components of work are time and intensity, increases in the recommended work RVU should typically be reflected in increases in the surveyed work time. We recognize that the total time for CPT code 26480 is increasing from 227 minutes to 263 minutes (an increase of 16 percent) due to changes in the code's post-operative office visits which will now take place at a higher level. However, this again does not match the increase in the recommended work RVU, which is increasing from 6.90 to 9.50 (approximately 38 percent). We believe that it would be more accurate to propose the survey 25th percentile work RVU of 9.00 for CPT code 26480 which more closely matches this increase in the total work time. We also noted that CPT codes 25310 and 26480 were surveyed as having identical work times and identical survey 25th percentile and survey median work RVUs. We concur with the RUC that these two codes should be valued at the same work RVU; however, we continue to believe that the survey 25th percentile work RVU of 9.00 is a more accurate choice in both cases.

We proposed the RUC-recommended direct PE inputs for all four codes in the family without refinement.

Comment: Several commenters disagreed with the CMS proposed work RVU of 9.00 for CPT code 25310 and stated that CMS should instead finalize the RUC-recommended work RVU of 9.50. Commenters stated that the RUC's recommendation of the survey median work RVU of 9.50 more accurately described the physician work involved in furnishing this service. Commenters stated that the decrease in intensity of CPT code 25310 could be inferred from referencing the intraservice work per unit of time (IWPUT) formula, however commenters stated that the change could be attributed to an artifact of adding 38 minutes of postoperative visit time and increasing the level of the postoperative visits to the IWPUT formula, not due to an actual change in the intensity of performing the procedure itself. Commenters stated that the RUC provided compelling evidence that changes in time and technology during the postoperative period have increased the physician work of CPT code 25310 and that the change in total work for CPT code 25310 is driven by a change in the intensity of the postoperative work. Commenters emphasized that the increase in postoperative work for CPT code 25310 adds significantly to the current work RVU of this service. Commenters compared CPT code 25310 to reference CPT codes 26356 (*Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); primary, without free graft, each tendon*) and 66184 (*Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft*), and stated that these reference codes supported the RUC's recommended work RVU of 9.50. Commenters also stated that the proposed work RVU of 9.00 for CPT code 25310 does not consider the intensity relativity of the RUC recommended work RVU of 9.50 to many other codes on the PFS and that finalizing this work RVU would create a rank order anomaly in terms of intensity. The commenters urged CMS to finalize the RUC's recommended work RVU of 9.50 for CPT code 25310.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 9.00 is a more accurate choice for CPT code 25310. We disagree with the statement from the commenters that the decrease in intensity for CPT code 25310 at the RUC's recommended work RVU of 9.50 is merely an ''artifact'' of adding 38 minutes of postoperative visit time and increasing the level of the postoperative visits. We have frequently been informed by the RUC and other interested parties that services with 10 and 90 day global periods must be evaluated in their entirety as part of magnitude estimation, and that it would be inappropriate to consider the postoperative visits as distinct from the rest of the procedure. We do not agree that the RUC's recommendation of increased postoperative visits for CPT code 25310 can be ignored when discussing the intensity of the procedure; as we stated in the proposed rule, the RUC recommended a decrease in intensity for this code which we believe better supports our proposed work RVU of 9.00. We do concur with the commenters that that changes in time and technology of the postoperative period have increased the physician work of CPT code 25310, which is why we proposed a work RVU of 9.00 as compared with the current work RVU of 8.08. The recommended work time in the service period for CPT code 25310 is decreasing relative to the current work time, which would not justify the work RVU increase that we proposed; we believe that the proposed work RVU increase from 8.08 to 9.00 accounts for this increase in the work carried out during the postoperative period.

We disagree with the commenters that reference CPT code 26356's work RVU of 9.56 justifies the recommended work RVU of 9.50 for CPT code 25310. While the two codes have similar work time values, CPT code 26356 has additional preservice and immediate postservice work time as compared with CPT code 25310. The RUC's recommendations also previously stated that CPT code 26356 is a more intensive service than CPT code 25310 which we believe supports proposing a lower work RVU for CPT code 25310. We also disagree with the commenters that the proposed work RVU of 9.00 for CPT code 25310 creates a rank order anomaly in terms of intensity. While it is true that the intensity for this code sits towards the lower end of the spectrum amongst 90 day global procedures with similar work time values, there are other CPT codes in this range with lower intensity values

such as CPT code 25116 (*Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum*) and 28485 (*e*). As such, CPT code 25310 would not create a rank order anomaly in terms of intensity. Furthermore, our proposed work RVU of 9.00 falls very much within the middle range of comparative work RVUs amongst 90 day global procedures with similar work time values. We note as well that commenters did not address our analysis of work time changes for CPT code 25310 discussed in the proposed rule: that the total time is increasing from 235 minutes to 263 minutes (an increase of 12 percent) which does not match the increase in the recommended work RVU, which is increasing from 8.08 to 9.50 (approximately 18 percent). We continue to believe that our proposal of the survey 25th percentile work RVU of 9.00 for CPT code 25310 is more accurate, which matches this increase in the total work time.

Comment: Several commenters disagreed with the CMS proposed work RVU of 10.50 for CPT code 25447 and stated that CMS should instead finalize the RUC-recommended work RVU of 11.14, which is the current work RVU for the service. Commenters stated that CPT code 25447 was last surveyed in 2005, and the specialties attested that the technique is the same, but physicians are now more familiar with the procedure and thus it may be performed in less work time. Commenters stated that the changes to the work and time of the postoperative care for CPT code 25447, along with higher surveyed preservice and immediate postservice time not recognized in 2005, offset the decrease in surveyed intraservice time. Commenters disagreed that there was a reduction in intensity for this code and stated that CMS' assumption of decreased intensity was mistaken; commenters stated that by maintaining the current work RVU of 11.14, the total global work and intraoperative intensity for CPT code 25447 would not change. Commenters referred to the top reference codes from the RUC survey and urged CMS to finalize the RUC's recommended work RVU of 11.14 for CPT code 25447.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 10.50 is more accurate for CPT code 25447. We disagree in particular with the commenters that by maintaining the current work RVU of 11.14, the intensity of CPT code 25447 does not change. The RUC survey found that the intraservice work time required to perform the procedure has decreased significantly, from 100 minutes previously to 75 minutes under the recent survey. The total time of the procedure remained essentially unchanged in the survey, previously 278 minutes and now slightly higher at 281 minutes. However, work time that was previously allocated to the intraservice period has now shifted to the preservice period and postoperative office visits. We do not agree that this represents ''no change'' in intensity, as additional time spent on preservice evaluation and postservice E/M visits take place at a lower intensity level than the intraservice performance of the arthroplasty itself. As we noted in the proposed rule, there is a sizable decrease in surveyed intraservice work time (a reduction of approximately 33 percent) for CPT code 25447, and since the statute requires that valuation should be based on time and intensity, we believe that this supports the proposed reduction to a work RVU of 10.50. We do not agree with the commenters that additional preservice work time and postoperative office visits are sufficient to offset this large decrease in the surveyed work time of the intraservice portion of the procedure. We continue to believe that our proposal of the survey 25th percentile work RVU of 10.50 for CPT code 25447 is the most accurate value.

Comment: Several commenters disagreed with the CMS proposed work RVU of 11.85 for CPT code 25448 and stated that CMS should instead finalize the RUC-recommended work RVU of 13.90. Commenters appreciated CMS recognizing the survey results but emphasized that the survey median work RVU of 13.90 was deemed more appropriate by the RUC to accurately describe the physician work involved in this new service. Commenters stated that the survey median work RVU of 13.90 supports relativity within the family and was warranted by the clinical complexity of the code. Commenters then described the clinical complexity of CPT code 25448, stating that this code encompasses the physician work of CPT code 25447 and the additional complex work of drilling and creating a hole through the base of the first metacarpal for passage of the radial half of the flexor carpi radialis from the second metacarpal to the first metacarpal. Commenters stated that this additional work beyond the work of CPT code 25447 is much more intense, resulting in a higher recommended value for surveyed code 25448 when compared with the other codes in the family. Commenters referred to the top reference codes from the RUC survey, such as CPT code 29298, and stated that the intensity of CPT code 25448 is not 50 percent of the intensity of CPT code 29828 as suggested by the CMS proposal. Commenters urged CMS to finalize the RUC's recommended work RVU of 13.90 for CPT code 25448.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 11.85 is more accurate for CPT code 25448. We would like to clarify for the commenters that we understand the RUC does not always recommend the survey 25th percentile work RVU for new codes. We noted in the proposed rule that the RUC ''typically'' values new codes such as CPT code 25448 using this survey 25th percentile work RVU to indicate that the use of the survey median in this case was unusually higher than most other recommendations for new codes. We concur with the commenters that CPT code 25448 requires additional work and has higher complexity than CPT code 25447. This is why we proposed a work RVU for CPT code 25448 which is 1.35 units higher than the work RVU for CPT code 25447, 11.85 as compared with 10.50, as well as why we proposed an intensity for CPT code 25448 which was higher than anything else in this code family. We believe that our proposed work RVU appropriate captures the increased work and intensity of CPT code 25448 relative to the other codes in this family.

We also disagree that the work and intensity of reference CPT code 29298 support the RUC's recommendation of a work RVU of 13.90 for CPT code 25448. As we wrote in the proposed rule, the RUC stated its recommendations that the arthroscopy described by CPT code 29828 is more intense than the arthroplasty procedures described by this family of codes, which we believe supports CPT code 29828 having a higher work RVU despite its lower work times. We also question whether CPT code 29298 is the best choice of comparator code in terms of work time with CPT code 25448; these two codes differ by about 15 percent in terms of both intraservice work time (90 minutes against 75 minutes) and total time (296 minutes against (252 minutes). This difference in surveyed work time makes direct comparisons on work and intensity more difficult; we believe that CPT code 25448 is more accurately compared to other 90 day globals with the same 90 minutes of intraservice time and similar total time. Our proposed work RVU of 11.85 falls very much in the middle of this group of related

services, and there are numerous other CPT codes with lower work RVUs and lower intensities than what we proposed (such as CPT codes 25608, 27339, and 28725). We continue to believe that our proposal of the survey 25th percentile work RVU of 11.85 for CPT code 25448 is the most accurate value.

Comment: Several commenters disagreed with the CMS proposed work RVU of 9.00 for CPT code 26480 and stated that CMS should instead finalize the RUC-recommended work RVU of 9.50. Commenters appreciated CMS recognizing the survey results but stated that the survey median work RVU of 9.50 was deemed more appropriate by the RUC to accurately describe the physician work involved in this service. Commenters echoed the earlier discussion of CPT code 25310, stating that global codes are made up of distinct packages of work and time and that the preservice and immediate postservice intensities have never been updated to match the increases over the years for E/M services. Commenters stated that the overall work per unit of time (WPUT) may be representative of time for services on a single date of service, but this same measure cannot be applied to varied services (evaluation, positioning, scrub/dress/wait, operation, recovery, ICU/hospital/office services) over a 90-day global period. Commenters stated that the level of visits has changed as supported by both medical decision-making and total time on the date of the encounter of CPT code 26480, and that the change in total work for CPT code 26480 is driven by a change in the intensity of the postoperative work. Commenters emphasized that the increase in postoperative work for CPT code 26480 adds significantly to the current work RVU of this service. Commenters also stated that the proposed work RVU of 9.00 for CPT code 26480 does not consider the intensity relativity of the RUC recommended work RVU of 9.50 to many other codes on the PFS and that finalizing this work RVU would create a rank order anomaly in terms of intensity. Commenters referred to the top reference codes from the RUC survey and urged CMS to finalize the RUC's recommended work RVU of 9.50 for CPT code 26480.

Response: We disagree with the commenters and continue to believe that the proposed work RVU of 9.00 is more accurate for CPT code 26480. As we noted in the proposed rule, CPT codes 25310 and 26480 were surveyed as having identical work times and identical survey 25th percentile and survey median work RVUs. We concur with the RUC that these two codes should be valued at the same work RVU; however, we continue to believe that the survey 25th percentile work RVU of 9.00 is more accurate in both cases. As such, many of the same comment responses provided earlier for CPT code 25310 equally apply to CPT code 26480.

We concur with the commenters that the postoperative visits have changed for CPT code 26480, however we disagree that intensity measures cannot be applied to varied services over a 90 day period. As we noted for CPT code 25310 above, we have frequently been informed by the RUC and other interested parties that services with 10 and 90 day global periods must be evaluated in their entirety as part of magnitude estimation, and that it would be inappropriate to consider the postoperative visits as distinct from the rest of the procedure. We do concur with the commenters that changes in time and technology of the postoperative period have increased the physician work of CPT code 26480, which is why we proposed a work RVU of 9.00 as compared with the current work RVU of 6.90. The recommended work time in the service period for CPT code 26480 is essentially unchanged relative to the current work time, which would not justify the work RVU increase that we proposed; we believe that the proposed work RVU increase from 6.90 to 9.00 accounts for this increase in the work carried out during the postoperative period.

We also disagree with the commenters that the proposed work RVU of 9.00 for CPT code 26480 creates a rank order anomaly in terms of intensity. Again, since CPT codes 25310 and 26480 were proposed at the identical work times and work RVUs, the comparisons with other codes across the wider PFS are exactly the same. While it is true that the intensity for these codes sits towards the lower end of the spectrum amongst 90 day global procedures with similar work time values, there are other CPT codes in this range with lower intensity values such as CPT code 25116 (*Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum*) and 28485 (*Open treatment of metatarsal fracture, includes internal fixation, when performed, each*). As such, CPT code 26480 would not create a rank order anomaly in terms of intensity. Furthermore, our proposed work RVU of 9.00 falls very much within the middle range of comparative work RVUs amongst 90 day global procedures with similar work time values, not anomalously low. We note as well that commenters did not address our analysis of work time changes for CPT code 26480 discussed in the proposed rule: that the total time is increasing from 227 minutes to 263 minutes (an increase of 16 percent) which does not match the increase in the recommended work RVU, which is increasing from 6.90 to 9.50 (approximately 38 percent). We continue to believe that our proposal of the survey 25th percentile work RVU of 9.00 for CPT code 26480 is more accurate, which more closely matches this increase in the total work time.

After consideration of the comments, we are finalizing the work RVUs for all four codes in the Hand, Wrist, & Forearm Repair & Recon family as proposed. We did not receive any comments on the direct PE inputs and we are also finalizing them as proposed.

(3) CAR–T Therapy Services (CPT Codes 38225, 38226, 38227, and 38228)

In September 2023, the CPT Editorial Panel deleted four category III codes (0537T–0540T) and approved the addition of four new codes (38225–38228) that describe only steps of the complex CAR–T Therapy process performed and supervised by physicians. The RUC recommended four different work RVUs for codes 38225, 38226, 38227, and 38228 and only recommended direct PE values for code 38228.

For CPT code 38225 (Chimeric antigen receptor T-cell (CAR–T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR–T cells, per day) the RUC recommended a work RVU of 1.94. For CPT code 38226 (*Chimeric antigen receptor T-cell (CAR–T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)*) the RUC recommended a work RVU of 0.79. For CPT code 38228 (*Chimeric antigen receptor T-cell (CAR–T) therapy; CAR–T cell administration, autologous*) the RUC recommended a work RVU of 3.00. For CPT code 38227 (*Chimeric antigen receptor T-cell (CAR–T) therapy; receipt and preparation of CAR–T cells for administration*) the RUC recommended a work RVU of 0.80 and for CPT code 38227, we proposed the RUC-recommended work RVU of 0.80. We proposed the RUC-recommended work RVUs for CPT codes 38225, 38226, and 38228 respectively.

As mentioned previously, the RUC recommended direct PE values for only one code, CPT code 38228, and the RUC recommended that the non-facility PE

RVU for CPT codes 38225–38227 should be contractor-priced. However, contractor pricing can only be applied at the whole code level, not to a single component of the valuation. Therefore, for CPT codes 38225–38227 we treated these codes as having no recommended direct PE values and sought comment on direct PE values for these codes. We proposed the RUC-recommended direct PE inputs for CPT code 38228.

Comment: The majority of commenters supported our proposal to pay separately for these services under the PFS. However, some commenters also highlighted that the existing CAR–T codes, CPT codes 0537T–0539T, are currently not payable under the OPPS and recommended that CMS should assign active payment for CAR–T services under the OPPS as well. Additionally, a few commenters mentioned that currently these services are not payable under the PFS, and a commenter highlighted the ''N/A'' that is currently listed for non-facility PE RVUs for the current CAR–T codes (CPT codes 0537T–0539T) under the PFS.

Response: We thank the commenters for their support for our proposal and recommendation for the OPPS. As the commenters pointed out, the predecessor codes for CAR–T services (CPT codes 0537T–0539T) are not separately payable under the OPPS, and we note that these same codes similarly have a bundled status under the PFS (meaning they are subsumed within other codes and separate payment is not made for the services they describe). In the CY 2019 OPPS final rule, we stated that ''the procedures described by CPT codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological'' (83 FR 58905). In consideration of our current policies under both the PFS and the OPPS to not pay separately for the predecessor codes (CPT codes 0537T–0539T), we are not finalizing our proposal and will instead continue to bundle payment under the PFS for CAR–T services described under CPT codes 38225, 38226, and 38227. We believe that bundled status is appropriate for these codes in order to remain in alignment with OPPS to not pay separately for each step used to manufacture a drug or biological. We will display the RUC-recommended work RVUs for these three services, as we do for a number of other bundled services on the PFS, however they will remain non-payable. CPT code 38228 is the replacement code for Category III CPT code 0540T, which does not have bundled status, and therefore, we are finalizing active pricing for CPT code 38228 at the proposed work RVU of 3.00 and with the proposed direct PE inputs.

(4) Therapeutic Apheresis and Photopheresis (CPT Codes 36514, 36516, and 36522)

In the CY 2024 PFS final rule, we finalized CPT codes 36514 (*Therapeutic apheresis; for plasma pheresis*), 36516 (*Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion*), and 36522 (*Photopheresis, extracorporeal*) as potentially misvalued, as we believed there may have been a possible disparity with the clinical labor type (88 FR 78848). As a result, the PE clinical labor type was reviewed for these three codes at the January 2024 RUC meeting, with no work review. The PE Subcommittee and the RUC agreed that clinical staff code L042A (RN/LPN) did not appropriately represent the work of an Apheresis Nurse Specialist. There is not a clinical staff code for an Apheresis Nurse Specialist; however, the RUC agreed with the specialty societies' recommendation that the training and experience of an oncology nurse (clinical staff code L056A, RN/OCN) would more accurately reflect the work of an apheresis nurse for these CPT codes. The RUC submitted new PE recommendations for these three codes based on the use of the L056A clinical labor type.

We proposed the RUC-recommended direct PE inputs for CPT codes 36514, 36516, and 36522 without refinement. The RUC did not make recommendations and we did not propose any changes to the work RVU for CPT codes 36514, 36516, and 36522.

Comment: Commenters agreed with CMS' proposed direct PE inputs for the Therapeutic Apheresis and Photopheresis code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing the direct PE inputs as proposed.

(5) Intra-Abdominal Tumor Excision or Destruction (CPT Codes 49186, 49187, 49188, 49189, and 49190)

In May 2023, the CPT Editorial Panel created five new codes to describe the sum of the maximum length of intra-abdominal (that is, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s) excised or destroyed: CPT code 49186 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5 cm or less*), CPT code 49187 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5.1 to 10 cm*), CPT code 49188 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 10.1 to 20 cm*), CPT code 49189 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 20.1 to 30 cm*), and CPT code 49190 (*Excision or destruction, open, intra-abdominal (i.e., peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); greater than 30 cm*). These new CPT codes will replace existing CPT codes 49203 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5 cm diameter or less*), 49204 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5.1–10.0 cm diameter*), and 49205 (*Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor greater than 10.0 cm diameter*) that described tumor excision or destruction based on the size of the single largest tumor, cyst, or endometrioma removed, no matter the number of tumors. For CY 2025, the RUC recommended a work RVU of 22.00 for CPT code 49186, a work RVU of 28.65 for CPT code 49187, a work RVU of 34.00 for CPT code 49188, a work RVU of 45.00 for CPT code 49189, and a work RVU of 55.00 for CPT code 49190.

We proposed the RUC-recommended work RVUs of 22.00 for CPT code 49186, 28.65 for CPT code 49187, and 34.00 for CPT code 49188.

We disagreed with the RUC-recommended work RVU of 45.00 for CPT code 49189 and we proposed a work RVU of 40.00 based on the survey 25th percentile. Compared to the predecessor CPT code 49205, the intra-service time ratio for CPT code 49189 suggested a work RVU of 41.51 and the total time ratio suggested a work RVU of 38.02. These changes in surveyed work time as compared with predecessor CPT

code 49205 suggested that the recommended work RVU of 45.00 was inappropriately high. We also noted that the RUC recommended the survey 25th percentile work RVU for CPT codes 49186, 49187, and 49188. Therefore, we believed that proposing a work RVU of 40.00 for CPT code 49189 kept the valuation consistent with the other CPT codes in this family. Our proposed work RVU of 40.00 for CPT code 49189 was supported by the following reference CPT codes with similar intra-service time (310 minutes) and similar total time (814 minutes): reference CPT code 69970 (*Removal of tumor, temporal bone*) with a work RVU of 32.41 with 330 minutes intra-service time and 793 minutes of total time, and reference CPT code 33864 (*Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (e.g., David Procedure, Yacoub Procedure)*) with a work RVU of 60.80 with 300 minutes of intra-service time and 838 minutes of total time. We believed the proposed work RVU of 40.00 was a more appropriate value overall than 45.00 when compared to the range of codes with similar intra-service time and similar total time.

We disagreed with the RUC-recommended work RVU of 55.00 for CPT code 49190 and we proposed a work RVU of 50.00 based on the survey 25th percentile. Compared to the predecessor CPT code 49205, the intra-service time ratio for CPT code 49190 suggested a work RVU of 48.21 and the total time ratio suggested a work RVU of 48.86. These changes in surveyed work time as compared with predecessor CPT code 49205 suggested that the recommended work RVU of 55.00 was inappropriately high. We also note again that the RUC recommended the survey 25th percentile work RVU for CPT codes 49186, 49187, and 49188. Therefore, we believed that proposing a work RVU of 50.00 for CPT code 49190 kept the valuation consistent with the other CPT codes in this family. Our proposed work RVU of 50.00 for CPT code 49190 was supported by the following reference CPT codes with similar intra-service time (360 minutes) and similar total time (1,046 minutes): reference CPT code 61598 (*Transpetrosal approach to posterior cranial fossa, clivus or foramen magnum, including ligation of superior petrosal sinus and/or sigmoid sinus*) with a work RVU of 36.53 with 377.7 minutes intra-service time and 1,048.1 minutes of total time, and reference CPT code 47140 (*Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)*) with a work RVU of 59.40 with 355 minutes of intra-service time and 1,073 minutes of total time. We believed the proposed RVU of 50.00 was a more appropriate value overall than 55.00 when compared to the range of codes with similar intra-service time and similar total time.

We also noted that the RUC's recommendations for the first three codes in the family (CPT codes 49186–49188) maintained the same amount of intensity as their respective predecessor codes, and in fact slightly decreased in intensity in the case of CPT codes 49186 and 49187. However, the RUC recommended a notable increase in intensity for CPT codes 49189 and 49190 over predecessor code 49205 due to its selection of the survey median work RVU in both cases. We did not believe that this increase in intensity for CPT codes 49189 and 49190 was warranted due to their clinical similarities to the previous coding in the family, especially given that CPT code 49205 had the lowest intensity in the family. We believed that this intensity argument further supported our choice to propose the survey 25th percentile work RVU for these two codes, matching the RUC recommendations for CPT code 49186–49188.

We proposed the RUC-recommended direct PE inputs for CPT codes 49186, 49187, 49188, 49189, and 49190 without refinement.

The following is a summary of the comments we received and our responses.

Comment: The commenters overwhelmingly supported our proposal to accept the RUC recommended work RVUs for CPT codes 49186, 49187, and 49188.

Response: We thank the commenters for their support.

Comment: A few commenters disagreed with the proposed work RVUs of 40.00 for CPT code 49189 and 50.00 for CPT code 49190. The commenters stated that we failed to recognize the increased burden, intensity, and complexity of removing not just a single tumor, but for multiple tumors as represented by CPT codes 49189 and 49190. The commenters also stated that per the RUC's compelling evidence statements it is important to note that the technical difficulty increases as the tumor size increases.

Response: We disagree with the commenters and note that by using the survey 25th percentile for CPT codes 49189 and 49190, we did propose values with a higher intensity than their predecessor code, CPT code 49205. Although we agree that the intensity of CPT codes 49189 and 49190 has increased as compared with predecessor CPT code 49205, the intensity of these new codes is not high enough to support using the survey median for either of them. The changes in surveyed work time as compared with predecessor CPT code 49205 suggested that the survey median work RVUs of 45.00 for CPT code 49189 and 55.00 for CPT code 49190 recommended by the RUC were both inappropriately high. For example, in reviewing CPT code 49189 we noted that the recommended intraservice time as compared with predecessor CPT code 49205 was increasing from 225 minutes to 310 minutes (38 percent), and the recommended total time was increasing from 645 minutes to 814 minutes (26 percent); however, the RUC-recommended work RVU was increasing from 30.13 to 45.00, which is an increase of nearly 50 percent. We believe that since the two components of work are time and intensity, changes in the work time should be reflected in similar changes to the work RVU. Our proposal of a work RVU of 40.00 for CPT code 49189, an increase of approximately 33 percent, better matches these changes in surveyed work time relative to the predecessor code.

We also noted that the RUC recommended the survey 25th percentile work RVU for CPT codes 49186, 49187, and 49188 and we believe it would better support relativity to utilize the same survey 25th percentile work RVU for the final two codes in the family. Therefore, we continue to believe that a work RVU of 40.00 for CPT code 49189, and a work RVU of 50.00 for CPT code 49190, is more appropriate.

Comment: We received comments regarding the reference codes we used in our proposal for CPT codes 49189 and 49190. The reference codes we used to support the proposed work RVU of 40.00 for CPT code 49189 were CPT codes 69970 and 33864, and the reference codes we used in support of the proposed work RVU of 50.00 for CPT code 49190 were CPT codes 61598 and 47140. For CPT code 49189, the commenters agreed that CPT code 33864 was an appropriate reference code but disagreed with our use of CPT code 69970 as the other reference code in support of the proposed work RVU of 40.00 because it was valued nearly 30 years ago and it is not clear how the value for this service was established at that time. Likewise, for CPT code 49190, the commenters agreed that CPT code 47140 was an appropriate reference code but disagreed with our use of CPT code 61598 as the other reference code that supported the proposed work RVU

of 50.00 because it was valued 30 years ago.

Response: We disagree with the commenters and continue to believe that the work RVUs of 40.00 for CPT code 49189, and 50.00 for CPT code 49190, both based on the survey 25th percentile for each code, are appropriate. We note that the reference codes we chose were only used to show support for using the surveyed 25th percentile values from the RUC for CPT codes 49189 and 49190, and that we did not propose to crosswalk the RVUs from any reference codes to CPT code 49189 or CPT code 49190. Furthermore, we note that the commenters supported our use of CPT code 47140 as a reference code, even though it was last valued 21 years ago.

After consideration of the public comments, we are finalizing the work RVU values for the Intra-Abdominal Tumor Excision or Destruction code family (CPT codes 49186, 49187, 49188, 49189, and 49190) as proposed. We are also finalizing the direct PE inputs for CPT codes 49186, 49187, 49188, 49189, and 49190 as proposed.

(6) Bladder Neck and Prostate Procedures (CPT Codes 53865 and 53866)

In September 2023, the CPT Editorial Panel created two Category I CPT codes to describe the insertion or removal of a temporary device to remodel the bladder neck and prostate using pressure to create necrosis and relieve lower urinary tract symptoms (LUTS) secondary to benign prostate hyperplasia (BPH). These two new 000-day global Category I codes were surveyed and reviewed for the January 2024 RUC meeting.

At the January 2024 RUC meeting, the specialty society indicated that CPT code 53865's survey 25th percentile work RVU of 3.91 was too high for this procedure compared to other services in the physician fee schedule with similar intra-service time. The specialty society recommended, and the RUC agreed that the recommended work RVU for CPT code 53865 should be crosswalked to CPT code 52284 (*Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed*). Because these procedures are similar in intensity and both require precise placement of an intraurethral device, we concur with the RUC and we are proposing the RUC recommended work RVU of 3.10 for CPT code 53865.

At the January 2024 RUC meeting, the specialty society indicated that CPT code 53866's survey 25th percentile work RVU of 2.00 was too high for this procedure compared to other services in the physician fee schedule with similar intra-service time. The specialty society recommended, and the RUC agreed, that CPT code 53866 should have a direct work RVU crosswalk to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*). We are proposing the RUC recommended work RVU of 1.48 for CPT code 53866.

We also proposed the RUC-recommended direct PE inputs for CPT codes 53865 and 53866 without refinement. However, we noted possible duplications in two of the supply items within CPT code 53865. Specifically, supply item SB027 (*gown, staff, impervious*) is already included in supply item SA042 (*pack, cleaning and disinfecting, endoscope*), and supply item SB024 (*gloves, sterile*) is included in supply items SA058 (pack, urology cystoscopy visit). We sought comments on whether a total of three SB027 impervious staff gowns and two SB024 pairs of sterile gloves would be typical and necessary when providing this procedure.

Comment: A commenter stated that they had completed over 150 sales of the iTind device (SD366), which is included as a direct PE input for CPT codes 53865 and 53866 at an ASP of $3,150, $3,350, or $3,420. The commenter requested that CMS increase the supply price for SD366 to its current sales price of $3,350 and submitted two invoices for use in updating supply pricing.

Response: We appreciate the submission of these additional invoices for assistance in pricing the SD366 supply item. After reviewing the invoices, we are finalizing an increase in the pricing of the SD366 supply from the proposed $2695 to $2972.50. This updated pricing is based on averaging together the price from all four invoices, two submitted by the RUC and two submitted by the commenter. We note that the difference in pricing for the SD366 supply on these invoices appears to be correlated with the quantity ordered, with a price of $3350 for the purchase of a single device as opposed to $2695 for ordering four devices together. We believe that averaging together these invoices will smooth out these quantity disparities and more closely reflect the typical market pricing.

(7) MRI-Monitored Transurethral Ultrasound Ablation of Prostate (CPT Codes 51721, 55881, and 55882)

At the April 2023 CPT Editorial Panel meeting, three new CPT codes were approved for MRI-monitored transurethral ultrasound ablation (TULSA). These codes were surveyed for the September 2023 RUC meeting and recommendations submitted to CMS for inclusion in the CY 2025 PFS proposed rule.

For CY 2025, we proposed the RUC-recommended work RVUs for all three CPT codes. However, we note that interested parties may have concerns regarding the experience of the survey respondents and the intra-service times provided in the survey data. We welcomed commenters to provide additional data that we could consider in the valuation of the work and direct PE inputs for these CPT codes. We proposed a work RVU of 4.05 for CPT code 51721 (*Insertion of transurethral ablation transducers for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed*), a work RVU of 9.80 for CPT code 55881 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation*), and a work RVU of 11.50 for CPT code 55882 (*Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of the thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed*). We also proposed the RUC-recommended direct PE inputs for CPT codes 51721, 55881, and 55882 without refinement.

Comment: Some commenters disagreed with the proposed work RVUs for all three CPT codes in this family. These commenters reiterated concerns regarding the experience of the RUC survey respondents, stating that the intra-service times provided in the RUC survey data were too low and did not reflect the actual time needed to perform these very complex and critical procedures. Commenters recommended intra-service times based on their experience and internal tracking data. For CPT code 51721, the suggested intra-service times varied from 40 to 101 minutes, as opposed to the RUC-recommended 29 minutes. For CPT code 55881, the suggested intra-service

times varied from 140 to 279 minutes, as opposed to the RUC-recommended 120 minutes. For CPT code 55882, the suggested intra-service times varied from 170 to 317 minutes, as opposed to the RUC-recommended 125 minutes. Due to these increased intra-service times, the commenters also recommended a revised work RVU of 6.75 for CPT code 51721, 13.13 for CPT code 55881, and 16.20 for CPT code 55882.

Response: We thank commenters for their feedback and the additional data provided; however, we do not agree with the intra-service times or work RVUs that commenters recommended for this code family. The values that commenters provided were mixed, but mostly significantly higher than the proposed values. We believe that the RUC survey respondents were familiar with the technology and since these CPT codes were recently converted from Category III to Category I, the survey results will be more robust as utilization increases over time. We continue to believe that the RUC-recommended intra-service times and work RVUs accurately reflects the time and intensity involved with these services, as supported by the survey results and reference codes. We look forward to re-reviewing these CPT codes when they are re-submitted on the RUC's New Technology list.

Comment: Many commenters were supportive of the proposed work RVUs and direct PE inputs for this code family. These commenters also acknowledged concerns from interested parties regarding the survey respondents' experience and intra-service times, specifically noting that the RUC process relies upon the clinical expertise of its multidisciplinary physician representatives and that its members are impartial and free from the external influences of interested parties. Additionally, commenters highlighted that they anticipate an initial low utilization of these services that will increase over time, and since these codes are on the RUC's New Technology list, they will be re-reviewed in 3 years.

Response: We thank commenters for their support and additional information provided.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for all three codes in the MRI-Monitored Transurethral Ultrasound Ablation of Prostate family as proposed.

(8) Insertion of Cervical Dilator (CPT Code 59200)

In the CY 2024 PFS final rule, we finalized CPT Code 59200 (*Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)*) as potentially misvalued. The code is to be used to report the total duration of time spent on a patient history and physical, reviewing lab resulting, discussing risk and benefits of the procedure, obtaining consent, performing the procedure, and assessing the patient post-procedure. The RUC reviewed the work RVU and PE inputs for CPT code 59200 at their January 2024 meeting. We proposed the RUC-recommended work RVU of 1.20 for CPT code 59200. We also proposed the RUC-recommended direct PE inputs for CPT code 59200 without refinements.

Comment: Commenters agreed with CMS' proposed work RVU and direct PE inputs for this code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing the work RVU and direct PE inputs as proposed.

(9) Guided High Intensity Focused Ultrasound (CPT Code 61715)

In September 2023, the CPT Editorial Panel created a new Category I code to describe magnetic resonance image guided high intensity focused ultrasound intracranial ablation for treatment of a severe central tremor that is recalcitrant to other medical treatments. This service is typically performed by a neurosurgeon without the involvement of a separate radiologist. This new code replaces the existing Category III code 0398T.

We did not propose the RUC-recommended work RVU of 18.95 for CPT code 61715 and instead proposed a work RVU of 16.60 based on a crosswalk to CPT code 61626 (*Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)*), which describes a similar tumor destruction service that has similar time and intensity values to this service, and we support this value by referencing CPT code 33889 (*Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral*) and 33894 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches*). We do not believe that this service is significantly more intense than the key reference codes, CPT codes 61736 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*) and 61737 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)*), as the RUC-recommended work value implies. Our proposed work RVU of 16.60 for CPT code 61715 largely matches the intensity of CPT code 61736 which we believe is a more accurate valuation for this service, as opposed to the RUC recommendation which would have significantly more intensity.

We proposed the RUC-recommended direct PE inputs for CPT code 61715 without refinement.

Comment: Many commenters disagreed with the CMS proposal of a work RVU of 16.60 for CPT code 61715. Commenters described the clinical benefits of CPT code 61715 as a non-invasive, real-time monitored and controlled acoustic surgery procedure that offers a treatment option for essential tremor in patients that are not candidates for, or do not want to undergo, open brain surgery. Commenters stated that this code is a complex procedure which requires a great deal of training and experience to develop expertise, and that it can be a lengthy and intense procedure taking a great deal of time to perform. Commenters objected to the CMS use of CPT code 61626 as a crosswalk for valuation, stating that this code was deemed ''Do Not Use to Validate for Physician Work'' in the RUC database and that the work time in this code was developed to be used for practice expense purposes only and has not been validated by the RUC. Commenters also stated that CPT code 61626 has been revised by the CPT Editorial Panel and surveyed by the RUC for the CPT 2026 cycle and should not be used as crosswalk during the re-review process.

Commenters disagreed with the other CMS reference codes by stating that they were less intense/complex to perform compared to CPT code 61715 despite having similar work time values. Commenters maintained that the two key reference codes from the survey, CPT codes 61736 and 61737, were appropriate comparators and that CPT code 61715 was more intensive that these survey references, both as indicated by the survey respondents and due to clinical reasons (due to the need for repeated neurologic assessments of the awake patients during treatment planning and delivery and because the

reference codes involve time for opening/closing that is of lower intensity than the treatment and not required as part of the work for the CPT code 61715). Commenters stated that a decline in reimbursement could adversely affect their ability to provide this vital treatment to Medicare patients and urged CMS to finalize the RUC's recommended work RVU of 18.95.

Response: We appreciate the additional discussion of the clinical nature of CPT code 61715 from the commenters and its intensity relative to the various reference codes discussed above. After consideration of the comments, we agree that CPT code 61715 is more accurately valued at the survey 25th percentile work RVU of 18.95 as recommended by the RUC based on their description of the complexity inherent to the procedure. We are finalizing this work RVU of 18.95 along with the proposed direct PE inputs for CPT code 61715.

(10) Percutaneous Radiofrequency Ablation of Thyroid (CPT Codes 60660 and 60661)

In January 2024, the RUC surveyed codes 60660 (*Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency*) and its respective add-on code 60661 (*Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, with imaging guidance, radiofrequency (List separately in addition to code for primary service*) and recommended both work RVUs and PE values for this code family.

For CPT code 60660, the RUC recommended a work RVU of 5.75 and we proposed the RUC-recommended work RVU of 5.75.

For add-on code CPT 60661, the RUC recommended a work RVU of 4.25 and we proposed the RUC-recommended work RVU for this code. We also proposed the RUC-recommended direct PE values for both codes 60660 and 60661.

Comment: Many commenters supported the CMS proposal of the RUC-recommended work RVUs for CPT codes 60660 and 60661. These commenters urged CMS to finalize the values as proposed.

Response: We appreciate the support for our proposed work RVUs from the commenters.

Comment: Several commenters stated that they supported the proposed work RVUs for CPT codes 60660 and 60661, however the commenters expressed significant concerns regarding the reimbursement challenges faced by endocrinologists in private non-facility-based practices for the Radiofrequency Ablation (RFA) of thyroid nodules. The commenters stated that there are critical issues that need to be addressed to ensure continued access to this important procedure for patients in need. These issues included the high cost of the RF electrode which poses a significant financial burden on practices, a reimbursement gap for endocrinologists in non-facility-based practices, the upfront costs of RFA equipment and consumables which threaten to impact patient access to these services, and that there are sustainability concerns regarding the current reimbursement model for RFA procedures. The commenters urged CMS to reconsider the reimbursement framework for RFA procedures, taking into account the full range of practice expenses, including essential consumables like the RF electrode.

Response: We appreciate the additional information submitted by the commenters regarding the issues involving reimbursement for these radiofrequency ablation services. Although this discussion is beyond the scope of this particular code family, if the commenters believe that the valuation of the RF electrode (SD368) supply at $1995.00 does not reflect current market pricing, we would encourage them to submit invoices via email to the *PE_Price_Input_Update@cms.hhs.gov* inbox as described in the PE section of this final rule.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Percutaneous Radiofrequency Ablation of Thyroid family as proposed.

(11) Fascial Plane Blocks (CPT Codes 64466, 64467, 64468, 64469, 64473, 64474, 64486, 64487, 64488, and 64489)

In September 2023, the CPT Editorial Panel created six new Category I CPT codes, CPT code 64466 (*Thoracic fascial plane block, unilateral; by injection(s), including imaging guidance, when performed*), 64467 (*Thoracic fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed*), 64468 (*Thoracic fascial plane block, bilateral; by injection(s), including imaging guidance, when performed*), 64469 (*Thoracic fascial plane block, bilateral; by continuous infusion(s), including imaging guidance, when performed*), 64473 (*Lower extremity fascial plane block, unilateral; by injection(s), including imaging guidance, when performed*), and 64474 (*Lower extremity fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed*) to report thoracic or lower extremity fascial plane blocks, typically used for post-operative pain management. Four existing CPT codes describing transversus abdominis plane (TAP) blocks, 64486 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)*), 64487 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)*), 64488 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)*) 64489 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)*), were included as part of this code family for RUC review in January 2024.

We proposed the RUC-recommended work RVU for all ten codes in this family. We proposed a work RVU of 1.50 for CPT code 64466, 1.74 for CPT code 64467, 1.67 for CPT code 64468, 1.83 for CPT code 64469, 1.34 for CPT code 64473, 1.67 for CPT code 64474, 1.20 for CPT code 64486, 1.39 for CPT code 64487, 1.40 for CPT code 64488, and 1.75 for CPT code 64489.

We also proposed the RUC recommended direct PE inputs for CPT codes 64467, 64468, 64469, 64474, 64487, 64488, and 64489. We disagreed with one of the RUC recommended direct PE inputs for CPT codes 64466, 64473, and 64486. The RUC stated they believe that there is a rounding error in the CA019 clinical labor time, ''Assist physician or other qualified healthcare professional—directly related to physician work time (67%)'', for these three codes. We disagreed with the RUC that there are rounding errors in these codes and we proposed to maintain the current 7 minutes of CA019 clinical labor time for CPT codes 64466, 64473, and 64486. We noted that this matches the pattern of CA019 clinical labor time for the rest of the codes in the family, which remained the same or slightly decreased in each case. This refinement to the CA019 clinical labor time also means that we proposed a decrease of 0.5 minutes to the equipment time for the stretcher (EF018) and 3-channel ECG (EQ011) which decreases from 25.5 to 25 minutes for these three codes. We proposed all of the other RUC-recommended direct PE inputs for CPT codes 64466, 64473, and 64486 without refinement.

Comment: Commenters agreed with CMS' proposed work RVU and direct PE inputs for this code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing the work RVU and direct PE inputs as proposed.

(12) Skin Adhesives (CPT Codes 64590 and 64595 and HCPCS Codes G0168, G0516, G0517, and G0518)

In April 2022, the RUC approved the use of SG007 (*adhesive, skin (Dermabond)*) for CPT code 64590 (*insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver*) and 64595 (*revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array*). In April 2023, the PE Subcommittee reviewed the following six codes on the Medicare Physician Fee Schedule 64590, 64595, G0168, G0516, G0517, G0518 that utilize Dermabond (supply code S6007) in order to identify justification for its use versus the generic version and present its findings to the RUC for approval. The RUC reviewed all six codes for PE only and did not submit work recommendations.

For CPT codes 64590 and 64595 and HCPCS code G0168 (*Wound closure utilizing tissue adhesive(s) only*), the RUC recommended that CMS remove the supply input SG007 adhesive, skin (Dermabond) and add one unit of SH076 adhesive, cyanoacrylate (2ml uou). We proposed the RUC-recommended direct PE inputs for CPT codes 64590 and 64595 and HCPCS code G0168. Similarly, for HCPCS codes G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant*), G0517 (*Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants*), and G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants*), the RUC recommended that CMS remove the supply input SG007 adhesive, skin (Dermabond) and add one unit of SH076 adhesive, cyanoacrylate (2ml uou). We proposed the RUC-recommended direct PE inputs for HCPCS codes G0516–G0518.

Comment: Commenters agreed with CMS' proposed direct PE inputs for this code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing the direct PE inputs as proposed. We did not propose and are not finalizing any changes to the work RVUs.

(13) Iris Procedures (CPT Codes 66680, 66682, and 66683)

In April 2023, the CPT Editorial Panel deleted three related Category III CPT codes, CPT code 0616T (*Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens*), CPT code 0617T (*with removal of crystalline lens and insertion of intraocular lens*), and CPT code 0618T (with secondary intraocular lens placement or intraocular lens exchange). At the same time, CPT created a new Category I code 66683 (*Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed*) which describes insertion of an artificial iris into an eye with a partial or complete iris defect due to a congenital defect or surgical or non-surgical trauma. The new Category I CPT code 66683 replaced the three Category III codes to simplify reporting. Concurrent with these updates, the RUC surveyed the two other 90-day global iris repair codes, CPT code 66680 (*Repair of iris, ciliary body (as for iridodialysis)*) and CPT code 66682 (*Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (eg, McCannel suture)*).

We disagreed with the RUC-recommended work RVU of 10.25 for CPT code 66680. We proposed a work RVU of 7.97 for CPT code 66680 based on a crosswalk to CPT code 67904 (*Repair of blepharoptosis; (tarso) levator resection or advancement, external approach*). When we reviewed CPT code 66680, we found that the RUC recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time of 45 minutes and similar total time around 182 minutes. The total time ratio between the current time of 159 minutes and the recommended time established by the RUC survey of 182 minutes equals 1.145 percent. This ratio, 1.145 percent, when applied to the current work RVU of 6.39 would suggest a work RVU of 7.31 which is far below the RUC's recommended work RVU of 10.25. Based on this total time ratio, we believe a more appropriate work valuation for CPT code 66680 is 7.97 based on a crosswalk to CPT code 67904.

We disagreed with the RUC-recommended work RVU of 10.87 for CPT code 66682. We proposed a work RVU of 8.74 based on the total time ratio between the current time of 169.5 minutes and the recommended time established by the RUC survey of 202 minutes. This ratio equals 1.192 percent, and 1.192 percent of the current work RVU of 7.33 suggests a work RVU of 8.74 for CPT code 66682. When we reviewed CPT code 66682, we found that the recommended work RVU was higher than nearly all of the other 90-day global codes with similar time values. The RUC's recommended work RVU does not maintain relativity with other 90-day global period codes with the same intraservice time value of 45 minutes and similar total time of 202. We found that work RVU crosswalks to CPT codes of similar intraservice and total time were too low, such as CPT code 45171 with a work RVU of 8.13. A more appropriate work RVU for CPT code 66682 is 8.74 based on the total time ratio.

The RUC recommended a work RVU of 12.80 for CPT code 66683, the RUC survey 25th percentile result, with an intraservice time of 60 minutes and a total time of 224 minutes. We disagreed with the RUC-recommended work RVU of 12.80 for CPT code 66683. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 66682 and 66683 is equivalent to the recommended interval of 1.93 RVUs. Therefore, we proposed a work RVU of 10.67 for CPT code 66683, based on the recommended interval of 1.93 additional RVUs above our proposed work RVU of 8.74 for CPT code 66682. This work RVU of 10.67 falls between the work RVU values of existing codes with similar intraservice and total time values. For example, CPT code 65850 (60 minutes of intraservice time and 233 minutes of total time) has a work RVU of 11.39 and CPT code 24164 with the same intraservice time and 228 minutes of total time has a work RVU of 10.00. We believe that the work valuation of these CPT codes, which bracket our work RVU of 10.67, provide additional support for our valuation.

We also disagreed with the RUC's recommended work RVUs for the codes in this family because they suggest that there has been a tremendous increase in intensity as compared to how these services have historically been valued. CPT code 66680 is more than doubling in intensity at the RUC's recommended work RVU of 10.25, which we do not believe to be the case given that the code descriptor remains unchanged and the surveyed intraservice work time is unchanged at 45 minutes. This same pattern holds true for CPT code 66682, which would be increasing in intensity

by more than 50 percent at the RUC's recommended work RVU of 10.87, and which similarly has no change in its code descriptor and a modest increase in its surveyed work time. We concur that the intensity of these services has likely gone up over time, which is why we proposed modest intensity increases for both codes; however, we continue to disagree that the very substantial intensity increases recommended by the RUC would be accurate for this code family. We believe that our work RVUs are more in line with how these services have historically been valued and better maintain relativity with the rest of the fee schedule.

We proposed the direct PE inputs as recommended by the RUC for all three codes in the family without refinement.

Comment: We received a few comments opposed to our proposal. Of these commenters, most asserted that CMS should finalize the RUC-recommended work RVU values for CPT codes 66680 and 66682. Commenters asserted that the direct work RVU crosswalk that CMS proposed for CPT code 66680 was inappropriate because assigning a work RVU of 7.97 based on a crosswalk to CPT code 67904 does not maintain relativity with other 90-day global intraocular procedures with which CPT code 66680 should be compared. Commenters stated that the procedure described by CPT code 66680 has a much higher risk and requires greater intensity than extraocular procedures. They criticized the CMS methodology as relying too heavily on time and not enough on the overall intensity, which is higher on account of greater expectations for restoring normal anatomical relationships. These commenters also stated that the proposed work RVU of 8.74 for CPT code 66682 does not adequately account for the increase in intensity and complexity which has occurred since its prior valuation in 1992. In their public comment, the RUC objected to the proposed methodology for assigning a work RVU to CPT code 66682, stating that any mathematical or computational methodology other than magnitude estimation used to value physician work is inappropriate, and inconsistent with RBRVS principles.

All commenters urged CMS to finalize the RUC recommended work RVU value of 12.80 for CPT code 66683. One commenter stated that they agreed that the relative difference in work between CPT codes 66682 and 66683 is equivalent to the recommended interval of 1.93 RVUs between CPT codes 66682 and 66683. They felt this interval should be applied to the RUC-recommended work RVU for CPT code 66682. Another commenter disagreed, saying that the relative complexity of CPT code 66683 as compared to CPT code 66682 is significantly greater than the 1.93 work RVU difference as noted by the RUC and in the proposed work RVUs for CPT codes 66682 and 66683.

Response: We thank the commenters for their feedback. However, we disagree with the commenters and are finalizing the work RVUs for CPT codes 66680, 66682 and 66683 as proposed. We continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains. We reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

We continue to disagree with the RUC and with commenters that the intensity for CPT code 66680 has more than doubled, given that the code descriptor remains unchanged and the surveyed intraservice work time is unchanged at 45 minutes. We also disagree with the RUC and with commenters that the intensity for CPT code 66682 has increased by more than 50 percent, given that CPT code 66682 has no change in its code descriptor and a modest increase in its surveyed work time. We noted in the proposed rule that we did not believe these substantial increases in intensity would be typical for these codes, and we did not receive new information from commenters that supported finalizing work RVUs that would warrant these intensity increases. We continue to believe that our proposed valuations, based on a crosswalk for CPT code 66680 and the use of a time ratio for CPT code 66682, more accurately value these codes since they do not result in the sizable increases in intensity as recommended by the RUC. We note again for commenters that the work RVU and the intensity are increasing for both CPT codes 66680 and 66682 at the values we proposed, as we recognize that these services now require additional work and intensity as compared with the time of their prior review.

For CPT code 66683, we agreed with commenters and the RUC that this code has greater intensity than CPT code 66682. Commenters agreed with our proposal that the relative difference in work between CPT codes 66682 and 66683 is equivalent to the recommended interval of 1.93 RVUs, only disagreeing on the work RVU of CPT code 66682 itself. We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We continue to believe that our proposed work RVU of 10.67 for CPT code 66683 is the most accurate valuation for this code.

With regard to the commenters' concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. For more details on our methodology for developing work RVUs, we again direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

After consideration of the comments and as stated above, we are finalizing the work RVUs for CPT codes 66680, 66682 and 66683 as proposed. We are also finalizing the direct PE inputs as proposed for all three codes in the family without refinement.

(14) Magnetic Resonance Examination Safety Procedures (CPT Codes 76014, 76015, 76016, 76017, 76018, and 76019)

In September 2023, the CPT Editorial Panel created a new code family to describe magnetic resonance (MR) examination safety procedures and capture the physician work involving patients with implanted medical devices that require access to MR diagnostic procedures: CPT code 76014 (*MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes*), CPT code 76015 (*MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)*), CPT code 76016 (*MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR exam, analysis of risk versus clinical benefit of performing MR exam, and determination of MR equipment, accessory equipment, and expertise required to perform examination with written report*), CPT code 76017 (*MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies with written report*), CPT code 76018 (*MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room with written report*), and CPT code 76019 (*MR safety implant positioning and/or immobilization under supervision of physician or qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces, magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room with written report*). For CY 2025, new CPT codes 76014 and 76015 are PE only services that represent the preparatory research and review completed by clinical staff (that is, MRI technologist and/or a medical physicist) that will be utilized by the physician or qualified health professional for the other four services (CPT codes 76016, 76017, 76018, and 76019) in this code family.

We proposed the RUC-recommended work RVU of 0.60 for CPT code 76016, the work RVU of 0.76 for CPT code 76017, the work RVU of 0.75 for CPT code 76018, and the work RVU of 0.60 for CPT code 76019.

We proposed the following refinements to the direct PE inputs. For CPT codes 76014, 76015, 76016, 76018, and 76019, we proposed to refine the clinical labor for the CA034 activity (*Document procedure (nonPACS) (e.g. mandated reporting, registry logs, EEG file, etc.)*) performed by the MRI Technologist from 2 minutes to 1 minute. We note that the clinical labor for the CA032 activity (*Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.*) included in the direct PE inputs for reference CPT code 70543 (*Magnetic resonance (e.g., proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences*) was a similar clinical labor activity and had 1 minute of time. We also noted that the Medical Physicist had 1 minute of recommended clinical labor time for the CA034 activity for CPT code 76017. Therefore, we believed that the MRI Technologist should have the same time (1 minute) for the CA034 activity for the remaining codes in the family to maintain consistency across these services.

For CPT code 76015, we proposed to refine the clinical labor for the CA021 activity (*Perform procedure/service—NOT directly related to physician work time*) from 27 minutes to 14 minutes. We believed this clinical labor time should be double the 7 minutes assigned to the CA021 activity for CPT code 76014. The description for CPT code 76014 is for the ''initial 15 minutes'' and CPT code 76015 is for ''each additional 30 minutes,'' that is, double the time of CPT code 76014. We believed that the clinical labor associated with the CA021 activity should match this pattern in which CPT code 76015 contains double the time of CPT code 76014. This proposed refinement to the CA021 clinical labor also resulted in a proposed decrease to the equipment time for the Technologist PACS workstation (ED050) from 45 minutes to 32 minutes.

For CPT code 76017, the RUC recommended 13 minutes of equipment time for the Professional PACS Workstation (ED053) listed as a Facility PE input. We believed this was an unintended technical error and we proposed to remove this time from the direct PE inputs for CPT code 76017.

For CPT codes 76018 and 76019, we proposed to refine the clinical labor time for the CA024 activity (*Clean room/equipment by clinical staff*) from 2 minutes to 1 minute. According to the PE recommendations, only the new equipment code EQ412 (*Vitals monitoring system (MR Conditional)*) was being cleaned and not the entire room. We believed that 1 minute of clinical labor time would be typical for cleaning the EQ412 equipment. Our proposed clinical labor refinement also resulted in a proposed decrease to the equipment time for EL008 (*room, MR*) and EQ412 by 1 minute for these two codes.

For CPT code 76019, we proposed to remove supply item SL082 (*impression material, dental putty (per bite block)*). We believed this was an error since the PE recommendations did not list SL082 as one of the included supplies for CPT code 76019 and it did not appear as a supply input for any of the other codes in the family.

The following is a summary of the comments we received and our responses.

Comment: The commenters overwhelmingly supported our proposal of the RUC recommended work RVUs for CPT codes 76016, 76017, 76018, and 76019.

Response: We thank the commenters for their support.

Comment: The commenters agreed with the proposed PE refinement to remove equipment time for the Professional PACS Workstation (ED053) for CPT code 76017 in the facility setting and agreed this was an unintended technical error.

Response: We thank the commenters for their support.

Comment: For CPT codes 76018 and 76019, the commenters agreed with the proposed PE refinement to remove 1 minute of clinical labor time from the Clean room/equipment by clinical staff (CA024) task, as well as the resulting decrease in equipment time for equipment codes EL008 and EQ412.

Response: We thank the commenters for their support.

Comment: We received several comments that disagreed with our proposal to remove 1 minute of clinical labor time from the Document procedure (nonPACS) (CA034) task for CPT codes 76014, 76015, 76016, 76018, and 76019. The commenters stated that the RUC recommendation of 2 minutes was necessary by describing the various requirements the MRI technologist must perform and detailing the evaluation and written report that is part of the documentation process (for example, evaluate implant components, special positioning requirements, include clinical staff records, and implant status post procedure).

Response: We appreciate the submission of this additional information from the commenters regarding the tasks performed by the MRI technologist. We agree with the commenters that 2 minutes is necessary given the technologist must write a detailed report to include evaluated implant components, MR conditions for the requested exam, implant programming requirements, special positioning requirements, acceptable radiofrequency coils, and necessary personnel for the exam. Also, CPT code 76017 only requires 1 minute for CA034 because the medical physicist typically documents the procedure in tandem with the performance of the MR procedure and needs less time to complete documentation upon completion of the procedure. Therefore, we are finalizing the RUC recommendation of 2 minutes for clinical labor activity CA034 for CPT codes 76014, 76015, 76016, 76018, and 76019.

Comment: Several commenters disagreed with our proposal to reduce the clinical labor time for the Perform procedure/service—NOT directly related to physician work time (CA021) task from 27 to 14 minutes for CPT code 76015. The commenters stated that there is significantly more work for the MRI technologist with CPT 76015 compared to parent CPT code 76014 because the MRI technologist typically has to call the patient's primary care physician's office to obtain additional information and detailed history related to the implant, assess an implant where there may be no implant information readily available in the medical chart (or the patient does not have any implant information), and if there have been subsequent revision surgeries to the original implant.

Response: After reviewing the comments for clinical labor activity CA021 for CPT code 76015, we believe a 7-minute increase from the proposed 14 minutes to 21 minutes would be appropriate. We believe that there may be some duplicative work from parent CPT code 76014 and that a more appropriate time to accomplish the additional tasks would be 3 times the 7-minute value for CA021 assigned to parent CPT code 76014, instead of the full 27 minutes recommended by the RUC. Our finalized clinical labor time of 21 minutes for the CA021 activity for CPT code 76015 also results in an increase in equipment time from the proposed 32 minutes to 39 minutes for equipment code ED050.

Comment: The commenters disagreed with our proposal to remove supply item SL082 from the direct PE inputs for CPT code 76019 and stated that a typo occurred in the PE Summary of Recommendation (SOR) which did not correctly list this supply code as a direct PE input.

Response: We agree with the commenters that supply item SL082 should have been included in the PE SOR. Therefore, we are finalizing the inclusion of the RUC recommended PE input of supply item SL082 for CPT code 76019.

After consideration of the public comments for the Magnetic Resonance Examination Safety Procedures code family (CPT codes 76014, 76015, 76016, 76017, 76018, and 76019), we are finalizing the work RVU values for CPT codes 76016, 76017, 76018, and 76019 as proposed. For CY 2025, CPT codes 76014 and 76015 are PE only services and have no work RVUs. We are finalizing the RUC recommended direct PE input of 2 minutes for clinical labor activity CA034 for CPT codes 76014, 76015, 76016, 76018, and 76019. For CPT code 76015, we are finalizing 21 minutes for clinical labor activity CA021 and 39 minutes for equipment code ED050. For CPT code 76019, we are finalizing the inclusion of the RUC recommended PE input for supply item SL082. All remaining direct PE inputs for CPT codes 76014, 76015, 76016, 76017, 76018, and 76019 are finalized as proposed.

(15) Screening Virtual Colonoscopy (CPT Code 74263)

As outlined in section III.K. of this final rule, we proposed to exercise our authority at section 1861(pp)(1)(D) of the Act to update and expand coverage for colorectal cancer screening and adding coverage for the computed tomography colonography procedure. Accordingly, we assigned an active payment status for CPT code 74263 (Computed tomographic (ct) colonography, screening, including image postprocessing). We noted that, as proposed previously, the OPPS cap would apply to this code, and payment for the TC of this service would be capped at the OPPS payment rate.

Comment: Many commenters supported our proposal to assign active payment status to align with the expanded coverage proposal for CPT code 74263 although many also expressed concern with the application of the OPPS cap, and stated that it would be a significant barrier to imaging centers providing this service because of the payment difference between the PFS payment amount and the OPPS payment amount, which has an estimated payment of $106.30.

Response: We appreciate the commenters' support of the proposal to assign active payment status to align with the expanded coverage proposal for CPT code 74263. We direct readers to section III.K. of this final rule for more information regarding the proposal, including a summary of comments received, and section II.E.3.b.

7. Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap of This Final Rule for More Information About the OPPS Cap

After consideration of the public comments, we are finalizing the proposal to assign active payment status for CPT code 74263.

(16) Ultrasound Elastography (CPT Codes 76981, 76982, and 76983)

This code family was flagged for re-review at the April 2023 RUC meeting by the new technology/new services screen. Due to increased utilization of CPT code 76981 (*Ultrasound, elastography; parenchyma (eg, organ)*), the entire code family was resurveyed for the September 2023 RUC meeting. We proposed the RUC-recommended work RVUs of 0.59, 0.59, and 0.47 for CPT codes 76981, 76982 (*Ultrasound, elastography; first target lesion*), and 76983 (*Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)*), respectively. We proposed

the RUC-recommended direct PE inputs for CPT codes 76981, 76982, and 76983 without refinement.

Comment: Commenters were supportive of our proposed RUC-recommended work RVUs and direct PE inputs for CPT codes 76981, 76982, and 76983.

Response: We appreciate the commenters' support and are finalizing the RUC-recommended work RVUs and direct PE inputs for CPT codes 76981, 76982, and 76983 as proposed.

(17) CT Guidance Needle Placement (CPT Code 77012)

CPT code 77012 (*Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) was reviewed at the September 2023 RUC meeting to account for deferred updates to the vignette to reflect the typical patient until updated utilization data was available to reflect coding changes that occurred in 2019. We proposed the RUC-recommended work RVU of 1.50 for CPT code 77012.

We proposed to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes. CPT code 77012 is a radiological supervision and interpretation (RS&I) procedure and there has been a longstanding convention in the direct PE inputs, shared by 38 other codes, to assign an equipment time of 9 minutes for the equipment room in these procedures. We made the same refinement in the CY 2019 PFS final rule (83 FR 59553 through 59554) and continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures. In response to the CY 2019 proposal, several commenters stated that they agreed with CMS that other RS&I codes use the 9 minutes for room time as a precedent, but that it is specific to angiographic rooms. We agreed with the commenters that at least some portion of the procedure is performed in the CT room, but we continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures in a more comprehensive fashion. We also disagreed with the commenters that this policy is specific to angiography rooms, as CPT codes 75989 (*Radiological guidance (ie, fluoroscopy, ultrasound, or computed tomography), for percutaneous drainage (eg, abscess, specimen collection), with placement of catheter, radiological supervision and interpretation*) and 77012 both employ CT rooms and currently utilize the standardized 9 minutes of equipment time, and CPT code 76080 (*Radiologic examination, abscess, fistula or sinus tract study, radiological supervision and interpretation*) employs a radiographic-fluoroscopic room with the 9 minute standard equipment time. We continue to believe that 9 minutes for EL007 is appropriate for this RS&I code; therefore, we are proposing to maintain the current equipment room time of 9 minutes for EL007 until this group of procedures can be subject to a more comprehensive review. We proposed all other RUC-recommended direct PE inputs for CPT code 77012.

Comment: Some commenters disagreed with our proposal to refine the equipment room time for the CT room (EL007) to maintain the current 9 minutes. Commenters reiterated that they believe the 9-minute convention only applies to RS&I codes in angiographic rooms, whereas this service is performed in a CT room. Commenters stated that 35 of the 38 RS&I codes are performed in the angiographic room, so the 9 minutes allocated is appropriate, and one code, CPT code 76080, is performed in the fluoroscopy room but is typically billed with CPT code 49424 (*Contrast injection for assessment of abscess or cyst via previously placed drainage catheter or tube (separate procedure)*) that also includes fluoroscopy room time. Commenters stated that the remaining two codes, CPT codes 77012 and 75989, are performed in the CT room and should have more than 9 minutes of room time.

Response: We continue to believe that it would not serve the interests of relativity to increase the equipment time for the CT room in CPT code 77012 without also addressing the equipment room time for the other radiological supervision and interpretation procedures in a more comprehensive fashion, especially considering commenters raised concerns about the equipment time for both CPT codes 77012 and 75989. Therefore, at this time, we continue to believe that 9 minutes for EL007 is appropriate for this RS&I code until this group of procedures can be subject to a more comprehensive review and are finalizing to maintain the current equipment room time of 9 minutes for EL007 as proposed. We are also finalizing the RUC-recommended work RVU of 1.50 as proposed.

(18) Telemedicine Evaluation and Management (E/M) Services (CPT Codes 98000, 98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98009, 98010, 98011, 98012, 98013, 98014, 98015, and 98016)

In February 2023, the CPT Editorial Panel added a new Evaluation and Management (E/M) subsection to the draft CPT codebook for Telemedicine Services. The Panel added 17 codes for reporting telemedicine E/M services: CPT code 98000 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.*); CPT code 98001 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*); CPT code 98002 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*); CPT code 98003 (*Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded. (For services 75 minutes or longer, use prolonged services code 99417));* CPT code 98004 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*); CPT code 98005 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*); CPT code 98006 (*Synchronous audio-*

video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.); CPT code 98007 (*Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*); CPT code 98008 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.)*); CPT code 98009 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.)*); CPT code 98010 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*); CPT code 98011 (*Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded. (For services 75 minutes or longer, use prolonged services code 99417)*); CPT code 98012 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 10 minutes must be exceeded.)*); CPT code 98013 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.)*); CPT code 98014 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.)*); CPT code 98015 (*Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded. (For services 55 minutes or longer, use prolonged services code 99417)*); CPT code 98016 (*Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5–10 minutes of medical discussion)*).

In April 2023, the AMA–RUC noted that the survey instrument they used to develop valuation recommendations for the telemedicine E/M codes did not include the time (when time is used for code selection) in the new telemedicine E/M services descriptors, or the E/M services displayed on the reference service list. The AMA–RUC made interim valuation recommendations and conducted a new survey for September 2023, which included the minimum required times in the code descriptors, and those minimum times were the same as appear in existing O/O E/M services code descriptors (CPT codes 99202–99205, 99212–99215); the new survey in September 2023 included code descriptors and times approved by the CPT Editorial Panel in May 2023. Also, additional specialties who perform E/M services participated in the second round of this survey. For CY 2025, the RUC recommended the following work RVUs: a work RVU of 0.93 for CPT code 98000, a work RVU of 1.6 for CPT code 98001, a work RVU of 2.6 for CPT code 98002, a work RVU of 3.50 for CPT code 98003, a work RVU of 0.70 for CPT code 98004, a work RVU of 1.30 for CPT code 98005, a work RVU of 1.92 for CPT code 98006, a work RVU of 2.60 for CPT code 98007, a work RVU of 0.90 for CPT code 98008, a work RVU of 1.60 for CPT code 98009, a work RVU of 2.42 for CPT code 98010, a work RVU of 3.20 for CPT code 98011, a work RVU of 0.65 for CPT code 98012, a work RVU of 1.20 for CPT code 98013.

In April 2023, the AMA–RUC Practice Expense Subcommittee approved the direct practice expense inputs as recommended by the specialty societies without modification, and CMS received these inputs as recommendations from the RUC. The specialty societies detailed their methodology for making some changes to specific clinical activity codes to adapt those clinical activity codes for telemedicine. The AMA edited both CA009 and CA013. The AMA revision to CA009 deletes, ''*greet patient, provide gowning*''; the AMA revision to CA013 deletes, ''Prepare room, equipment and supplies''. CA009 now reads, ''*Ensure appropriate medical records are available*'' and CA013 now reads, ''*Prepare patient for the visit (i.e. check audio and/or visual*''. The RUC, using the Practice Expense subcommittee recommendations, also recommended to CMS that a camera and microphone ''should be considered typical in the computer contained in the indirect overhead expense.'' This determination is consistent with CMS' longstanding position that items that are not specifically attributable to the individual services should not be included for valuation of specific codes.

The AMA–RUC recommended the direct practice expense inputs as submitted by the AMA-member specialty societies, and as affirmed by the AMA–RUC Practice Expense Subcommittee. All supply and equipment costs were zeroed out from the reference services, and as a result, the new telemedicine E/M codes did not include any supply or equipment costs in the recommended direct practice expense inputs that the AMA submitted to CMS. The direct PE inputs removed from the reference services to create the new telemedicine E/M codes are: CA010 (obtain vital signs), CA024 (clean room/equipment by clinical staff), SA047 (pack, EM visit), SM022 sanitizing cloth-wipe (surface, instruments, equipment), EQ189 (otoscope-ophthalmoscope [wall unit]), EF048 (Portable stand-on scale), and EF023 (table, exam).

Sixteen of the telemedicine E/M codes describe use of either audio-video or audio-only telecommunications technology to furnish the individual service. The CPT Editorial Panel finalized eight codes for synchronous audio-video services (CPT codes 98000 to 98007), and eight codes for synchronous audio-only services (CPT codes 98008 to 98014), and one code for an asynchronous service (CPT code 98016). The audio-video and audio-only code family subsets have parallel codes for new patients and established patients. Like other E/M codes, these codes may be reported based on the level of medical decision making (MDM) or total time on the date of the encounter. For each set of four codes, there is a code that may be reported for a straightforward, low, moderate and high level of MDM.

The CPT Editorial Panel also established new CPT code 98016 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit (that is, a visit described by one of the office/outpatient E/M codes). The code descriptor for CPT code 98016 mirrors existing HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*) and, per the CPT Editorial Panel materials, is intended to replace that code. As described in CPT Editorial Panel final edits, CPT code 98016 does not require the use of audio or video technology and is expected to be patient-initiated. Furnishing the complete service described by CPT code 98016 must involve 5–10 minutes of medical discussion (and the code descriptor does not include MDM as means of code selection). CPT code 98016 should not be reported if it originates from a related E/M service furnished within the previous 7 days, or, if the clinical interaction leads to another E/M or procedure within the next 24 hours or the soonest available appointment. The final CPT Editorial Panel draft language explains that if the virtual check-in described by CPT 98016 leads to an E/M visit in the next 24 hours, and if that E/M is reported based on time, then the time from the virtual check-in may be added to the time of the resulting E/M visit to determine the total time on the date of encounter for the resulting E/M. The RUC recommended a work RVU of 0.30 for 98016.

The CPT Editorial Panel also deleted three codes (99441–99443) for reporting telephone E/M services. We note that CPT codes 99441, 99442, and 99443, each are assigned provisional status on the Medicare telehealth services list and would return to bundled status when the telehealth flexibilities expire on December 31, 2024. For further background, we referred readers to our discussions in previous rulemaking, where CMS explains the rationale for this policy (88 FR 78871–78878).

CMS has a longstanding interpretation of section 1834(m) of the Act as specifying the circumstances under which Medicare makes payment for services that would otherwise be furnished in person but are instead furnished via telecommunications technology. Specifically, section 1834(m)(2)(A) of the Act expressly requires payment to the distant site physician or practitioner of an amount equal to the amount that such physician or practitioner would have been paid had such service been furnished without the use of a telecommunications system. This means that we must pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). In the CY 2019 PFS final rule, we stated that ''[w]e have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional'' (83 FR 59483). Under this interpretation, services that are coded and valued based on the understanding that they are not ordinarily furnished in person, such as remote monitoring services and communication technology-based services, are not considered Medicare telehealth services under section 1834(m) of the Act, and thus, not subject to the geographic, site of service, and practitioner restrictions included therein.

Information provided to CMS from the RUC indicates that CPT codes 98000–98015 describe services that would otherwise be furnished in person, and as such the services described by these codes are subject to section 1834(m) of the Act. In the summary of the coding changes, the AMA states that these services are ''patterned after the in-person office visit codes.'' The draft CPT prefatory language states that ''[t]elemedicine services are used in lieu of an in-person service when medically appropriate to address the care of the patient and when the patient and/or family/caregiver agree to this format of care.'' The draft CPT prefatory language likewise states that when a telemedicine E/M is billed on the same day as another E/M service ''the elements and time of these services are summed and reported in aggregate, ensuring that any overlapping time is only counted once,'' which indicates that the work of the telemedicine E/M service is identical to the work associated with an in-person, non-telehealth E/M. The code descriptors and requirements for billing the codes generally mirror the existing office/outpatient E/M codes with the exception of the technological modality used to furnish the service. The audio-video telemedicine E/M codes have nearly identical recommended work RVUs to parallel office/outpatient E/M codes. In general, the audio-only telemedicine E/M codes have lower recommended work RVUs than parallel office/outpatient E/M codes. The RUC stated that this is because, when surveyed, specialty societies indicated that ''the audio-video and in-person office visits require more physician work than the audio-only office visits.''

Table 14 describes the similarities between 16 of 17 telemedicine E/M codes and the parallel office/outpatient E/M codes. The table shows that except for the element of ''modality'' (that is, audio-video or audio-only), the service elements of the new telemedicine E/M code family are no different than the O/O E/M codes (for each enumerated row 1 through 16 the columns display the analogous elements). When comparing code descriptors, as described at the start of this section,, the only difference (as represented in Table 14 when comparing the elements of E/M services represented by columns C, D, E, and F) is that these new telemedicine E/M code descriptors lead with the phrase ''synchronous audio-video'' or ''synchronous audio only'' before describing the visit in full exactly as the existing office/outpatient E/M visit codes describe a visit in the long descriptor of the analogous service.

TABLE 14: Comparison of Elements and Work RVU between Telemedicine E/M Codes (98000 through 98015) and Office/Outpatient E/M Codes (99202 through 99215)

	A	B	C	D	E	F	G	H
	Telemedicine E/M HCPCS	RUC-recommended Work RVU	Modality	Level of Medical Decision-Making	Time Threshold (minutes)	New or Established Patient?	Analogous Current Office/Outpatient E/M Code	Current Work RVU
1	98000	0.93	Audio/Video (A/V)	Straightforward	15	new	99202	0.93
2	98001	1.60	A/V	Low	30	new	99203	1.60
3	98002	2.60	A/V	Moderate	45	new	99204	2.60
4	98003	3.50	A/V	High	60	new	99205	3.50
5	98004	0.70	A/V	Straightforward	10	established	99212	0.70
6	98005	1.30	A/V	Low	20	established	99213	1.30
7	98006	1.92	A/V	Moderate	30	established	99214	1.92
8	98007	2.60	A/V	High	40	established	99215	2.80
9	98008	**0.90**	Audio-only	Straightforward	15	new	99202	0.93
10	98009	1.60	Audio-only	Low	30	new	99203	1.60
11	98010	**2.42**	Audio-only	Moderate	45	new	99204	2.60
12	98011	**3.20**	Audio-only	High	60	new	99205	3.50
13	98012	**0.65**	Audio-only	Straightforward	10	established	99212	0.70
14	98013	**1.20**	Audio-only	Low	20	established	99213	1.30
15	98014	**1.75**	Audio-only	Moderate	30	established	99214	1.92
16	98015	**2.60**	Audio-only	High	40	established	99215	2.80

There are services already describing audio-video and audio-only telemedicine E/M codes on the Medicare telehealth services list—the office/outpatient E/M code set—that can be furnished via synchronous two-way, audio/video communication technology generally and via audio-only communication technology under certain circumstances to furnish Medicare telehealth services in the patient's home for the purpose of diagnosis and treatment of a mental health disorder or SUD. Additionally, as stated above, section 1834(m)(2)(A) of the Act requires us to pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). Were we to accept the AMA's recommendations and add the telemedicine E/M codes to the Medicare telehealth services list, we would need to establish RVUs for the telemedicine E/M codes to equal the corresponding non-telehealth services to satisfy the requirements for payment under section 1834(m)(2)(A) of the Act.

We do not believe that there is a programmatic need to recognize the audio/video and audio-only telemedicine E/M codes for payment under Medicare. We proposed to assign CPT codes 98000–98015 a Procedure Status indicator of ''I'', meaning that there is a more specific code that should be used for purposes of Medicare, which in this case would be the existing office/outpatient E/M codes currently on the Medicare telehealth services list when billed with the appropriate POS code to identify the location of the beneficiary and, when applicable, the appropriate modifier to identify the service as being furnished via audio-only communication technology.

Section 4113 of the Consolidated Appropriations Act (CAA), 2023 extended the availability of Medicare telehealth services to beneficiaries regardless of geographic location or site of service by temporarily removing such statutory restrictions under section 1834(m) of the Act until the end of 2024. Under the current statute, the geographic location and site of service restrictions on Medicare telehealth services will once again take effect for services furnished beginning January 1, 2025. Although there are some important exceptions, including for behavioral health services and ESRD-related clinical assessments, most Medicare telehealth services will once again, in general, be available only to

beneficiaries in rural areas and only when the patient is located in certain types of medical settings. As previously discussed, the introduction of new CPT coding to describe telemedicine E/M services does not change our authority to pay for visits furnished through interactive communications technology in accordance with section 1834(m) of the Act. We recognize that there are significant concerns about maintaining access to care through the use of Medicare telehealth services with the expiration of the statutory flexibilities that were successively extended by legislation following the PHE for COVID–19. We understand that millions of Medicare beneficiaries have utilized interactive communications technology for visits with practitioners for a broad range of health care needs for almost 5 years. We sought comment from interested parties on our understanding of the applicability of section 1834(m) of the Act to the new telemedicine E/M codes, and how we might potentially mitigate negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization. On the latter point, we noted that we have developed PFS payment rates for CY 2025, including the statutory budget neutrality adjustment, based on the presumption that changes in telehealth utilization will not affect overall service utilization. We also noted that historically we have not considered changes in the Medicare telehealth policies to result in significant impact on utilization such that a budget neutrality adjustment will be warranted. However, we are unsure of the continuing validity of that premise under the current circumstances where patients have grown accustomed over several years to broad access to services via telehealth. We sought comment on what impact, if any, the expiration of the current flexibilities will be expected to have on overall service utilization for CY 2025. We referred readers to section e. of this final rule for our discussion of budget neutrality adjustments.

Given the similarity between CPT code 98016 and HCPCS code G2012, we proposed to accept the RUC-recommended values for CPT code 98016, and we proposed to delete HCPCS code G2012. For CPT code 98016, we proposed to accept the RUC-recommended work RVU of 0.30, and proposed the RUC-recommended direct PE inputs. We noted that our proposal does maintain the same direct PE inputs, which the RUC recommendations leave unchanged from the current G2012 in total amount, and allocate the same 3 minutes of time to the same level of staff (Clinical Staff code L037D, RN/LPN/MTA). We believe that the coding and payment recommendations for CPT code 98016, submitted to CMS by the AMA RUC, accurately reflect the resources associated with this service and believe that maintaining separate coding for purposes of Medicare payment could create confusion. We noted that, similar to our current policy for payment of HCPCS code G2012, CPT code 98016 will be considered a communication technology-based service that is not subject to the requirements in section 1834(m) of the Act applicable to Medicare telehealth services.

Comment: Many commenters, including specialty societies representing primary care and behavioral health practitioners, supported our proposal and stated that they agreed with CMS' interpretation of section 1834(m) of the Act. Given the limitations of the statute, these commenters stated that the office/outpatient E/M codes currently on the Medicare telehealth services list are sufficient to describe visits furnished to beneficiaries through telecommunications technology and that adopting the new telemedicine E/M codes would create confusion with the existing office/outpatient E/M codes already on the Medicare telehealth services list.

Other commenters, including the AMA, disagreed with our interpretation of Medicare telehealth services under section 1834(m) of the Act and stated that, as these codes describe a service that is definitionally not furnished in person, they would not be subject to the statutory restrictions. The AMA provided a detailed rebuttal of our proposal stating that the valuation of the telemedicine E/M codes reflects the use of telecommunications technology and as a result they are not ''coded and paid'' as though the service occurred in person. Furthermore, these commenters stressed that CMS should use every tool at its disposal to maintain access to Medicare telehealth services in the face of the expiration of the statutory flexibilities, and that by recognizing and making payment for the telemedicine E/M codes, CMS would preserve access to care for many beneficiaries.

Other commenters encouraged CMS, even if we do not pay separately for the telemedicine E/M codes, to publish values in our payment files in case private payors wish to recognize the codes. Lastly, a few commenters also suggested that it would be helpful to have educational materials to better inform interested parties on how to bill telehealth services appropriately.

Response: We thank commenters for their support for our proposal.

We do not find the comments put forth by the AMA and other commenters who opposed our proposal to be persuasive. They do not adequately address how or why the services described by the sixteen new telemedicine E/M codes are distinct from E/M services ordinarily furnished in person such that they are outside the scope of section 1834(m) of the Act. Except for the service delivery modality, the new telemedicine E/M codes appear to describe the same services that are provided in person and billed under the existing office/outpatient E/M codes (99202–99215) and expressly referenced in section 1834(m)(4)(F)(i) of the Act as telehealth services. Although commenters suggest that the services described by the two code sets are different because there are different resources (PE and work) involved in furnishing them, those differences merely reflect delivery of the services through different modalities (in person or as telehealth services). Moreover, under section 1834(m)(2)(A) of the Act, CMS is required to make payment for Medicare telehealth services, regardless of the resources involved in furnishing the telehealth service, at ''an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.'' As such, we do not believe that the differences in the resources involved in furnishing the same service in-person or via telehealth are a relevant consideration for purposes of payment for Medicare telehealth services. We are concerned that were we to accept the position that the new telemedicine E/M codes are not subject to section 1834(m) of the Act because the codes describe services that are ''inherently'' not a substitute for an in-person service, we would circumvent the express requirements of section 1834(m) of the Act simply by creating new parallel codes that describe the same services when furnished remotely using telecommunications technology.

We note in response to the comments requesting that CMS display RVUs for these services, the RVU values for these services are displayed in Addendum B of the PFS, which is available for download at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.* We will also consider issuing additional guidance and educational materials regarding appropriate billing for

Medicare telehealth services in the future.

Comment: Commenters were universally supportive of our proposal to replace HCPCS code G2012 with CPT code 98016.

Response: We thank commenters for their support.

After consideration of the comments, we are finalizing our proposal to not pay separately for CPT codes 98000, 98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98009, 98010, 98011, 98012, 98013, 98014, 98015, and to pay separately for CPT code 98016 in lieu of HCPCS G2012.

(19) Genetic Counseling Services (CPT Code 96041)

In September 2023, the CPT Editorial Panel deleted CPT code 96040 (*Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family*) and created CPT code 96041 (*Medical genetics and genetic counseling services, each 30 minutes of total time provided by the genetic counselor on the date of the encounter*) for medical genetics and genetic counseling services to be provided by the genetic counselor. Prior to its deletion, CPT code 96040 will only be reported by genetic counselors for genetic counseling services, though genetic counselors are not among the practitioners who can bill Medicare directly for their professional services. As we stated in the CY 2012 PFS final rule (76 FR 73096 through 73097), physicians and NPPs who may independently bill Medicare for their services and who are counseling individuals will generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling; therefore, CPT code 96040 was considered bundled into O/O E/M visits.

For CPT code 96041, we proposed the RUC-recommended direct PE inputs. We note that the code descriptor now specifies that the service is provided by a genetic counselor; therefore, we considered assigning Procedure Status ''X'' to CPT code 96041. Because the PE RVUs will not display for the code with that assignment and that may impact access to the service with other payors, we instead proposed bundled status (Procedure Status ''B'') for CPT code 96041 to maintain the status of predecessor CPT code 96040, and we sought feedback from interested parties regarding the appropriate procedure status for this code. CPT guidelines for CPT code 96041 state that a physician or other qualified healthcare professional (QHP) who may report evaluation and management services will not be able to report CPT code 96041. Instead, these physicians and QHPs will use the appropriate evaluation and management code.

Comment: A few commenters expressed disappointment that CMS did not propose to reintegrate the cost of the pedigree software subscription. As part of their revaluation of this service, the AMA RUC recommended the removal of the software as equipment based on their interpretation of CMS guidelines regarding what constitutes as direct versus indirect PE. Commenters stated that the software is a critical part of genetic counseling as it both creates the genetic family history and calculates risk based on validated models. The commenters also stated that cost of pedigree is very specialized and used exclusively for patient and family evaluations specific to genetic services and recommended that CMS consider re-including the cost of pedigree software that was included in the predecessor code.

Response: We disagree with the commenters that the costs associated with the pedigree system should be included as a direct PE input. We continue to believe that both the cloud-based pedigree subscription and the pedigree software previously included as a direct PE input for CPT code 96040 constitute forms of indirect PE. We note that there have been occasions in the past where we have finalized the inclusion of software as a direct PE expense if it met our criteria as typical and medically necessary for the service in question and could be individually allocable to a particular patient for a particular service, but we believe that the annual licensing requirements and costs for the cloud-based pedigree subscription are administrative costs that are not unique to individual procedures. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses not directly allocable to an individual service.

Comment: In their comment letter, the AMA RUC reiterated their request for the establishment of a new clinical labor type for genetic counseling assistants (GCAs) but supported the crosswalk to Physical Therapy Assistant (L039B) and agreed that it is an appropriate proxy for the clinical labor rate per minute. The AMA RUC also supported our proposal to maintain the Procedure Status ''B'' of its predecessor CPT code 96040, and thanked CMS for publishing the values for other payors to be able to utilize. Numerous other commenters also supported the proposal to assign Procedure Status ''B'' to CPT code 96041.

Response: We appreciate the commenters' support and are finalizing the RUC-recommended direct PE inputs and Procedure Status ''B'' for CPT code 96041 as proposed.

(20) COVID Immunization Administration (CPT Code 90480)

On August 14, 2023, new CPT codes were created to consolidate over 50 previously implemented codes and streamline the reporting of immunizations for the novel coronavirus (SARS–CoV–2, also known as COVID–19). The CPT Editorial Panel approved the addition of a single administration code (CPT code 90480) for administration of new and existing COVID–19 vaccine products. The RUC reviewed the specialty societies' recommendations for this code at the September 2023 RUC meeting.

We proposed the RUC-recommended work RVU of 0.25 for CPT code 90480 (*Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (coronavirus disease [COVID–19]) vaccine, single dose*). We also proposed the RUC-recommended direct PE inputs for CPT code 90480 without refinement.

Comment: Several commenters stated their support for the proposed work RVU and thanked CMS for proposing the RUC recommendations.

Response: We appreciate the support from the commenters for our proposals.

Comment: Several commenters requested that CMS consider a longer phase-in period to implement the RUC-recommended work RVUs for COVID–19 vaccine administration to allow ample time for provider education and preparation for potential payment reductions. The commenters stated although CMS is proposing to maintain the $40 administration fee through the year in which Food and Drug Administration (FDA) rescinds the Emergency Use Authorization (EUA) Declaration, the commenters believe that, if it is adopted into the PFS, COVID–19 vaccine administration reimbursement rates would likely decline for providers serving patients with Medicaid and commercial insurance coverage. The commenters requested that CMS not list the RVUs for CPT code 90480 in the Physician Fee Schedule final rule until the EUA declaration is rescinded as the policy is counter to population health initiatives and could result in stakeholder confusion regarding the payment rate

for this code within the Medicare program versus other markets.

Response: We appreciate the feedback from the commenters and clarify that payment for CPT code 90480 is already addressed under previously finalized policies associated with the EUA declaration (see for example the vaccine pricing section of the CMS website at *https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing*). We agree with the commenters that it would avoid potential confusion if we do not display the RVUs for CPT code 90480 as payment will not be made using this valuation under the PFS. The proposal to assign separate pricing under the PFS for CPT code 90480 was an unintended error; we did not intend any confusion that may have been caused by the publication of these RVUs in the proposed rule.

After consideration of the comments, we are not finalizing the RUC-recommended work RVU and direct PE inputs for CPT code 90480 at this time. We refer readers to our current policies for paying for the service described by CPT code 90480, available at *https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing* as well as the discussion in section III.B of this final rule.

(21) Optical Coherence Tomography (CPT Codes 92132, 92133, 92134, and 92137)

At the February 2023 CPT Editorial Panel meeting, CPT code 92137 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina including OCT angiography*) was created in response to new technology that allows imaging of the retina using optical coherence tomography (OCT) with and without non-dye OCT angiography (OCT–A). This code family also includes CPT code 92132 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral*), CPT code 92133 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; optic nerve*), and CPT code 92134 (*Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina*). These codes were reviewed at the April 2023 RUC meeting. The RUC determined the survey results were inaccurate due to underestimation of time, so the entire code family was re-surveyed and reviewed at the September 2023 RUC meeting.

We proposed the RUC-recommended work RVUs for all codes within the Optical Coherence Tomography code family. We proposed a work RVU of 0.29 for CPT code 92132, a work RVU of 0.31 for CPT code 92133, a work RVU of 0.32 for CPT code 92134, and a work RVU of 0.64 for CPT code 92137. We also proposed the RUC-recommended direct PE inputs for all four codes in the family.

Comment: Commenters generally agreed with CMS' proposed work RVU and direct PE inputs. One commenter disagreed with CMS' proposed work RVUs for CPT codes 92132, 92133, and 92134 and urged CMS to maintain the current work RVUs for those codes and adopt the RUC-recommended work RVU for CPT code 92137.

Response: We thank commenters for their support. We also acknowledge the commenter's request to maintain the current work RVUs for CPT codes 92132, 92133, and 92134. We disagree with the commenter and continue to believe that the RUC-recommended work RVUs for these 3 codes, that are cross-walked from other codes with similar intensity and that align with the surveyed reduction of intraservice times, appropriately account for the physician work required to perform this service. After consideration of all comments, we are finalizing the work RVUs and direct PE inputs as proposed.

(22) Transcranial Doppler Studies (CPT Codes 93886, 93888, 93892, 93893, 93896, 93897, 93898, and 93890)

The RUC's Relativity Assessment Workgroup (RAW) requested action plans in September 2022 to determine if specific code bundling solutions should occur for CPT codes 93890/93886, 93890/93892, 93892/93886, and 93892/93890. The RAW referred this issue to the CPT Editorial Panel which created three new add-on codes to report when additional studies are performed on the same date of services as a complete transcranial Doppler study. The RUC reviewed these three new add-on codes, as well as CPT codes 93886, 93888, 93892 and 93893 for the September 2023 RUC meeting.

We proposed the RUC-recommended work RVU for all seven codes in the Transcranial Doppler Studies code family. We proposed a work RVU of 0.90 for CPT code 93886 (*Transcranial Doppler study of the intracranial arteries; complete study*), a work RVU of 0.73 for CPT code 93888 (*Transcranial Doppler study of the intracranial arteries; limited study*), a work RVU of 1.15 for CPT code 93892 (*Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection*), a work RVU of 1.15 for CPT code 93893 (*Transcranial Doppler study of the intracranial arteries; venous-arterial shunt detection with intravenous microbubble injection*), a work RVU of 0.81 for CPT code 93896 (*Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete*), a work RVU of 0.73 for CPT code 93897 (*Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete*), and a work RVU of 0.85 for CPT code 93898 (*Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete*). We also proposed the direct PE inputs as recommended by the RUC for all seven codes in this family.

We note that the billing instructions for this code family specify that the three new add-on codes should be used in conjunction with CPT code 93886, and that CPT code 93888 should not be used in conjunction with CPT codes 93886, 93892, 93893, 93896, 93897, and 93898. However, we believe that it would be beneficial for the CPT Editorial Panel to state more explicitly that CPT code 93897 should not be used in conjunction with CPT code 93892 and that CPT code 93898 should not be used in conjunction with CPT code 93893. The work performed in the add-on codes would be duplicative of the base codes in these situations and result in unnecessary overbilling of services.

Comment: Several commenters stated their support for the CMS proposal of the RUC's recommended work RVUs and direct PE inputs for these seven codes. Commenters also acknowledged the CMS recommendation to the AMA CPT Editorial Panel to more explicitly state that CPT code 93897 should not be used in conjunction with CPT code 93892 and CPT code 93898 should not be used in conjunction with 93893. Commenters stated that they were committed to providing education to their members on the appropriate use of the revised code set for 2025.

Response: We appreciate the support from the commenters for our proposals, as well as their recognition on the need for clarification on the billing of certain add-on codes.

Comment: Several commenters disagreed with the proposal of the RUC's recommended direct PE inputs, specifically the equipment times for the vascular ultrasound room (EL016) and

the technologist PACS workstation (ED050). Commenters stated that the RUC based its recommendations for the technical component of these codes on a small sample size survey distributed to selected members of three societies that are not representative of all transcranial doppler (TCD) practices. Commenters stated that they conducted a survey of their TCD-focused membership which found that the RUC—and now CMS—systematically overcounted time for the PACS workstation and undercounted time in the ultrasound room. Commenters stated that PAC workstation and ultrasound exam times can vary widely depending on the patient and results needing to be reviewed; staffing time and scheduling are a constant challenge due to these variables. Commenters urged CMS not to finalize the proposed changes to the TCD base codes and, at the least, CMS should conduct additional study before making any changes in light of the commenters' data from practitioners that frequently perform TCD.

Response: We understand the difficulty of determining accurate equipment times due to the variation that can take place depending on the patient and results needing review. For this reason, our PE methodology bases valuation on the typical case, understanding that some cases will involve fewer time/resources and other cases will be more complex and difficult. This is also why we typically use standardized formulas to calculate equipment times; we believe that the use of these standardized equipment time formulas allows for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times across the wider PFS.

For the specific case of the codes in the TCD Studies family, the RUC recommended and we proposed equipment times based on these standard equipment time formulas. We specifically proposed equipment time for the vascular ultrasound room (EL016) based on the standard for highly technical equipment. As we have addressed in past rulemaking, we believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the pre-service or post-service tasks performed by clinical labor on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure. Since the direct PE input database should reflect the typical resource costs of medical equipment, we believe that the reduced minutes and increased utilization rate for these highly technical equipment items are complementary, not contradictory (77 FR 69028).

The surveyed equipment times for the vascular ultrasound room (EL016) submitted by the commenter are all higher than our proposed equipment times based on the use of this standard for highly technical equipment. For example, the survey submitted by the commenter lists 61–65 minutes of equipment time for CPT code 93886 as opposed to our proposed 57 minutes. However, the total intraservice clinical labor time for CPT code 93886 is only 70 minutes which would mean that the vascular ultrasound room would be in use for nearly the entirety of this period if we were to use the commenter's equipment time suggestions. As we discussed above, we believe that many of the preservice and post-service clinical labor tasks typically take place outside of resource-intensive equipment rooms to maximize use of capital-intensive resources since monopolizing the room for fewer minutes per patient maximizes the availability of the machines. We do not believe that it would be typical to perform tasks such as Greeting/gowning the patient (CA009), Obtain vital signs (CA010), or Provide education/obtain consent (CA011) in the vascular ultrasound room, some or all of which would need to take if the survey times submitted by the commenter were to be true. Therefore, we continue to believe that the RUC's recommended equipment times, based on the use of standardized equipment time formulas, best reflect the typical case for these Transcranial Doppler Studies codes.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for the CPT codes in the Transcranial Doppler Studies family as proposed.

(23) RSV Monoclonal Antibody Administration (CPT Codes 96380 and 96381)

At the September 2023 CPT meeting, the CPT Editorial Panel created two codes to report passive administration of respiratory syncytial virus, monoclonal antibody, seasonal dose, with and without counseling. CPT codes 96380 and 96381 were reviewed the following week at the September 2023 RUC meeting and the RUC submitted recommendations to CMS.

We proposed the RUC-recommended work RVU of 0.24 for CPT code 96380 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional*) and the RUC-recommended work RVU of 0.17 for CPT code 96381 (*Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection*). We understand that these are interim work recommendations from the RUC, and that the RUC intends to conduct a more complete review at a future RUC meeting which we will then consider in future rulemaking. We also proposed the direct PE inputs as recommended by the RUC for both codes.

Comment: A commenter stated that they supported these changes but recommended that the RUC conduct a more complete review for these codes.

Response: We appreciate the support for our proposed valuations from the commenter.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for the CPT codes in the RSV Monoclonal Antibody Administration family as proposed.

(24) Hyperthermic Intraperitoneal Chemotherapy (CPT Codes 96547 and 96548)

In September 2022, the CPT Editorial Panel created two time-based add-on Category I codes, CPT code 96547 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)*) and CPT code 96548 (*Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes (List separately in addition to code for primary procedure)*), to report HIPEC procedures for 2024. At the January 2023 RUC meeting, the RUC reached the conclusion that the survey data was flawed due to a lack of work definition and guidelines, and the RUC recommended contractor pricing for CPT codes 96547 and 96548 for CY 2024 with further clarification from the CPT editorial panel. CMS proposed and finalized contractor pricing for CPT codes 96547 and 96548 for 2024. At the May 2023 CPT Editorial Panel meeting, new guidelines and descriptions of work activities were approved and the codes were resurveyed for the September 2023 RUC meeting with recommendations for national pricing.

We proposed the RUC-recommended work RVU of 6.53 for CPT code 96547

and the RUC-recommended work RVU of 3.00 for CPT code 96548. The RUC did not recommend, and we did not propose, any direct PE inputs for the Hyperthermic Intraperitoneal Chemotherapy codes (CPT codes 96547 and 96548).

Comment: Commenters agreed with CMS' proposed work RVU and direct PE inputs for this code family.

Response: We thank commenters for their support. After consideration of the public comments, we are finalizing the work RVU and direct PE inputs as proposed.

(25) Laser Treatment—Skin (CPT Codes 96920, 96921, and 96922)

In April 2022, the RUC referred CPT codes 96920 (*Excimer laser treatment for psoriasis; total area less than 250 sq cm*), 96921 (*Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm*), and 96922 (*Excimer laser treatment for psoriasis; over 500 sq cm*) to the CPT Editorial Panel to capture expanded indications beyond what was currently noted in the codes' descriptions to include laser treatment for other inflammatory skin disorders such as vitiligo, atopic dermatitis, and alopecia areata, which could result in changed physician work based on the expanded indications. The coding change application was subsequently withdrawn from the September 2023 CPT Editorial meeting when it was determined that existing literature was insufficient and did not support expanded indications at that time. Therefore, these CPT codes were re-surveyed and reviewed at the April 2023 RUC meeting without any revisions to their code descriptors.

We disagreed with the RUC-recommended work RVUs for CPT codes 96920, 96921, and 96922 of 1.00, 1.07, and 1.32, respectively. The RUC noted that there have been multiple reviews of these CPT codes, and the valuation of the codes is currently based on the original valuation over two decades ago in 2002 where the physician time values were lower than the current times. A subsequent review in 2012 adopted new survey times while maintaining the work RVUs from 2002 for CPT codes 96920 and 96922. The RUC noted that, for both CPT code 96920 and 96922 with the largest treatment area, the total times have not changed since first implemented more than 20 years ago. While we understand that the physician times have fluctuated over the course of several years and several reviews, yet the work RVUs have remained mostly constant as shown in Table 15, this was not addressed in the 2012 recommendations, and we believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely over or underestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. We also believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs.

TABLE 15: Physician Time and RVUs for CPT Codes 96920, 96921, and 96922

CPT Code		Intraservice Time	Total Time	RUC Recommended Work RVU
96920	2002	17	27	1.15
	Current (from 2012)	23	35	1.15
	Recommended	10	23	1.00
96921	2002	20	30	1.17
	Current (from 2012)	30	42	1.30
	Recommended	12	25	1.07
96922	2002	30	40	2.10
	Current (from 2012)	45	57	2.10
	Recommended	18	31	1.32

For CPT code 96920, we proposed a work RVU of 0.83 based on a crosswalk to CPT code 11104 (*Punch biopsy of skin (including simple closure, when performed); single lesion*), which has the same 10 minutes of intraservice time and 23 minutes of total time as CPT code 96920. We noted that of the 15 other 000-day global codes with a total time of 20 to 25 minutes, only four codes fall above the RUC-recommended work RVU of 1.00. While we understand that commenters will dispute the validity of the current time values, we note that the 2002 intraservice time was 17 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 10 minutes of 0.68 work RVUs ((10 minutes/17 minutes) * 1.15). We noted our work RVU of 0.83 maintains the intensity associated with the 2002 review of CPT code 96920, which we believe to be more appropriate than the significant increase in intensity that results from the RUC-recommended work RVU of 1.00 which nearly doubles the current intensity of the code. We have no evidence to indicate that the intensity of CPT code 96920 is increasing to this degree given how the surveyed work time is substantially decreasing.

For CPT code 96921, we proposed a work RVU of 0.90 based on a total time ratio to CPT code 96920 ((25/23)*0.83) and a crosswalk to CPT code 11301 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm*), which has 3 additional minutes of intraservice time and 1 additional minute of total time compared to CPT code 96921. We also noted that our work RVU of 0.90 for CPT code 96921 maintains the RUC-

recommended incremental difference between CPT codes 96920 and 96921 of 0.07 work RVUs. Like CPT code 96920, we understand that commenters will dispute the validity of the current time values, but we note that the 2002 intraservice time was 20 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 12 minutes of 0.70 work RVUs ((12 minutes/20 minutes) * 1.17). Like CPT code 96920, we noted that work RVU of 0.90 for CPT code 96921 maintains the intensity associated with the 2002 review of CPT code 96921, which we believe is more appropriate than the intensity increase that results from the RUC-recommended work RVU of 1.07 which again nearly doubles the current intensity of the code.

For CPT code 96922, we proposed a work RVU of 1.15 based on the RUC-recommended incremental difference between CPT codes 96921 and 96922 of 0.25 work RVUs. Like CPT code 96920 and 96921, we understand that commenters will dispute the validity of the current time values, but we noted that the 2002 intraservice time was 30 minutes, which yields an intraservice time ratio between the 2002 intraservice time and the recommended intraservice time of 18 minutes of 1.26 work RVUs ((18 minutes/30 minutes) * 2.10). We note that the RUC recommended CPT code 96922 as having the lowest intensity of the three codes in this family and that our work RVU of 1.15 maintains in relationship to the other codes.

For the direct PE inputs, we proposed to refine the clinical staff time for the CA024 activity ''Clean room/equipment by clinical staff'' to the standard of 3 minutes for CPT codes 96920, 96921, and 96922. We noted that 3 minutes is the current CA024 time for these three CPT codes. A rationale for extending clinical staff beyond the standard 3 minutes for the CA024 activity was absent from the PE Summary of Recommendations; therefore, we believe the current and standard 3 minutes is more appropriate than the RUC-recommended 5 minutes. We also proposed equipment times of 36, 38, and 44 minutes for the power table (EF031) and exam light (EQ168) equipment for CPT codes 96920, 96921, and 96922, respectively, to account for the refinement for CA024 to the standard 3 minutes.

We also disagreed with the RUC-recommended creation of new supply items for the excimer laser and proposed to re-include the equipment time for the excimer laser (EQ161) using the current methodology where its cost is accounted for in the equipment of these CPT codes' direct PE. The RUC submitted recommendations to change this equipment item to new supply items to account for the per-use cost to rent the equipment, stating that the business model has changed from the standard equipment ownership that CMS recognizes using standardized equipment formulas to a per-use rental or subscription model. While we understand that there may have been a change in business model, we do not believe a rental, subscription, or per-use fee of an equipment item that is still available to be purchased and is already accounted for with our equipment methodology is appropriate, especially given its implications for direct PE costs for these CPT codes. Therefore, we proposed reincorporating equipment times of 36, 38, and 44 minutes for the EQ161 equipment for CPT codes 96920, 96921, and 96922, respectively, based on the refined service period clinical labor times. We proposed to remove the three pay-per-use excimer lasers listed as supplies and recommended by the RUC for these three codes.

We have repeatedly stated in past rulemaking that rental and licensing fees are typically considered forms of indirect PE under our methodology. In the CY 2020 PFS final rule, we omitted the inclusion of several invoices for the monthly rental price of a PET infusion cart (ER109), and only accounted for the four purchase invoices for the equipment. We noted as well for future reference that although we appreciated the submission of the rental invoices, we were unable to use invoices for a monthly rental fee to determine the typical purchase price for equipment. We believe that invoices for a monthly rental fee would not be representative of the purchase price for equipment, in the same fashion that the rental fee for a car differs from its purchase price (84 FR 62771). Similarly, while we appreciate the submission of per-use, rental, and partnership invoices for the excimer laser, we believe that the excimer laser is appropriately and adequately accounted for in the equipment formula and note that EQ161 has a very high cost per minute of $0.5895/minute. Compared to the nearly 700 other equipment items in our database, only 55 equipment items have higher costs per minute (based on our standardized formula which accounts for years of useful life, utilization rate, purchase price, and minutes per year of use, outlined in detail in section II.B. of this final rule, Determination of PE RVUs) and only 53 equipment items have higher purchase prices than the excimer laser at $151,200. We do not believe that CPT codes 96920 through 96922 should be valued based on a significantly more expensive pay-per-use rental version of the excimer laser when the same treatment is cheaper and available as a purchasable form of equipment.

Therefore, we sought comment on the difference in direct PE costs between the purchase and per-use rental of the laser. We noted that using the equipment cost per minute formula, outlined in detail in section II.B. of this final rule, Determination of PE RVUs, yields direct PE costs of about $21.22, $22.40, and $25.94 for CPT codes 96920, 96921, 96922, respectively. Alternatively, the new supply items for the per-use fee of the laser yielded direct PE costs of $80, $83, and $100 for CPT codes 96920, 96921, 96922, respectively. These direct PE disparities represent a 277 percent, 270.5 percent, and 285.5 percent increase for CPT codes 96920, 96921, 96922, respectively. Given this, we are interested in feedback from interested parties on the payment disparity between this equipment as a per-use or rental versus how we currently account for the purchase of equipment using the standard equipment formula, as we understand that both manufacturers and physicians may be inclined to shift to a per-use or rental business models to limit overhead for purchase and maintenance of expensive equipment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters disagreed with the proposed work RVUs of 0.83, 0.90, and 1.15 for CPT codes 96920, 96921, and 96922, respectively, and encouraged CMS to finalize the RUC-recommended work RVUs of 1.00, 1.07, and 1.32, respectively. Some commenters disagreed with the crosswalks of CPT code 11104 to CPT code 96920, and CPT code 11301 to CPT code 96921, because the intensity of CPT codes 96920 and 96921 is greater than CPT codes 11104 and 11301 as excimer laser treatment requires a high amount of skill and precision to ensure that healthy tissues are not damaged and the procedure causes significant pain requiring patients to have numbing agents applied to their lesions. The commenters also stated that the excimer laser treatment occurs over a large body surface area and is associated with risks, including burns, swelling, and increased skin sensitivity to light.

Commenters also disagreed with our application of total time ratios to both the current times and original 2002 intraservice times, the latter of which the AMA RUC and commenters reiterate

that the current valuations are based on. Commenters disagreed with the use of total time ratios to account for changes in time as the physician times were increased in 2012 without a commensurate work RVU increase, untethering the current assigned times and work RVUs. In their comment letter, the AMA RUC stated that RUC recommended crosswalks already reflected significant decreases from the current valuations of these codes to reflect the differences in work in treating different body surface areas for this condition. Further, the RUC stated in its rationale that there have been multiple reviews of this code set, and the valuation of the codes is currently based on the original valuation over two decades ago in 2002, where the time was lower than the current times, therefore the current work RVUs are based on the lower 2002 times, not the current times. The AMA RUC reiterated their support of their recommended work RVU crosswalk of CPT code 96920 to CPT code 20606 with a work RVU of 1.00. For CPT code 96921, the AMA RUC reiterated their support of an incremental 0.07 work RVU difference between CPT codes 96920 and 96921 but disagreed with a starting point of 1.00 work RVUs for CPT code 96920.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, so we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We also continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. Consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

With regards to the current work RVUs and physician time becoming untethered, we refer readers back to our intraservice time ratios between the 2002 times and the RUC-recommended times, which result in lower work RVUs than our proposed work RVUs. We also reiterate that our proposed work RVUs maintains the intensity associated with the 2002 review of CPT codes 96920, which commenters and the AMA RUC assert that the work RVUs are tethered to the 2002 physician times.

With regards to the relativity of intensity and complexity of CPT codes 96920 compared to CPT code 11104, we continue to believe that the intensity of the two services are similar. Commenters stated that excimer laser treatment requires a high amount of skill and precision to perform to ensure that healthy tissues are not damaged, and the procedure causes significant pain that requires patients to have numbing agents applied to their lesions. Similarly, according to CPT code 11104's vignette and pre-service activities, deeply invasive basal or squamous cell carcinoma may be involved, therefore requiring similar skill and precision to perform, and CPT code 11104 involves the injection of the appropriate local anesthetic at the procedure site.

Similarly, we continue to believe that the intensity of CPT codes 96921 and 11301 are similar because CPT code 11301 requires significant skill and precision to perform based on the intraservice activities described and it also involves the injection of anesthetic into both subcutaneous and dermal compartments to facilitate the appropriate dermal depth removal.

We have no evidence to indicate that the intensity of CPT codes 96920 and 96921 is increasing to the degree that the AMA RUC recommended, given how the surveyed work time is substantially decreasing from both current and 2002 physician times. We also believe maintaining the intensities associated with the 2002 review for these codes is more appropriate than the significant intensity increases that results from the RUC-recommended work RVUs, particularly given the excimer laser manufacturer's comment stating that there has been no device or procedural change that would increase the intensity or decrease the physician times, as the RUC recommended.

Comment: One commenter stated that, although the April 2023 surveyed changes in physician time to perform the procedures resulted in reduced work RVU recommendations, the way the procedures are performed today are essentially unchanged from the earlier time study so reductions in physician time would not be expected, particularly in the amounts suggested by the surveys. The commenter believes the survey should be redone, with a population that reflects actual users of the device because there has been no device or procedural change that warrants such dramatic changes in treatment time.

Response: We acknowledge the commenter's concerns regarding the surveyed physician time decreases for CPT codes 96920 through 96922 and encourage the commenter to coordinate with the RUC to facilitate a reconsideration of the physician work times if the commenter believes the physician times reported by the surveys are incorrect.

Comment: The AMA RUC disagreed with our proposal to refine the clinical staff time for the CA024 activity ''Clean room/equipment by clinical staff'' to the

standard and current time of 3 minutes for CPT codes 96920, 96921, and 96922 because a rationale for increasing clinical staff time beyond the standard 3 minutes for the CA024 activity was absent from the PE Summary of Recommendations. The AMA RUC stated that, during the laser treatment, each treatment site is covered with mineral oil to aid in the transmission of ultraviolet laser light through psoriatic plaques and the patient is repeatedly repositioned which results in the mineral oil getting all over the treatment table and often on the floor. The commenter stated that, after treatment, multiple greasy topical medications are applied to the treated sites and the standard time for room and equipment cleaning of 3 minutes is inadequate to properly clean greasy surfaces. The commenter requested that we refine CA024 for the three codes to provide an additional 2 minutes that is required for this vital staff function.

Response: We appreciate the AMA RUC's clarification on the additional 2 minutes beyond the 3-minute standard for CA024. We note that we proposed to refine this activity to the standard because a rationale for increasing clinical staff time beyond the standard 3 minutes for the CA024 activity was absent from the PE Summary of Recommendations. We agree with the commenter that 5 minutes would be more appropriate to properly clean multiple greasy surfaces and are finalizing the RUC-recommended 5 minutes for CA024 for CPT codes 96920, 96921, and 96922. We note that, as a result of changing CA024, we are finalizing the equipment times of 38, 40, and 46 minutes for the power table (EF031) and exam light (EQ168) equipment for CPT codes 96920, 96921, and 96922, respectively, to account for the finalized refinement for CA024 to the RUC-recommended 5 minutes.

Comment: An excimer laser vendor commented that a dermatology office would need to perform at least 1,150 excimer laser procedures a year to breakeven on the purchase cost of an excimer laser. The commenter stated that the breakeven volume is approximately 3.5 times higher than the actual volume, with typical utilization of 344 treatments per excimer laser per year. The commenter stated that the PE cost for one excimer treatment should be no less than $90.45 to achieve breakeven on the purchase of an excimer laser.

The commenter also stated that, when the AMA RUC reviewed the cost of the excimer laser, it made changes to the cost elements that are not reflective of the actual sales cost of the excimer laser, or its cost of maintenance. The commenter suggested that the sales price has gone up, along with the increased costs associated with service, inflation, training. The excimer laser vendor also confirmed in their comment letter that although they sell the excimer laser to private dermatology practices and hospital facilities, it is not common. The commenter stated that about 900 devices of the 1,200 excimer lasers operating in the Unites States are based on the subscription model.

Another commenter supported our proposal to maintain the equipment time for EQ161 and remove the three pay-per-use excimer laser subscriptions from the list of supplies and stated that the equipment associated with these services can be purchased rather than leased, and a ''change in business model'' for some practices does not warrant a drastic shift in how the Agency reimburses for equipment costs borne by practices. Additionally, the commenter expressed concern that such a policy could alter market dynamics, pushing more vendors to compel physician practices into subscription models. The commenter stated that these models often lead to higher long-term costs, and diminished flexibility, as ongoing fees and usage restrictions can directly impact patient care. The commenter also stated that the dependency on vendors' subscription agreements can erode practices' control over essential equipment, resulting in unfavorable terms and potential price hikes over time. The commenter stated that subscription models may worsen disparities in access to advanced medical technologies, impede the adoption of innovative treatments, raise significant concerns about data security and privacy, and increase the risk of market monopolization, where a few vendors could dominate, driving up costs and limiting choices for practices. Lastly, the commenter stated that if CMS were to use vendor subscription charges as the basis for practice expense payments, there would be no market discipline and encourage vendors to increase subscription costs, knowing that the increased cost would be borne by CMS.

Response: We appreciate the commenter's support and input relating to our request for additional information regarding the difference in direct PE costs between the purchase and per-use rental of the laser and the payment disparity between this equipment as a per-use or rental versus how we currently account for the purchase of equipment using the standard equipment formula. We understand that both manufacturers and physicians may be inclined to shift to a per-use or rental business models to limit overhead for purchase and maintenance of expensive equipment. We also understand that as the PE data age, these issues involving subscriptions and other forms of digital tools become more complex. We look forward to continuing to seek out new data sources to help in updating the PE methodology.

We also acknowledge the excimer laser vendor's concern that the purchase price for the excimer laser has increased and the receipt of invoices related to the parts and labor for the maintenance of a purchased laser. However, we did not receive invoices that would be useful to update the purchase price, and that the maintenance of equipment is accounted for in our price per minute equation for equipment. We welcome additional information and invoices to substantiate the claim that the purchase price has increased. We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. We remind the commenter that we implemented a new methodology for calculating PE RVUs for CY 2007 where we utilize a ''bottom-up'' approach to calculate the direct costs instead of using the ''top-down'' approach to calculate the direct PE RVUs, under which the aggregate direct and indirect costs for each specialty are allocated to each individual service. Under the ''bottom up'' approach, we determine the direct PE by adding the costs of the resources (that is, the clinical staff, equipment, and supplies) typically required to provide each service. The resource costs are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC. Therefore, we disagree with the commenter's suggestion to implement the ''breakeven cost'' of the excimer laser in the equipment formula.

While we understand that there may have been a change in business model, we do not believe a rental, subscription, or per-use fee of an equipment item that is still available to be purchased, as confirmed by the excimer laser vendor, and is already accounted for with our equipment methodology is appropriate, especially given its implications for direct PE costs for these CPT codes. We continue to believe that the excimer laser is appropriately and adequately accounted for in the equipment formula, which accounts for years of useful life, utilization rate, purchase price, interest rate, maintenance, and minutes per year

of use, discussed in detail in section II.B. of this final rule, Determination of PE RVUs, and note that EQ161 has a very high cost per minute of $0.5895/minute.

Comment: Most commenters disagreed with the CPT Editorial Panel's decisions regarding the codes' indications, which are currently limited to psoriasis only, stating that the changes have already had far reaching consequences. Commenters stated that the CPT Editorial Panel's decisions have negatively impacted a sizable portion of the patient population with inflammatory skin diseases, particularly for people with skin of color who are more susceptible to vitiligo. One commenter requested that CMS create a G code that is based on the 2022 CPT codes for the excimer laser to substitute for the 2024 revisions.

Response: We appreciate and acknowledge commenters' concerns regarding the CPT coding. However, based on our understanding, the coding change application was withdrawn from the September 2023 CPT Editorial Panel meeting when it was determined that existing literature was insufficient and did not support expanded indications at that time, and the codes were resurveyed at the April 2023 RUC meeting without any revisions to the code descriptors. Therefore, we disagree with the commenter that there is a programmatic need for a G code. We also note that concerns related to the CPT changes are considered out of scope for our proposal and we encourage the commenter to coordinate with the CPT Editorial Panel to address their concerns regarding the expanded indications for other inflammatory skin disorders such as vitiligo, atopic dermatitis, and alopecia areata. After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 96920, 96921, 96922 as proposed with the exception of the finalized refinements of clinical staff time for the CA024 to 5 minutes and equipment times of 38, 40, and 46 minutes for the power table (EF031) and exam light (EQ168) equipment for CPT codes 96920, 96921, and 96922, respectively, to conform to the increased clinical staff time for CA024.

(26) Physical Medicine and Rehabilitation (CPT Codes 97012, 97014, 97016, 97018, 97022, 97032, 97033, 97034, 97035, 97110, 97112, 97113, 97116, 97140, 97530, 97533, 97535, 97537, and 97542 and HCPCS Code G0283)

The RUC's Health Care Professionals Advisory Committee (HCPAC) previously reviewed 19 physical medicine and rehabilitation codes in February 2017. In the CY 2024 PFS proposed rule, CMS received public nominations on these same 19 therapy codes as potentially misvalued (88 FR 78851 and 78852). An interested party asserted that the direct PE clinical labor minutes reflected inappropriate multiple procedure payment reductions (MPPR), which were duplicative of the CMS MPPR policy implemented in CMS' claims processing systems. CMS reviewed the clinical labor time entries for these 19 therapy codes and concluded that a payment reduction should not have been applied in some instances to the 19 nominated therapy codes' clinical labor time entries since the payment valuation reduction would be duplicative of the MPPR applied during claims processing. CMS indicated that the valuation of these services would benefit from additional review through the RUC's HCPAC valuation process; they were therefore reviewed by the HCPAC for PE only, with no work review, at the January 2024 RUC meeting for inclusion in the CY 2025 PFS proposed rule.

The HCPAC's direct PE recommendations were based on the typical number of services reported per session, which was 3.5 units according to CMS data, to ensure that there was no duplication in the standard inputs for preservice and postservice time. To account for the MPPR, the HCPAC determined that 3.5 codes are billed per session, with the first paid at 100% and the second and subsequent units paid at half and so forth for PE (for example, 1.00 + 0.5 + 0.5 + 0.25 = 2.25). This resulted in the HCPAC recommending that many of the standard clinical labor times be divided by 2.25 to account for the MPPR, such as taking the standard 3 minutes for greeting and gowning the patient and dividing it by 2.25 to arrive at the recommended time of 1.33 minutes (1.33 + 0.67 + 0.67 + 0.34 = 3 minutes). In most cases, the HCPAC recommended using the standard equipment time formula aside from a few exceptions such as the use of the whirlpool in CPT code 97022 which would require additional time for the cleaning of the equipment.

Following the January 2024 RUC meeting, representatives from the American Physical Therapy Association (APTA) and the American Occupational Therapy Association (AOTA) met with CMS to express concern with the HCPAC's recommended direct PE inputs for this family of codes. Representatives from these trade associations stated that the HCPAC had inappropriately recommended too few equipment minutes for these procedures. These interested parties requested utilizing an alternate equipment time formula for the 19 reviewed therapy codes based on adding together the intraservice work time together with the clinical labor for the preservice and postservice portion of the service period. For 17 of the 19 reviewed therapy codes, this alternate equipment time formula would result in an increase over the HCPAC's equipment time recommendations. Table 16 lists the direct PE costs of each HCPCS code under their current pricing, under the HCPAC recommendations, and the alternate APTA and AOTA recommendations:

TABLE 16: Direct PE Costs for Physical Medicine and Rehabilitation Codes

HCPCS	Current	HCPAC	APTA/AOTA	Utilization
97012	2.62	3.22	3.30	434,921
97014	3.60	4.16	4.33	ProcStat "I"
97016	2.94	3.50	3.67	876,440
97018	2.29	2.92	2.96	146,909
97022	8.04	7.27	7.18	135,480
97032	2.61	3.17	3.34	621,599
97033	6.61	6.74	6.90	33,953
97034	4.08	4.17	4.17	6,964
97035	4.03	4.41	4.65	1,358,936
97110	8.42	8.63	9.11	61,204,041
97112	10.23	9.87	11.08	24,990,205
97113	13.89	14.65	14.61	1,588,852
97116	8.35	8.58	9.03	4,011,592
97140	7.25	8.09	8.21	28,413,744
97530	15.01	14.38	16.40	29,187,934
97533	35.72	36.56	36.69	60,507
97535	11.50	11.64	12.67	3,118,258
97537	9.69	10.09	10.78	15,556
97542	9.26	9.41	10.42	98,989
G0283	3.60	4.16	4.33	5,721,078

After consideration of these recommendations, we proposed the direct PE inputs as recommended by the HCPAC for all 19 codes in the Physical Medicine and Rehabilitation code family. We believe that the HCPAC's equipment time recommendations better maintain relativity with the rest of the fee schedule through primarily using standard equipment time formulas, along with limited exceptions for additional equipment time in cases where more time for equipment cleaning or patient positioning would be typical. We also believe that the alternate equipment time formula recommended by APTA and AOTA leads to inconsistent equipment times for many of these procedures, such as recommending 23.98 equipment minutes for CPT code 97110 which is a timed code billed in 15-minute increments. Although we agreed that some additional equipment time beyond the timed 15 minutes will be typical for setup and cleaning, 9 additional minutes for each billing of CPT code 97110 did not appear to reflect typical equipment usage.

Given the complexity of determining appropriate direct PE inputs across multiple billings of these therapy codes, and the need to factor in the MPPR, we believe that this code family may benefit from additional review, specifically review focused on the subject of appropriate equipment minutes. The HCPAC review of these codes was primarily focused on the clinical labor portion of the PE inputs and the equipment times did not receive the same degree of scrutiny as the clinical labor. We believe that the HCPAC's recommended direct PE inputs are the most accurate values based on the current information that we have available, however this is a topic that may warrant additional review to ensure that this family of codes is properly valued.

Comment: A commenter stated that although there remains some uncertainty about the appropriate equipment minutes for this code set, the commenter applauded CMS and stated that they looked forward to final resolution on the subject of appropriate equipment minutes.

Response: We appreciate the support from the commenter.

Comment: Several commenters disagreed with the CMS proposal of the HCPAC's recommended direct PE inputs. Commenters questioned why it was appropriate to apply the MPPR first through the valuation of the direct PE inputs and then again during claims processing. Commenters stated that they remained confused as to whether considering the MPPR, and how it will reduce clinical labor times for the whole session across the provided codes, was appropriate for valuing each individual code. Commenters disagreed with the proposal of 1.33 minutes of clinical labor time for most of the tasks included in the reviewed therapy codes, stating that for the second and third services, there is only 40 seconds allotted to tasks such as positioning the patient, cleaning the separate equipment, or developing post-treatment recommendations. One commenter stated that spending one and a third minutes is inadequate for most, if not all, procedures and spending only 40 seconds is not a realistic allocation of time to ensure that a patient is appropriately and safely positioned. Commenters suggested that the clinical labor time for many of the labor tasks assigned 1.33 minutes should in fact be the full 3 minutes that other non-therapy procedures are allotted for similar clinical labor tasks. Commenters agreed that a more thorough discussion of these codes will be required at a future date, however the commenters did not wish to take these 19 codes back to the HCPAC until such time as it was clearer how clinical labor and equipment time should be calculated.

Response: Determining the proper valuation of the clinical labor, supply, and equipment inputs for these therapy services has been a difficult task due to multiple billings being typical for the same patient on the same day. We have a longstanding policy such that in cases where multiple services are typically furnished to a beneficiary on the same day, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. For example, in cases where a service is typically furnished to a beneficiary on the same day as an E/M

service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. As such, we disagree with the commenters that it would be appropriate to allocate the full standard 3 minutes of clinical labor time for tasks such as greeting and gowning the patient (CA009), which would only take place one time. For therapy services which are typically billed in 3.5 sessions, this would result in 10.5 minutes of clinical labor time for the CA009 activity, which would be too high and not maintain relativity with other PFS services. At the same time, if we were to discount the clinical labor times too heavily by overapplying the MPPR, we run the risk of under-allocating sufficient clinical labor to cover the typical case, which could result in the safety issues identified by the commenters.

With this context in mind, we continue to believe that the direct PE inputs as recommended by the HCPAC are the most accurate values based on the current information that we have available. As we noted in the proposed rule, this is a topic that may warrant additional review to ensure that this family of codes is properly valued, both in terms of the equipment minutes discussed in the proposed rule and the clinical labor times raised by commenters. We agree with the observation from the commenters that discussing nineteen codes at the same time appears to have been significantly burdensome on the HCPAC, and we believe a more robust discussion might take place by reviewing fewer codes at a time. We remain open to further discussion of this subject with interested parties of how to most accurately capture the typical and medically necessary direct PE inputs for these therapy services in light of the challenges that they pose for valuation.

We wish to clarify for the commenters that we do not believe patient positioning and similar activities would typically take place in 40 seconds. We consistently proposed 1.33 minutes of clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) clinical labor task for these therapy codes based on the HCPAC's recommendation. As detailed in the proposed rule, this was based on dividing the standard clinical labor times by 2.25 to account for the MPPR, such as taking the standard 3 minutes and dividing it by 2.25 to arrive at the proposed time of 1.33 minutes (1.33 + 0.67 + 0.67 + 0.34 = 3 minutes). In other words, we believe that the standard 3 minutes of positioning time would typically take place over the course of a therapy session lasting roughly 45–60 minutes, as billed across the typical 3.5 services. We did not propose that patient positioning or room cleaning would typically take place in 40 seconds as several of the commenters suggested.

Comment: A few commenters asked CMS to use its authority to temporarily suspend, reduce, or defer the budget neutrality requirement for RVU adjustments to prevent further payment cuts to therapy services. One commenter stated that CMS should use its enforcement discretion and suspend the 50 percent PE reduction due to MPPR from the 19 therapy codes until the therapy codes have been properly valued.

Response: We remind the commenters that CMS does not have authority under section 1848 of the Act to suspend the budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act.

After consideration of the comments, we are finalizing the direct PE inputs for the 19 CPT codes in the Physical Medicine and Rehabilitation family as proposed.

(27) Acupuncture—Electroacupuncture (CPT Codes 97810, 97811, 97813, and 97814)

In September 2022, the RUC's Relativity Assessment Workgroup identified the acupuncture codes with 2020 Medicare utilization over 10,000 where the service was surveyed by one specialty but is now performed by a different specialty. CPT codes 97810–97814 were selected and surveyed for the April 2023 RUC meeting.

For CY 2025, we proposed the RUC-recommended work RVUs for all four CPT codes. We proposed a work RVU of 0.61 for CPT code 97810 (*Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*), a work RVU of 0.46 for CPT code 97811 (*Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)*), a work RVU of 0.74 for CPT Code 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*), and a work RVU of 0.47 for CPT code 97814 (*Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)*). We also proposed the RUC-recommended direct PE inputs for CPT codes 97810, 97811, 97813 and 97814 without refinement.

Comment: Commenters agreed with the CMS proposed work RVUs and direct PE inputs for CPT codes 97810 and 97813.

Response: We thank commenters for their support.

Comment: Commenters disagreed with the proposed work RVUs for CPT codes 97811 and 97814, stating that reduction of the work RVUs could potentially discourage the delivery of acupuncture and limit the availability of this beneficial service to the elderly population. These commenters encouraged CMS to maintain the current work RVUs of 0.50 for CPT code 97811 and 0.55 for CPT code 97814.

Response: We appreciate the feedback but note that the RUC's Summary of Recommendations (SOR) for CPT codes 97811 and 97814, contained two key reference codes that appropriately support the proposed valuation for each code. Without additional data provided by the commenters, we continue to believe that the RUC-reviewed survey 25th percentile work RVU of 0.46 for CPT code 97811 and 0.47 for CPT 97814 accurately reflects the intra-service and total times for these codes.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for all four codes in the Acupuncture—Electroacupuncture family as proposed.

(28) Insertion, and Removal and Insertion of New 365-Day Implantable Interstitial Glucose Sensor System (HCPCS Codes G0564 and G0565)

In the CY 2023 PFS final rule (87 FR 6923), we revised national pricing for two Category III CPT codes that describe continuous glucose monitoring for a 180-day period. Category III CPT codes 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*) and 0448T (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*) describe the services related to the insertion, and removal and insertion of an implantable 180-day interstitial glucose sensor from a subcutaneous pocket. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provide glucose trend information, and signal alerts for detection and prediction of episodes of

low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

Interested parties submitted a public comment in response to the CY 2025 PFS proposed rule that asked CMS to establish coding and payment similar to CPT codes 0446T and 0448T for services related to a newly FDA approved implantable 365-day continuous glucose monitoring system. The commenter stated that creating new coding will allow for continuity of this service during the manufacturer's transition from the 180-day monitoring service as described by the current codes, to the new 365-day monitoring service.

We agree with the commenters request and are establishing two new HCPCS codes to describe services related to the new 365-day monitoring service. Specifically, we are establishing HCPCS code G0564 (*Creation of subcutaneous pocket with insertion of 365-day implantable interstitial glucose sensor, including system activation and patient training*) and G0565 (*removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365-day implantable sensor, including system activation*). We believe it is important for beneficiaries to have continued access to this valuable service during the transition from a 180 to 365-day monitoring period. HCPCS codes G0564 and G0565 are contractor priced and effective January 1, 2025. CPT codes 0446T and 0448T should continue to be used to bill for the 180-day continuous glucose monitoring service.

(29) Annual Alcohol Screening (HCPCS Codes G0442 and G0443)

In April 2022, the Relativity Assessment Workgroup identified services with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2020, including HCPCS codes G0442 (*Annual alcohol misuse screening, 5 to 15 minutes*) and G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*). In September 2022, the RUC recommended that these services be surveyed for April 2023 after CMS published the revised code descriptor for HCPCS code G0442 in the CY 2023 PFS final rule (87 FR 69523).

We proposed the RUC-recommended work RVU of 0.18 for HCPCS code G0442 (*Annual alcohol misuse screening, 5 to 15 minutes*). We also proposed the RUC-recommended work RVU of 0.60 for HCPCS code G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*).

The RUC recommended an increase in the work RVU for HCPCS code G0443 from 0.45 to 0.60 which we believe is warranted based on time and intensity of the service in preventing alcohol misuse. In valuing this code, the time and work valuation is for separate and distinct services from same-day E/M services since HCPCS codes G0442 and G0443 are typically billed with an annual wellness visit (AWV) or office visit. We believe that the codes in the adjacent Behavioral Counseling & Therapy family, which includes HCPCS codes G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*), G0446 (*Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes*), and G0447 (*Face-to-face behavioral counseling for obesity, 15 minutes*), may be undervalued as their respective intensities may be lower than what is warranted for these services. We believe that the intensity for these G-codes may be more in line with the intensity of HCPCS code G0443 which we noted had an increase in intensity as recommended by the RUC. As such, we believe that the Behavioral Counseling & Therapy codes may benefit from additional review in the future to recognize the intensity of these services.

We proposed to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0442. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and we do not believe that it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We believe that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. We also proposed to maintain 15 minutes of corresponding equipment time for the EF023 exam table as a result of our proposed clinical labor time refinement. We proposed the RUC-recommended direct PE inputs for HCPCS code G0443 without refinement.

We thank the RUC for their review of this code family and for highlighting an important consideration specifically for services that fall under the Medicare preventive services benefit. We are now considering how best to implement and maintain payment for preventive services and may develop new payment policies in future rulemaking to address this issue more comprehensively to ensure consistent access to these services. We considered the recommended PE inputs for this code family, as well as for the Annual Depression Screening (HCPCS code G0444) and Behavioral Counseling & Therapy services (HCPCS codes G0445, G0446, and G0447) within this context, as noted below.

We received comments on this proposal. Below is a summary of the comments received.

Comment: Commenters generally supported the CMS proposal of the RUC's work RVU recommendations for HCPCS codes G0442 and G0443. Commenters noted the importance of improving rates in connection to strengthening access to care. Several commenters asked CMS to include other settings where these services can be furnished such as Certified Community Behavioral Health Clinics (CCBHCs) and Community Mental Health Centers (CMHCs) as they would anticipate this screening would be just as effective in a community setting and there may be cases where the entity may have an eligible practitioner on staff who is seeing an individual and recognizes that the annual screening and brief counseling is clinically appropriate for an individual in need. Another commenter asked CMS to continue to monitor research on alcohol screening, counseling, and treatment and incorporate research findings into the valuation and payment of these services.

Commenters also expressed overwhelming support regarding the proposed PE refinements, noting that it would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the 5 minutes recommended by the RUC. One commenter disagreed with the proposed PE refinements stating that this work was duplicative with the E/M visit that is being billed on the same day.

Response: We appreciate the support from commenters regarding the proposed work RVUs for HCPCS codes G0442 and G0443. We appreciate the commenters' suggestion of including CCBHCs and CMHCs as settings where these services can be performed. We note that practitioners who practice in these settings and who are enrolled in Medicare and able to bill directly for their services may be able to bill for HCPCS codes G0442 and G0443 under the PFS.

After consideration of public comments, we are finalizing the work RVUs for HCPCS codes G0442 and G0443 as proposed.

For the direct PE inputs, we agree with commenters that it would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the 5 minutes recommended by the RUC. Given the overwhelming support from commenters and the fact that these are preventative services, we are finalizing as proposed to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0442. We are also finalizing to maintain 15 minutes of corresponding equipment time for the EF023 exam table because of our proposed clinical labor time refinement. We are finalizing the RUC-recommended direct PE inputs for HCPCS code G0443 without refinement.

(30) Annual Depression Screening (HCPCS Code G0444)

In 2012, HCPCS code G0444 (*Annual depression screening, 5 to 15 minutes*) was added to the PFS (77 FR 68955 and 68956) to report annual depression screening for adults in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, treatment and follow up. In April 2022, the Relativity Assessment Workgroup identified this service with Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2015 through 2020. In September 2022, the RUC recommended that this service be surveyed for April 2023 after CMS published the revised code descriptor in the CY 2023 PFS final rule (87 FR 69523).

We proposed the RUC-recommended work RVU of 0.18 for HCPCS code G0444.

We proposed to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0444. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and we do not believe that it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We believe that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. We also proposed to maintain 15 minutes of corresponding equipment time for the EF023 exam table as a result of our clinical labor time refinement.

We received comments on our proposals. Below is a summary of the comments received.

Comment: Commenters generally supported the CMS proposal of the RUC's recommended work RVU for G0444. Several commenters asked CMS to include other settings where these services can be furnished such as Certified Community Behavioral Health Clinics (CCBHCs), Community Mental Health Centers (CMHCs), as well as substance use treatment settings, as they would anticipate this screening would be just as effective in a community setting and there may exist cases where the entity may have an eligible provider on staff who is seeing an individual and recognizes that the annual screening and brief counseling is clinically appropriate for an individual in need. A few commenters encouraged CMS to use the most recent data available to determine the appropriate payment for Mental Health (MH) and Substance Use Disorder (SUD) services to address workforce shortages. Commenters overwhelmingly agreed with CMS regarding the clinical labor time and stated that the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. One commenter disagreed with CMS' proposed refinements to the PE inputs stating this work was duplicative with the E/M that is being billed on the same day.

Response: We thank the commenters for their support of this proposal. We appreciate the commenters' suggestion of including CCBHCs and CMHCs as settings where these services can be performed. We note that practitioners who practice in these settings and who are enrolled in Medicare and able to bill directly for their services may be able to bill for these codes under the PFS.

After consideration of public comments, we are finalizing the work RVU for HCPCS code G0444 as proposed.

For the direct PE inputs, we thank the commenters for their support and agree with commenters that it would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the 5 minutes recommended by the RUC. Given the overwhelming support from commenters and the fact that this is a preventative service, we are finalizing as proposed to maintain the current 15 minutes of clinical labor time for the CA021 ''Perform procedure/service—NOT directly related to physician work time'' activity for HCPCS code G0444. We are also finalizing as proposed to maintain the 15 minutes of corresponding equipment time for the EF023 exam table because of our proposed clinical labor time refinement.

(31) Behavioral Counseling & Therapy (HCPCS Codes G0445, G0446, and G0447)

CMS created HCPCS codes G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*), G0446 (*Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes*), and G0447 (*Face-to-face behavioral counseling for obesity, 15 minutes*) effective with the 2012 Medicare PFS (77 FR 68892). HCPCS codes G0445–G0447 were identified to be reviewed at the April 2023 RUC meeting because they were services with Medicare utilization of 10,000 or more that had increased by at least 100% from 2015 through 2020.

The specialty societies surveyed HCPCS codes G0445–G0447 for the April 2023 RUC meeting but did not obtain the required number of survey responses. After the resurvey, which occurred after the April 2023 RUC meeting, the specialty societies were again unable to achieve the required minimum number of survey responses for any of the codes in this family for the September 2023 RUC meeting. The RUC reviewed HCPCS codes G0445–G0447 at the September 2023 RUC meeting. Given the insufficient number of survey responses and considering that these are CMS-created time-based codes, the RUC determined it would be most appropriate to maintain the current work values and flagged these codes for review in 3 years. We proposed the RUC-recommended work RVU of 0.45 for each of these three HCPCS codes, G0445–G0447.

We did not propose the RUC-recommended direct PE inputs for these codes because of the insufficient number of survey responses, and further, we did not agree with some of the RUC's refinements to the direct PE inputs for this service. We did not propose the RUC-recommended direct PE inputs for G0445, G0446, and G0447, which include the SK062 patient education booklet being eliminated in favor of the SK057 paper, laser printing (each sheet) in the amount of 10 sheets and the equipment minutes being modified to equal the sum of clinical staff time plus the physician/QHP time

as reflected by the survey median. We do not agree that these changes are substantiated given the insufficient number of survey responses and we proposed to maintain the current values for each of these direct PE inputs.

We proposed the RUC recommended refinements to clinical staff time for HCPCS code G0445. We proposed to move two minutes from CA021 Perform procedure/service—NOT directly related to physician work time to CA035 Review home care instructions, coordinate visits/prescriptions. We agree with the RUC that this more accurately reflects the clinical work involved in arranging follow-up and/or referrals with clinical and community resources and providing educational materials. Currently, for HCPCS code G0445, PE includes a whip mixer (EP086) and biohazard hood (EP016) among the equipment assigned to the code. We also proposed the RUC recommendations to eliminate both of these pieces of equipment from the PE for HCPCS code G0445.

We noted that the Behavioral Counseling & Therapy code family (HCPCS codes G0445–G0447) should be reviewed in the future by the RUC and we anticipate the recommendations that will come from the review for this family.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally expressed support regarding the proposed PE refinements although one commenter disagreed with the proposed PE refinements, stating that this work was duplicative with the E/M visit that is being billed on the same day. Commenters recommended an increase in the work RVUs for HCPCS codes G0445–G0447 in alignment with HCPCS code G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*) to reflect the intensity of the services, stimulate additional access to these services, and maintain relativity across these codes. Commenters also noted the importance of improving the accuracy of the rates in order to strengthening access to care.

Response: We thank commenters for their support of our PE refinements. We disagree that the PE of the counseling service is duplicative of the E/M visit that is being billed on the same day, as the counseling service requires additional time and practice expense not originally accounted for in the valuation of the E/M visit that is billed on the same day. We appreciate the information that commenters provided regarding the proposed work RVU for HCPCS codes G0445–G0447. We were persuaded by commenters that these services should all be valued consistently to reflect the intensity of the service and to maintain relativity across these codes. We are finalizing 0.60 work RVUs for HCPCS code G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes).

After consideration of public comments, we are finalizing the work RVU of 0.60 for HCPCS codes G0445–G0447 and finalizing our PE and clinical staff time refinements as proposed.

(32) Autologous Platelet Rich Plasma (HCPCS Code G0465)

HCPCS code G0465 (*Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)*) was created for CY 2022 (retroactively dated back to the effective date of the policy, April 13, 2021) and assigned contractor pricing (NCD 270.3, CR 12403).

Following the publication of the CY 2023 PFS proposed rule, we received two comments on the pricing of HCPCS code G0465, and the 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically debrided wounds (87 FR 69420). One commenter submitted invoices associated with the pricing of the 3C patch system (SD343) supply for which we established a price of $625.00 in the CY 2021 PFS final rule (85 FR 84498). The commenter requested that CMS update its supply database based on invoices submitted for SD343 to reflect an updated price of $750.00 per unit. The commenter also requested national pricing for HCPCS code G0465, expressing concern that insufficient payment disproportionately impacts vulnerable populations. The commenter requested a payment rate of $1,408.90 for HCPCS code G0465 in the office setting, stating that this rate would appropriately account for the purchase of the 3C patch, as well as the other related costs and supply inputs required for point of care creation and administration.

In response, we stated in the CY 2023 PFS final rule that we did not have enough information to establish national pricing at this time for HCPCS code G0465 (87 FR 69420). We stated that we would consider the commenters' feedback for future rulemaking while maintaining contractor pricing for CY 2023, which would allow for more flexibility for contractors to establish appropriate pricing using available information. We appreciated the invoice submission with additional pricing information for the SD343 supply and we updated our supply database for supply code SD343 at a price of $678.57 based on an average of the submitted invoices.

Since the publication of the CY 2023 PFS final rule, interested parties have continued to request national pricing for HCPCS code G0465 due to their perception of inconsistent and insufficient payment for this service by the MACs. CMS has asked the interested parties to engage with the MACs to establish adequate payment for HCPCS code G0465. The interested parties have continued to state that most MACs have not established consistent payment rates and the rates are heterogeneous; some are significantly below the cost of performing this service, leading to an unpredictable process and inadequate rates, creating barriers to access this service.

Due to these concerns, we proposed to establish national pricing for HCPCS code G0465 for CY 2025. We proposed to value HCPCS code G0465 using a crosswalk to CPT code 15271 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*), drawing from a selection of relevant studies.[20] [21] [22] [23] We proposed a work RVU of 1.50 for HCPCS code G0465 based on the crosswalk to CPT code 15271 because wound surface area sizes in current literature appear to be less than 100 sq cm for patients with diabetes and/or chronic ulcers. We also proposed to use the direct PE inputs included with CPT code 15271 for valuing HCPCS code G0465, with the additional inclusion of the 3C patch system (SD343) supply that we priced in CY 2023. We noted that the

[20] Gethin, G et al. ''The profile of patients with venous leg ulcers: A systematic review and global perspective.'' *Journal of tissue viability* vol. 30,1 (2021): 78–88. *doi:10.1016/j.jtv.2020.08.003.*

[21] Sheehan, Peter et al. ''Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial.'' *Plastic and reconstructive surgery* vol. 117,7 Suppl (2006): 239S–244S. *doi:10.1097/01.prs.0000222891.74489.33.*

[22] Oyibo, S O et al. ''The effects of ulcer size and site, patient's age, sex and type and duration of diabetes on the outcome of diabetic foot ulcers.'' Diabetic medicine: a journal of the British Diabetic Association vol. 18,2 (2001): 133–8. *doi:10.1046/j.1464–5491.2001.00422.x.*

[23] Patry, Jérôme et al. ''Outcomes and prognosis of diabetic foot ulcers treated by an interdisciplinary team in Canada.'' *International wound journal* vol. 18,2 (2021): 134–146. *doi:10.1111/iwj.13505.*

payment includes debridement, which may involve a wound reaching the bone. Therefore, debridement may not be billed separately. In addition, we currently sought comments on other available crosswalks from the broader medical community. For example, CPT code 15277 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children*) with a work RVU of 4.00 and CPT code 15273 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children*) with a work RVU of 3.50 could also be viable crosswalk options. We solicited comments regarding our selection of CPT code 15271 as a crosswalk code, as well as general comments and available studies regarding the appropriate valuation of HCPCS code G0465.

Comment: While many commenters supported establishing national pricing for HCPCS code G0465 for CY 2025, they disagreed with the proposed crosswalk to CPT codes 15271, 15273, and 15277. Commenters asserted that these codes do not accurately reflect the work RVUs and non-facility PE RVUs required for providing this treatment in a physician office setting. Commenters stated that autologous blood-derived products are not skin substitutes, and therefore, the proposed skin substitute crosswalk codes do not adequately account for all the steps involved in preparing and delivering this wound care treatment. They highlighted that platelet-rich plasma (PRP) requires significant point-of-care preparation, unlike skin substitutes. According to the commenters, the physician work for G0465 includes multiple steps, such as drawing blood, preparing the blood-derived gel, and applying it to complex wounds—procedures that are more involved than applying a skin substitute. The commenters emphasized that the proposed work RVUs based on the crosswalks are too low and do not account for the substantial physician effort required. Several commenters instead suggested alternative crosswalks to CPT codes related to epidermal or dermal autografts, such as CPT codes 15110 (*Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children*), 15115 (*Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children*), 15120 (*Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)*), which they believe better align with the actual work involved.

Several commenters also stated that debridement is a crucial part of the physician's work when performing the service described by HCPCS code G0465, particularly for complex wounds that may involve tunneling or contact with bone. They emphasized that debridement, which is essential before each application of an autologous blood-derived product, should be factored into the RVU calculation for HCPCS code G0465. Commenters recommended considering relevant debridement codes, such as CPT codes 11042 (Debridement, subcutaneous tissue (*includes epidermis and dermis, if performed); first 20 sq cm or less*), 11043 (*Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less*), 11044 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less*), and 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*). Assuming debridement is not separately payable, a few commenters suggested increasing the work RVUs for HCPCS code G0465 by incorporating values from these debridement codes.

In addition, some commenters stated that the proposed pricing for supply code SD343, the 3C patch system, is outdated and inaccurate. They stated that the SD343 supply does not reflect the typical supply costs for PRP services because certain necessary components for PRP preparation and application are not included in the 3C patch system. Commenters also asserted that only products with FDA-cleared indications for wound care should be included in the national pricing for HCPCS code G0465, and products that do not meet these requirements should be excluded. Commenters stated that there may be other products in the market that do not meet the NCD requirements and cautioned that these other products likely have vastly different costs than products that do meet the NCD requirements. Commenters stated that the FDA-cleared manufacturers sell their proprietary ingredients and supplies as a complete package, which are necessary for use in each manufacturer's process for creating the autologous blood-derived products, and they are not interchangeable between manufacturers. Commenters submitted a series of invoices and requested that CMS use them to update the pricing of the SD343 supply.

Response: We thank commenters for their feedback. We were persuaded by commenters that the higher work valuation would provide a more accurate crosswalk for HCPCS code G0465, as PRP may require more work and complexity in using these products. To ensure adequate valuation of both physician work and practice expense, we are modifying our original proposal and instead finalizing national pricing for HCPCS code G0465 for CY 2025 using a crosswalk to CPT code 15275 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*) instead of CPT code 15271 because we believe this code more accurately reflects the work involved in furnishing the service described by HCPCS code G0465.

After reviewing the invoices submitted by commenters, we agree that the pricing data indicates an increase in the typical price of the SD343 supply over time. Therefore, we are finalizing an increase in the supply price from $678.57 to $770.83, based on twelve submitted invoices. Where prices appear inaccurate, and direct inputs do not reflect the full range of available PRP products, we encourage interested parties to submit invoices or other relevant information by February 10th of the following year to improve pricing accuracy in the direct PE database, following a process similar to our consideration of RUC recommendations.

Lastly, while we acknowledge that the service provided under HCPCS code G0465 may differ from skin substitutes, we consider the work to be comparable, which is why we are using CPT code 15275 as the crosswalk. Because the code descriptor for HCPCS code G0465 includes description of all other preparatory procedures, we do not agree that the additional work described in the debridement codes referenced by commenters is not accounted for in the valuation of HCPCS code G0465. Therefore, we are finalizing a work RVU of 1.83 for HCPCS code G0465, which

is higher than the work RVU for CPT code 15271 as proposed, based on a crosswalk to CPT code 15275. Additionally, we are finalizing an increase in the supply price to $770.83, based on twelve submitted invoices.

(33) Temporary Female Intraurethral Valve-Pump (CPT Codes 0596T and 0597T)

In the CY 2024 PFS proposed rule, an interested party nominated two Category III CPT codes, CPT codes 0596T (*Initial insertion of temporary valve-pump in female urethra*) and 0597T (*Replacement of temporary valve-pump in female urethra*), as potentially misvalued. The nominator expressed concern about variability in MAC pricing for the contractor-priced service. Additionally, the nominator highlighted that the payment amounts determined by MACs were inadequately low and did not account for the time and effort required to furnish the services. In their submission, the nominator discussed their anticipated inputs for both codes. For CPT code 0596T, the nominator stated that a physician typically spends 60 minutes inserting the Vesiflo inFlow System. The nominator stated that CPT code 0596T included various supplies, equipment, and clinical labor time totaling $1,902.76, with the inflow supply items making up about 99 percent of the total cost of supplies. For CPT code 0597T, the nominator stated that a physician spends 25 minutes replacing the Vesiflo inFlow System and PE items were similar, with supplies, equipment and clinical labor time costing $505.30, with the inflow supply items making up about 98 percent of the total cost of supplies. We direct interested parties to the CY 2024 PFS final rule (88 FR 78850) for more detailed submission information regarding CPT codes 0596T and 0597T. After reviewing, we concluded that these codes were not potentially misvalued because they are Category III codes describing relatively new and low-volume services. Category III codes are contractor priced under the PFS, meaning that each MAC can establish pricing for the code within its jurisdiction, resulting in variability in payments.

This year, the nominator newly informed CMS that their analysis of national payment rates showed that in most CMS jurisdictions, not only are these codes misvalued, but in most cases, they are not valued at all, with fee schedule amounts in most CMS jurisdictions at or near zero dollars. The nominator further emphasized that three physician experts, all employed in major university medical centers, have highlighted the challenges posed by the combination of high supply costs and inadequate fee schedule payments, which have hindered their ability to provide services covered by these codes over several years. According to the nominator, these selected physicians also expressed frustration with the reluctance of MACs to address or discuss this issue. Moreover, the nominator highlighted high access barriers as a significant concern. These barriers primarily affect Medicare's most vulnerable beneficiaries, particularly women experiencing permanent urinary retention (PUR), although we note that no quantifiable evidence was provided to support these statements. We acknowledge and appreciate the nominator's efforts in reaching out to experts in the field and patients who rely on these services to elucidate their significant needs.

Since these two Category III CPT codes were not identified as potentially misvalued and were consequently priced by contractors, each MAC can set pricing for the code within its jurisdiction. This could result in inevitable variability in MAC pricings until they receive a higher number of claims, as stated by the nominator. Through our engagement with MACs, we found that claims for the two Category III CPT codes are reviewed on a case-by-case basis for medical necessity. If the claim is payable, the price will be determined at that time by the MAC. Additionally, these codes were a topic of discussion within the MAC pricing workgroup, and we observed that there was not a significant difference among the MACs in terms of allowances based on the proposed pricing methodologies. However, there is variance in how MACs load pricing for Category III codes. For instance, some MACs publish the price for the service before they receive any claims, while others set the price only after they receive claims that help determine the appropriate pricing. If a MAC does not load a price for a code before receiving any claims, the service can still be paid, but the allowance has not been published.

We continue to hear concerns about these payment inconsistencies for CPT codes 0596T and 0597T. As a result, we recommended that the MACs establish more consistency in pricing, enabling the appropriate inclusion of the Vesiflo system in the code's PE valuation. Therefore, for CY 2025, we encouraged interested parties to provide more accurate and appropriate cost data, along with additional information regarding work RVU, work time, indicators, and utilization estimates for the MACs. This should complement the information provided by the nominator in the CY 2024 final rule (88 FR 78850) and will facilitate the process. To aid in this process, we are adding three new supplies to our direct PE database based on invoices submitted by interested parties: the inFlow Measuring Device at a price of $140 (SD370), the inFlow Valve-Pump Device at a price of $495 (SD371), and the inFlow Activator Kit at a price of $1,250 (SD372). Although we did not propose national pricing for these two Category III codes, we did note for the benefit of the MACs that CPT code 0596T will typically include one of each of these supplies, whereas CPT code 0597T will typically include only one of the supplies (SD371).

We encouraged the MACs to continue to engage with interested parties by providing information on how they price these services. We welcomed additional comments from the broader medical community regarding the usage of this service, particularly concerning its safety and effectiveness, as well as potential factors contributing to its low utilization.

Comment: Commenters supported the establishment of new supply codes (SD370, SD371, and SD372) for the inFlow™ female voiding prosthesis system (the inFlow System), which addresses the needs of women with permanent urinary retention (PUR). According to the commenters, the inFlow System offers a critical alternative to traditional intermittent catheterization, providing significant improvements in both health outcomes and quality of life for women with neurological conditions that limit their ability to self-catheterize. They stated that creating three new supply codes would standardize and improve payment rates by Medicare Administrative Contractors (MACs), thereby reducing access barriers and increasing the utilization of the inFlow system. They emphasized that finalizing appropriate pricing for these device-intensive procedures, as proposed, is essential to ensuring that Medicare beneficiaries have access to this important, life-enhancing technology.

Response: We thank commenters for their overwhelming support for our proposal. After consideration of public comments, we are finalizing creation of three new supply codes in the PE database to facilitate appropriate pricing by the MACs: the inFlow Measuring Device at a price of $140 (SD370), the inFlow Valve-Pump Device at a price of $495 (SD371), and the inFlow Activator Kit at a price of $1,250 (SD372) as proposed.

(34) PE-Only Replacement Code for Heart Failure System

Interested parties have expressed concern about the lack of coding and a billing mechanism when practitioners incur costs replacing identified components of the CardioMEMS™ Heart Failure System used in the physician service described by CPT code 33289 (*Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed*).

The CardioMEMS™ Heart Failure System furnished during this service allows practitioners treating heart failure patients to wirelessly monitor and measure pulmonary artery pressure and heart rate in patients with heart failure and transmit the information to the physician to inform the treatment plan for the patient. The system includes two critical components: first, a miniaturized, wireless monitor, which is implanted into a patient's pulmonary artery, and second, a smart pillow (the CardioMEMS™ Patient Electronics System), which captures and transmits readings via safe radio frequency from the patient's implanted CardioMEMS™ Heart Failure System. Overall, the CardioMEMS™ Heart Failure System enables patients to transmit critical heart failure status information to clinicians regularly, potentially eliminating the need for frequent clinic or hospital visits.

Interested parties have highlighted the critical importance of the device for heart failure patients who require close monitoring of weight and blood pressure to prevent fluid buildup around the heart and have requested that CMS establish coding to describe when practitioners incur costs during clinical scenarios when crucial components of the system require replacement. Given that these components are crucial for system functionality and there is no existing coding framework to address their replacement, we believe that establishing appropriate coding and payment mechanisms can facilitate the provision of these services more effectively in the office and hospital settings. Given provided information, we proposed assigning contractor pricing to this PE-only code for CY 2025. We proposed a new code, HCPCS code G0555 (Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional). We sought feedback from interested parties on our contractor pricing approach with the aim of establishing national pricing through future rulemaking that can be billed under the OPPS and PFS specifying an ongoing care visit for the CardioMEMS™ Heart Failure System along with the provision of the replacement part. We are specifically looking for information from the broader medical community regarding direct costs from invoices for the replacement component referenced above, utilization estimates, and potential indicators. Additionally, we solicited comments on additional direct PE inputs that we should consider.

Comment: Many commenters disagreed with our proposed new code, HCPCS code G0555 (*Provision of replacement patient electronics system (for example, system pillow) for home pulmonary artery pressure monitoring including provision of materials for use in the home and reporting of test results to physician or qualified health care professional*). Many commenters stated that the proposed HCPCS code G0555 does not align with the current distribution and billing framework because it conflates two distinct functions: replacement of the patient electronics system (PES), often furnished by durable medical equipment (DME) suppliers, and reporting test results to the physician, usually performed by outpatient hospital departments (OPDs) and independent diagnostic testing facilities (IDTFs). Due to these separate functions handled by different parties, some commenters recommended splitting HCPCS code G0555 into two distinct codes—one for PES replacement and another for reporting test results. They agreed that contractor pricing the proposed new code would be appropriate for the replacement PES.

Additionally, commenters raised concerns regarding the removal of the previous monitoring code (G2066) for CardioMEMS monitoring. Some commenters stated that CMS's decision to delete HCPCS code G2066, which was used for reporting the technical component of remote monitoring, has created a billing gap for IDTFs and OPDs. Commenters recommended creating a new code to allow these facilities to report the technical aspects of monitoring; they specifically asked for the establishment of coding that enables IDTFs and OPDs to bill for these services, with contractor pricing as an interim solution.

Response: First, we note that the replacement of the PES does not meet the criteria of DME as outlined in section 1861(n) of the Act. For more information, please refer to the DMEPOS Public Meeting on 6/1/2016, Application #16.019—Request to establish a new Level II HCPCS code to identify the replacement Patient Electronic System at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2016-06-01-HCPCS-Application-Summary.pdf*. Secondly, we clarify that the last part of the proposed code descriptor (reporting of test results to physician or qualified health care professional) refers to the capability of the equipment, not the act of reporting. In other words, the code is not describing two distinct services; therefore, separate coding is unnecessary. We also believe that establishing additional coding for reporting the technical component of remote monitoring is unnecessary. Following CMS's decision to delete HCPCS code G2066, the services previously reported using HCPCS code G2066 will now be reported using the technical component of CPT codes 93297 and 93298. Our rationale for finalizing these values was discussed extensively in the CY 2024 PFS final rule (88 FR 78913 through 78914).

After considering the public comments, we are finalizing the proposed descriptor with modifications. The final descriptor for HCPCS code G0555 is *Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring.* We believe these revisions will allow flexibility in coding and provide greater access for patients. We are finalizing contractor pricing as proposed.

(35) Portable X-Ray (HCPCS Codes R0070–R0075)

Several Portable X-Ray (PXR) suppliers and trade organizations continue to express longstanding concerns with how payment is established for transportation related to these services (HCPCS codes R0070–R0075). CMS has worked with interested parties over the past several years to understand the costs of these services while taking into consideration the MACs perspective on pricing of these costs. Through recent ongoing discussions with interested parties, we learned that interested parties are concerned with the recognition of costs incurred from PXR services and are wanting more consistency in the pricing

of these services, including the application of an inflation factor.

We acknowledged the interested parties' concerns and clarified that interested parties may best engage with the MACs through appropriate reporting of cost data in the MAC requested format. This information provided by interested parties can help MACs establish payment rates that are more reflective of costs incurred. MACs are then able to consider this cost information and apply an inflation factor to update changes in costs year over year.

However, CMS recognizes that we should maintain consistency in pricing these services that are more indicative of changes in costs that occur yearly. While still preserving MAC discretion, CMS highlights the usage of an ambulance inflation factor (AIF) that is typically used to adjust ambulance services, which include transportation costs. The AIF is updated annually, and we believe MACs may consider using the AIF to price PXR services when establishing payment rates that are more consistent and reflective of costs incurred.

Additionally, interested parties highlighted inconsistency with language found in our manual and program memoranda policies related to transportation costs. Therefore, to remain consistent and transparent in the pricing of PXR services, we proposed to revise language in our Medicare Claims Processing manual (Chapter 13, 90.3 and Chapter 23, 30.5) to reflect any updates to our guidance for these services.

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to revise language in the Medicare Claims Processing Manual (MPCM) and believe this will help assure that MACs apply appropriate inflation factor and other required updates to PXR services.

Response: We thank commenters for their support of our proposal.

Comment: Commenters also mentioned a few additional policy refinements for PXR services including requiring transparency from MACs regarding the annual update as well as with the PFS ratesetting process for direct and indirect costs, establishing guidelines for a timelier periodic review process, and specifically consolidating two sections of the MCPM related to PXR transportation (Ch. 13, 90.3 and Ch. 23, 30.5) to ensure a single guidance document for both MACs and PXR suppliers.

Response: We thank commenters for these suggestions and may take them into consideration for future rulemaking.

After consideration of the comments received, we are finalizing our proposal to revise language in our Medicare Claims Processing manual (Chapter 13, 90.3 and Chapter 23, 30.5) to reflect updates to our guidance for these services. The Medicare Claims Processing manual is available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.*

(36) Non-Chemotherapy Administration

CMS received inquiries from several external parties with concerns that MACs have developed local coverage determinations (LCDs) and local coverage articles (LCAs) that down code or restrict payment for complex and non-chemotherapeutic drug administration for CPT code series 96401–96549, when used for the administration of several biologic and infusion drugs, including drugs furnished to treat, for example, rheumatology related conditions.

CMS requested information in the CY 2024 PFS proposed rule (88 FR 52837) seeking public feedback regarding the concerns of down coding or denials for the administration of non-chemotherapeutic infusion drugs. We received comments that asked for additional clarification from CMS regarding the payment guidelines for the complex non-chemotherapeutic administration code series and updates to the IOM. Commenters urged CMS to provide additional guidance clarifying the conditions under which these complex infusion drugs should be payable.

In response to the comments received, and in response to continuing inquiries on downcoding and or restrictions on payment for non-chemotherapy complex infusion services, we proposed an updated policy based largely on the IOM Medicare Claims Processing Manual, Chapter 12, section 30.5, to include language currently consistent with CPT code definitions for the complex non-chemotherapy infusion code series stating that the administration of infusion for particular kinds of drugs and biologics can be considered complex and may be appropriately reported using the chemotherapy administration CPT codes 96401–96549. We noted that CPT guidance describes requirements for these non-chemotherapy complex drugs or biologic agents to include the need for staff with advanced practice training and competency, such as, a physician or other qualified health care professional to monitor the patient during these infusions due to the incidence of severe adverse reactions. There are also special considerations for preparation, dosage, or disposal for these infusion drugs. These services do involve serious patient risk which requires frequent consults with a physician or other qualified healthcare professional. Based on these facts and comments, we proposed to update our subregulatory guidance accordingly.

This will also provide complex clinical characteristics for the MACs to consider as criteria when determining payment of claims for these services. The current IOM language does not include the unique characteristics of the administration of these drugs that could provide additional context to the MACs when they are determining appropriate payment. Updating the IOM with the increased detail of these codes would be responsive to the concerns and requests of external parties and will ensure the IOM is consistent with published guidance.

Therefore, we solicited and welcomed comments on our proposal to revise the IOM to better reflect how complex non-chemotherapeutic drug administration infusion services are furnished and billed.

Comment: Commenters were generally very supportive of CMS' proposal to update the IOM with additional detail and considerations of complexity for the administration of complex non-chemotherapeutic drugs. Commenters also stated they were pleased that MACs have retired the LCAs related to this service and that CMS has issued previous instructions to the MACs regarding down coding. A few commenters suggested additional clarifications and revisions beyond the proposed language in the IOM, such as a clarification that stem cell transplant and CAR–T services should not be billed using the chemotherapy administration code series. Another commenter requested that CMS remove ''chemotherapy'' terminology and replace it with ''immunomodulatory'' and that CMS extend additional IOM guidance to subcutaneous injections. One commenter also requested that CMS refer the entire code series to the CPT Editorial Panel for review.

Response: We appreciate commenters support for our proposed revisions to the IOM for these services and we acknowledge commenters additional suggestions to clarify the guidance. Currently, we believe that additions beyond our proposed changes to the IOM and revisions to terms beyond the scope of general coding guidance are not

required. We continue to believe that the proposed increased detail in alignment with current CPT coding definitions will provide clear guidance and considerations when MACs are determining appropriate payment for these services. Additionally, CMS is an active participant in the CPT Editorial Panel review process and encourages interested parties to pursue coding change requests by CPT as necessary.

Comment: Several commenters requested that CMS take additional steps to prevent future down coding of these services. Commenters stated that CMS should establish documentation requirements in the patient medical record to demonstrate that the reported complex drug administration code meets IOM guidance. Commenters also requested that CMS release a Medicare Learning Network (MLN) article to educate MACs and physicians on the finalized guidance. Commenters also urged CMS to prohibit audits and recoupments for these services until the effective date of the finalized IOM revisions.

Response: We thank commenters for their suggested additional steps to prevent future down coding of these services. Currently, we believe that the proposed increased detail and considerations of complexity to the IOM will sufficiently assist MACs with their determination of proper payment for these services. We are encouraged by the positive feedback from commenters regarding the retired LCAs and the previous instructions issued to the MACs via TDL and CR. We will continue to monitor all feedback from external parties and will pursue additional steps to ensure proper payment for these services as necessary.

After consideration of all public comments, we are finalizing revisions to the IOM to update guidance on complex non-chemotherapeutic drug administration as proposed.

(37) Hospital Inpatient or Observation (I/O) Evaluation and Management (E/M) Add-On for Infectious Diseases (HCPCS Code G0545)

Interested parties have continued to engage with CMS and provide recommendations to recognize the increased work associated with diagnosis, management, and treatment of infectious diseases that may not be adequately accounted for in current hospital inpatient or observation E/M codes. Infectious diseases are unique in that they present infection control risks for the patient and close contacts, including healthcare staff, that require attention to safely care for the patient. They present unique challenges in diagnosis in that any previous healthcare interaction could affect the individual resistance patterns of pathogens infecting the individual patient and require close contact with public health agencies since resistance patterns are constantly changing, so a much more extensive medical review is required. Additionally, individual decisions regarding treatment are unique in that use in one patient affects resistance patterns of the entire population, which requires additional expertise to inform antimicrobial selection and management.

We believe that the timing is appropriate for establishing a payment rate for infectious disease physician services since the COVID–19 PHE has ignited a hypervigilance for infectious diseases. Therefore, for CY 2025, we proposed a new HCPCS code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease performed by a physician with specialized training in infectious diseases. The full descriptor for the hospital I/O E/M visit complexity add-on code is HCPCS code G0545 (*Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent*). We anticipate that HCPCS code G0545 would be reported by physicians with specialized infectious disease training.

We stated in the proposed rule that we do not believe we should limit the scope of codes with which this add-on HCPCS code could be billed based on visit level; or initial, same day discharge, or subsequent hospital inpatient or observation codes. We proposed HCPCS code G0545 as an add-on code (ZZZ global period) separately reportable in addition to CPT codes 99221 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*), 99222 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 55 minutes must be met or exceeded.*), 99223 (*Initial hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 75 minutes must be met or exceeded.*), 99231 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*), 99232 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), 99233 (*Subsequent hospital inpatient or observation care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*), 99234 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*), 99235 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 70 minutes must be met or exceeded.*), and 99236 (*Hospital inpatient or observation care, for the evaluation and management of a patient including admission and discharge on the same date, which requires a*

medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 85 minutes must be met or exceeded.). Based on feedback from commenters on the CY 2022 PFS proposed rule comment solicitation regarding infectious diseases (86 FR 65125 through 65126) and feedback from interested parties, HCPCS code G0545 would include the following proposed service elements:

1. Disease Transmission Risk Assessment and Mitigation

- Developing, following, and supervising specialized, individualized infection control protocols for an individual patient based on their diagnosis and risks in order to reduce risk of disease transmission.
- Coordinating with human resources regarding infection prevention and control measures to enable healthcare facility staff to safely care for patient.
- Counseling patients, family members and caregivers regarding infection prevention.
- Managing infection prevention and treatment protocols associated with transitions of care for complex patients.

2. Public Health Investigation, Analysis, and Testing

- In-depth patient chart review that entails going back farther in time and assessing the complete breadth of all health care interactions, with higher-level synthesis for complex diagnoses.
- Communicating with the clinical microbiology lab and directly reviewing specimens.
- Coordinating specialized diagnostic evaluations (for example, identifying and facilitating diagnostic laboratory tests only available at specialized laboratories, the state health department, and/or the Centers for Disease Control & Prevention).
- Coordinating with Federal, State and local public health agencies and laboratories to assist with contact tracing, obtaining specimens for specialized testing, and/or identifying prior testing and treatment for communicable diseases in other jurisdictions.

3. Complex Antimicrobial Therapy Counseling & Treatment

- Counseling patients, family members, and caregivers regarding antimicrobial stewardship and resistance for the patient.
- Engaging in complex medical decision-making associated with antimicrobial prescribing including considerations such as antimicrobial resistance patterns, emergence of new variants/strains, recent antibiotic exposure, interactions/complications from comorbidities including concurrent infections, public health considerations to minimize development of antimicrobial resistance, and emerging and re-emerging infections.

For HCPCS code G0545, we proposed a work RVU of 0.89 based on the work RVU for HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*), which is 0.33, multiplied by a ratio of the work RVUs for CPT codes 99223 and 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*), 3.50 and 1.30, respectively. (This ratio is the work RVU of CPT code 99223 divided by the work RVU of CPT code 99213, 3.50 divided by 1.30, which equals 2.69. Multiplying the 0.33 work RVU of HCPCS code G2211 times 2.69 results in our work RVU of 0.89.) We stated in the proposed rule that we believe the relationship between the complexity add-on HCPCS code G2211 and a common base code for the add-on code, CPT code 99213, would strike the correct balance to estimate the time and complexity associated with the proposed new HCPCS code G0545, compared to what we believe would be a common base code for this new add-on code, CPT code 99223. HCPCS code G2211 has a total time of 11 minutes; therefore, we proposed a total time of 30 minutes for HCPCS code G0545 based on the same ratio (11 minutes times the same 2.69 ratio equals 30 minutes). HCPCS code G2211 has no direct PE inputs, and we proposed the same for HCPCS code G0545.

We stated that we believe that the work RVU appropriately falls between the following bracket add-on codes: HCPCS code G0316 (*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (do not report g0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99418, 99415, 99416). (do not report g0316 for any time unit less than 15 minutes)*) with a work RVU of 0.61 and the professional principal care management, chronic care management, and complex chronic care management CPT codes 99425 (*Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99437 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), and 99489 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30*

minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)) with work RVUs of 1.00.

To help inform whether our proposed descriptor is appropriate and reflects the typical service, we sought comment on the typical amount of time infectious disease physicians spend on the service elements and the relative intensity compared to similar service elements of other CPT codes. We noted that the valuation of HCPCS code G0545 is meant to capture the visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant that is not accounted for in the appropriate hospital inpatient or observation E/M base code billed by the infectious disease physician.

Interested parties have stated that consultations are a common E/M service performed by infectious disease clinicians, particularly in the inpatient setting, but stated that these services are no longer recognized by Medicare. Interested parties have also stated that this has resulted in a significant reduction in reporting and payment for infectious disease physician services. We noted that we addressed this in the CMS Claims Processing Manual, Chapter 12, section 30.6.9 F, stating that ''Physicians may bill initial hospital care service codes (99221–99223), for services that were reported with CPT consultation codes (99241–99255) prior to January 1, 2010, when the furnished service and documentation meet the minimum key component work and/or medical necessity requirements. Physicians may report a subsequent hospital care CPT code for services that were reported as CPT consultation codes (99241–99255) prior to January 1, 2010, where the medical record appropriately demonstrates that the work and medical necessity requirements are met for reporting a subsequent hospital care code (under the level selected), even though the reported code is for the provider's first E/M service to the inpatient during the hospital stay.'' Accordingly, we sought comment on any potential barriers for infectious disease physicians to use the initial and subsequent day hospital inpatient or observation codes, CPT codes 99221 through 99223 and 99231 through 99233, for consultations if they meet the coding requirements for time and/or medical decision making (MDM). We noted that understanding the barriers to utilizing these codes is important, as these codes would serve as the base codes for the proposed HCPCS code G0545 and would be billed by the infectious disease physician prior to billing HCPCS code G0545.

Finally, we recognized that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G codes and adopted them through the CPT Editorial Panel process. We noted that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to create a new HCPCS code to describe intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease. Specifically, commenters supported the code's creation, the proposed work RVU, code descriptor, code structure to be an add-on code to certain I/O E/M codes, and the three proposed service elements of the codes.

Some commenters requested clarification on certain aspects of the code. Specifically, some commenters requested clarification that performing one, or any combination, of the three proposed service elements would be sufficient to bill for the code because it would not be feasible to require all three in a single instance. One commenter asked for clarification regarding the intention to recognize the inherent complexity for all infectious diseases (for example, bacterial infections, MRSA, C. diff, COVID–19) or primarily emerging viral/microbial infections with epidemic potential. The commenter also requested clarification on the exclusion of the I/O E/M discharge CPT codes 99238 (*Hospital inpatient or observation discharge day management; 30 minutes or less on the date of the encounter*) and 99239 (*Hospital inpatient or observation discharge day management; more than 30 minutes on the date of the encounter*), on the specified list of applicable base codes for HCPCS code G0545, and the inclusion of CPT code 99213 (low MDM) in the work RVU analysis. The commenter stated that diagnosing and managing suspected, known, or emerging infectious diseases typically involves high medical decision making, therefore, CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*) would be more appropriate for potential work RVU comparisons. Lastly, the commenter requested clarification on the proposed total time of 30 minutes. The commenter asked if the proposed total time of 30 minutes is used to determine the quantity of reportable units of HCPCS code G0545, or if only one unit of HCPCS code G0545 is reportable per encounter.

Some commenters requested clarification that that no additional documentation requirements were being established, similar to HCPCS code G2211, and suggested that the infectious disease specialist's medical record should sufficiently demonstrate inherent complexity.

Response: We appreciate the overwhelming support from commenters regarding all elements of the proposed HCPCS code G0545. Regarding the clarifications requested about the three proposed service elements, we confirm that HCPCS code G0545 is intended to be used for one, or any combination, of the three proposed service elements. We recognize that each service element may not be medically appropriate for every patient with an infectious disease. Furthermore, we are clarifying that HCPCS code G0545 is intended to recognize the inherent complexity for all infectious diseases, and not just emerging infectious diseases with epidemic potential. *Clostridium Difficile* infection, for example, can complicate antibiotic selection and can spread from patient to patient in an inpatient setting without proper infection prevention strategies put in place, requiring several of the code descriptor elements be performed by the treating clinician. As stated in the proposed rule, we continue to believe the relationship between HCPCS code G2211 and a common base code for the add-on code, CPT code 99213, would strike the correct balance to estimate the time and complexity associated with HCPCS code G0545, compared to what we believe would be a common base code for this new add-on code, CPT code 99223. This assumption is supported by 2022 Medicare utilization data for the infectious disease specialty, available on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* If we take the commenter's suggestion and use CPT code 99215 in our analysis to represent the high MDM O/O E/M visit, this would decrease the work RVU for

HCPCS G0545 (that is, the work RVU of CPT code 99223 divided by the work RVU of CPT code 99215, 3.50 divided by 2.80, which equals 1.25. Multiplying the 0.33 work RVU of HCPCS code G2211 times 1.25 would result in a work RVU of 0.41.). We acknowledge that this was likely not the commenter's intention, and that CPT code 99223, used in the proposed work RVU analysis, represents the most common initial I/O E/M visit billed by the infectious disease specialty in 2022 Medicare utilization data, and represents high MDM. Additionally, CPT code 99232 is the most common I/O E/M visit billed by the infectious disease specialty, which represents the subsequent I/O E/M visit with moderate MDM, but using this code in the work RVU analysis would also decrease the work RVU calculation for HCPCS code G0545 (that is, the work RVU of CPT code 99232 divided by the work RVU of CPT code 99213, 1.59 divided by 1.30, which equals 1.22. Multiplying the 0.33 work RVU of HCPCS code G2211 times 1.22 would result in a work RVU of 0.40.). We note that the work RVU analysis for HCPCS code G0545 was not intended to indicate an assumption about the level of medical decision making associated with diagnosing and managing suspected, known, or emerging infectious diseases, and we continue to believe that the comparison of HCPCS code G2211 and CPT code 99213, compared to CPT code 99223 strikes the correct balance to estimate the typical time and complexity associated with HCPCS code G0545, therefore we are finalizing our proposed work RVU of 0.89 for HCPCS code G0545. Additionally, we agree with the commenter that the I/O E/M discharge day management CPT codes are applicable base codes for HCPCS code G0545, as they were inadvertently omitted from the list of applicable base codes in the CY 2025 PFS proposed rule, therefore we are finalizing the inclusion of CPT codes 99238 and 99239 to the list of base codes.

We note that, while we proposed a total time of 30 minutes for HCPCS code G0545, similar to HCPCS code G2211, HCPCS code G0545 is not intended to be a time-based code. The proposed total time adheres to a longstanding practice of establishing times for a new code to represent the anticipated typical time of a service and should not be used to determine reportable units of the code. We acknowledge that I/O E/M visit levels and prolonged service codes are intended to account for additional minutes of time for individual patients, whereas HCPCS code G0545 is intended to account for the visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease. For time-based reporting of additional incremental time, we refer the commenter to the prolonged hospital I/O E/M code, HCPCS code G0316 (*Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to cpt codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (do not report g0316 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99418, 99415, 99416). (do not report g0316 for any time unit less than 15 minutes)*).

Like HCPCS code G2211, we did not specify any additional medical record documentation requirements for reporting the HCPCS code G0545 add-on code. Our medical reviewers may use the medical record documentation to confirm the medical necessity of the visit and the confirmed or suspected infectious disease as appropriate. We would expect that information included in the medical record or in the claims history for a patient/practitioner combination, such as diagnoses, the practitioner's assessment and medical plan of care, and/or other codes reported could serve as supporting documentation for billing HCPCS code G0545. Practitioners should consult their Medicare Administrative Contractor (MAC) regarding documentation requirements related to the underlying I/O E/M visit.

Comment: Some commenters requested the code to be modified to a stand-alone code rather than an add-on code because the work described by this code may be done with or without the medical necessity of a face-to-face visit. Commenters stated that there are barriers for infectious disease specialists in reporting the inpatient daily care codes that are proposed as base codes for HCPCS code G0545 because the medical decision-making is based on review of significant amounts of data in medical records and can be done without a face-to-face visit with the patient. Therefore, commenters requested that HCPCS code G0545 be a stand-alone code rather than an add-on code to the proposed hospital I/O E/M codes.

Response: We appreciate the commenters' suggestion of modifying HCPCS code G0545 to be a stand-alone code given the possible barriers to reporting the proposed base codes. However, at this time, we are finalizing HCPCS code G0545 as an add-on code as proposed because we did not receive any commenter input on appropriate definition or valuation for the code as a stand-alone code such as a code descriptor, service elements, physician time, work RVU, and what codes would be inappropriate to bill alongside a stand-alone infectious disease code to avoid duplicative payment for these services.

We also note that there are interprofessional consultation codes, CPT codes 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician or other qualified health care professional, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*), and 99446 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician or other qualified health care professional, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review*) through 99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician or other qualified health care professional, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review*), that could be used to report non-face-to-face consults furnished by infectious disease specialists. These six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis

and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional (83 FR 59489).

Comment: One commenter requested clarification about reporting both HCPCS codes G2211 and G0545 because infectious disease specialists are likely to report their visits with the office/outpatient (O/O) E/M codes, since they are rarely the physician ordering and providing the observation service who will report the hospital I/O E/M codes.

Response: We appreciate the commenter's input regarding the use of the new HCPCS code G0545. However, HCPCS codes G2211 and G0545 have differing base codes and therefore, cannot be reported together. We acknowledge that some commenters raised concerns about barriers to reporting the proposed base codes for HCPCS code G0545, but no other commenters raised that they typically use the O/O E/M codes. We also note that 2022 Medicare utilization data, available on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html* does not support the assertion that infectious disease specialists are likely to report their visits with the office/outpatient (O/O) E/M codes, therefore, we continue to believe that the proposed base codes for HCPCS code G0545 are appropriate. We are open to feedback from interested parties and may consider additional information for future rulemaking.

Comment: Some commenters requested that we allow a broader scope of qualifying practitioners to be able to bill for HCPCS code G0545 in order to ensure nurses and other qualified practitioners can bill for the expert care they provide in treating infectious diseases.

Response: We appreciate the commenters' suggestion to broaden the scope of practitioners who may bill for HCPCS code G0545. We agree with commenters that it is possible that practitioners other than physicians could provide vital care in treating infectious diseases. Therefore, we are finalizing a modified code descriptor for HCPCS code G0545 that refers to ''an infectious diseases specialist'' to enable all practitioners with specialized training in infectious diseases who can independently bill Medicare for E/M visits to report the HCPCS code G0545 add-on code to the following I/O E/M base codes: CPT codes 99221 through 99223, 99231 through 99233, 99234 through 99235, and 99238 through 99239. The finalized full descriptor for the hospital I/O E/M visit complexity add-on code is HCPCS code G0545 (*Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases specialist, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and/or complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, subsequent or discharge*). We maintain the expectation that HCPCS code G0545 will be reported by practitioners who have the requisite specialized infectious disease training, including but not limited to physicians, nurse practitioners, physician assistants, and certified nurse specialists.

Comment: A few commenters did not support the creation of HCPCS code G0545, stating that they do not support specialty-specific codes because these codes favor the expertise of one specialty more than others. The commenters stated that CPT codes are not meant to be specialty specific, and this proposal goes against long-standing convention and can cause additional imbalances. Instead, the commenters requested a generalized G code for complex inpatient non-procedural care that all specialties could use, like HCPCS code G2211. Commenters stated that there is no clear reason to solely enhance payment for infectious disease specialists via an add-on code when there are various other specialties that frequently provide vital E/M services in inpatient settings whose professional services are undervalued under the current fee schedule. Commenters stated that this represents a broader issue with undervaluation of E/M services, and that they are willing continue to work with CMS, as well as legislators and other stakeholders, on strengthening physician payment to meet broader workforce needs.

Response: We appreciate the commenters' input regarding specialty-specific codes. We continue to believe that the increased work and unique complexity associated with diagnosis, management, and treatment of infectious diseases are not adequately accounted for in the current hospital I/O E/M codes. We reiterate our belief that infectious diseases are unique in that they present infection control risks for the patient and close contacts, including healthcare staff, that require attention to safely care for the patient, healthcare staff, and other patients in the facility. They present unique challenges in diagnosis in that any previous healthcare interaction could affect the individual resistance patterns of pathogens infecting the individual patient and require close contact with public health agencies since resistance patterns are constantly changing, so a much more extensive medical review is required. Additionally, individual decisions regarding treatment are unique in that use in one patient affects resistance patterns of the entire population, which requires additional expertise to inform antimicrobial selection and management to achieve broader public health goals.

After consideration of public comments, we are finalizing the creation of HCPCS code G0545 as proposed with modifications to the HCPCS code descriptor. We reiterate that we would consider using any newly available CPT coding to describe infectious disease services in future rulemaking.

(38) Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)

To facilitate prompt beneficiary access to PrEP for CY 2024, we established 3 HCPCS G codes that describe the service of counseling and administration of Human Immunodeficiency Virus (HIV) pre-exposure prophylaxis drugs. Specifically, HCPCS codes G0011 (*Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15–30 minutes*) and G0013 (*Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence*) describe the counseling portion of the service, and G0012 (*Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle*) describes the injection of the medication.

CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. This proposed NCD announced CMS' intent to cover and pay for those drugs under the section 1861(ddd) additional preventive services authority, and a final NCD was published on September 30, 2024. For CY 2025, we proposed national rates for these HCPCS codes that reflect the relative resource costs associated with the counseling and drug administration portions of the service,

pending finalization of the NCD. For HCPCS code G0011, we proposed a work RVU of 0.45 based off work and direct PE inputs crosswalked from HCPCS code G0445 (*High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes*). For HCPCS code G0012, we proposed a work RVU of 0.17 based on the work and direct PE crosswalked from CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*), and for HCPCS code G0013 we proposed a work RVU of 0.18 based on the work and direct PE inputs crosswalked from CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*). We appreciate having this opportunity for interested parties to provide feedback on the most accurate way to value these services.

Comment: We received several comments regarding CMS' proposed national payment rates for HCPCS codes G0011, G0012, and G0013. Some commenters agreed with CMS' proposed work RVU and direct PE inputs for this code family while one commenter disagreed with the crosswalk code, CPT code 99211, for HCPCS code G0013. This commenter suggested that CMS crosswalk this code to CPT code 99213 to better account for time and complexity.

Response: We appreciate commenters' support for the proposed national payment rates for this service. We disagree with commenters and continue to believe that CPT code 99211 is the appropriate crosswalk for HCPCS code G0013 because CPT code 99211 describes a counseling service conducted by clinical staff as opposed to a physician or QHP. This aligns with the code descriptor for G0013 (*Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence*) which also describes the work of clinical staff.

Comment: We received several comments expressing a variety of concerns related to the coverage policy for this service as described in the proposed NCD. Many comments included a request for better inclusion of pharmacists. Some comments would like CMS to partner with pharmacies to allow pharmacists to order HIV PrEP medications, as well as provide the counseling portion of the service. Commenters also asked CMS to clarify that pharmacists are considered clinical staff and/or streamline billing processes to enable pharmacists to bill for PrEP services under their own National Provider Identifier (NPI).

Response: We appreciate and acknowledge commenters' concerns regarding the coverage policy in our proposed NCD. However, concerns related to the coverage policy of HIV PrEP are considered out of scope for our proposal regarding the national payment rates for this service.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for HIV PrEP as proposed.

(39) Opfolda

For CY 2024, to facilitate beneficiary access to treatment of late-onset Pompe disease with miglustat in combination with cipaglucosidae alfa-atga, we created a new HCPCS code, G0138, describing the service of administration of cipaglucosidase alfa-atga (Pombiliti), which includes the intravenous administration of cipaglucosidase alfa-atga, the provider or supplier's acquisition cost of miglustat, clinical supervision, and oral administration of miglustat. HCPCS code G0138 (*Intravenous infusion of cipaglucosidase alfaatga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga*) was added to the PFS effective April 1, 2024, as a contractor priced service. More information regarding the creation of HCPCS code G0138 can be found at *https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-updated-1/30/2024.pdf*.

For CY 2025, we proposed national pricing for this service that reflects the relative resource costs associated with the infusion administration of Cipaglucosidae alfa-atga and clinical supervision and provision of Miglustat oral with acquisition costs. We proposed a work RVU of 0.21 for HCPCS code G0138 based on a crosswalk from CPT code 96365 (*Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour*). This includes a crosswalked total time of 9 minutes and an intraservice time of 5 minutes. We also proposed to crosswalk the direct PE inputs from CPT code 96365 for use in valuing HCPCS code G0138. However, we are adding 1 minute of L056A clinical staff time during the preservice portion of the service period to capture the RN/OCN observation of the patient during administration of the Opfolda pill. In addition, to account for the cost of the provision of the self-administered Opfolda as a direct PE input, we are incorporating the wholesale acquisition cost (WAC) data from the most recent available quarter. We proposed a price of $32.50 for the supply input that describes a 65mg capsule of Opfolda (supply code SH111). We sought feedback from interested parties on our proposal of national pricing, as well as our work RVU and direct PE inputs for HCPCS code G0138 to ensure proper payment for this service.

Comment: Regarding the proper payment for this service, one commenter stated that the correct WAC for supply code SH111 (65mg Opfolda pill) is $33.00 per pill and that the typical dosage of SH111 is 3 to 4 pills per patient, which would mean the total acquisition cost would be $132. The commenter also stated that they believe the infusion time for Cipaglucosidae alfa-atga incorporated in G0138 should be 4 to 5 hours instead of 1 hour and that the CPT crosswalk code 96365 does not adequately account for that time. Finally, the commenter requested that CMS incorporate the overhead and clinical staff expenses incurred after the administration of Opfolda and while the patient is observed.

Response: We thank the commenter for providing information to update the national payment for this service. We agree with the commenter that the prescribing information indicates that the typical dosage of Opfolda is 260mg for patients weighing ≥50 kg. We also agree with the commenter that the typical infusion time for Cipaglucosidae alfa-atga is 4 hours. However, we disagree with the commenter and continue to believe that CPT code 96365 is the appropriate crosswalk code for the infusion portion of the service. The overall increase in infusion time can be added to the direct PE equipment input to account for the extra 3 hours. We also believe that the 1 minute of L056A clinical staff time during the preservice portion of the service period adequately captures the RN/OCN observation of the patient during self-administration of the Opfolda pill. After consideration of the public comments, we are increasing the quantity of supply code SH111 in HCPCS code G0138 to 3.5 pills based on an average patient weight at a WAC of $33.00 per pill. We are also increasing the direct PE equipment time for EQ032 IV infusion pump and EF009 medical recliner chair from 60 minutes to 240

minutes. The work RVU and other direct PE inputs will be finalized as proposed.

(40) Payment for Caregiver Training Services

a. Background

In the CY 2017 PFS final rule (81 FR 80330 through 80331), we finalized payment for new CPT code(s) describing administration of a patient-focused health risk assessment instrument as well as administration of a caregiver-focused health risk assessment instrument. In the CY 2024 PFS final rule (88 FR 78914), we finalized the assignment of a payable status for caregiver training services (CTS) for therapy and behavior management/modification services (without the patient present) and finalized the RUC-recommended valuations for these services to better recognize the role that caregivers play in reasonable and necessary care for Medicare beneficiaries. These codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient in carrying out the treatment plan.

We finalized in the CY 2024 PFS final rule that payment may be made for CTS when the treating practitioner identifies a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered treatment plan. We also finalized that because CTS are furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS. Additionally, we finalized that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record. These finalized policies apply to current CTS coding and we also proposed for them to apply to the newly proposed CTS coding that follows. We continue to receive questions and requests from interested parties about how we can refine payment for these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters requested clarification that caregiver training services (described by CPT codes 97550, 97551, 97552, 96202, and 96203, as well as any caregiver training services HCPCS codes finalized in this year's rule, and any subsequently created caregiver training service codes) may be provided by auxiliary personnel incident to the services of a billing practitioner.

Response: Payment for CTS may be made to physicians, nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), physician assistants (PAs) and clinical psychologists (CPs) under the PFS when they bill for CTS personally performed by them or by other practitioners or auxiliary personnel as an incident to their professional services.

Comment: Commenters requested that we clarify whether practitioners who are limited by statute to performing services for the diagnosis and treatment of mental illness (such as clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors) can furnish caregiver training services.

Response: Clinical social workers, marriage and family therapists, and mental health counselors can bill Medicare directly for caregiver training services they personally perform for the diagnosis or treatment of mental illness, so long as all other billing requirements are met. However, clinical social workers, marriage and family therapists, and mental health counselors cannot directly bill Medicare for caregiver training services if they were provided by auxiliary personnel, as they are not authorized to supervise, bill, and be paid directly by Medicare for services that are provided by auxiliary personnel incident to their professional services.

Comment: Commenters requested clarification of the minimum amount of time of caregiving training that must be furnished to report the code.

Response: Caregiver training services are treated the same as most other timed services, and the full-time listed in the code descriptor is required.

Comment: Commenters recommended that CMS avoid creating duplicative caregiver training HCPCS codes and instead work with the AMA to consider revisions to CPT coding. Other commenters suggested we work with CPT to create simpler caregiver training codes or re-create current coding to be more inclusive of different types of caregiver training services.

Response: We understand the desire from commenters for simpler coding for caregiver training. However, we also understand the immediate needs of beneficiaries for varying types of caregiver training services that are not currently represented by CPT coding. CMS is available to meet with the CPT Editorial Panel and the AMA to provide input and feedback regarding caregiver training CPT coding for future code creation or editing. Until then, we believe that it is paramount for patients to have appropriate access to these types of services through the creation of HCPCS G codes.

b. Caregiver Assessment

In response to interested parties' requests for assessment of a caregiver's knowledge to be included in caregiver training, we clarified that when reasonable and necessary, assessing the caregiver's skills and knowledge for the purposes of caregiver training services could be included in the service described by CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)* to determine if caregiver training services are needed. We also note that CPT code 96161 is currently on the Medicare Telehealth list.

We note that, as specified in the CY 2017 PFS final rule (81 FR 80330), in particular cases, caregiver-focused health risk assessments can be necessary components of services furnished to Medicare beneficiaries. Examples where this service may be reasonable and necessary may include assessment of maternal depression in the active care of infants, assessment of parental mental health as part of evaluating a child's functioning, assessment of caretaker conditions as indicated where atypical parent/child interactions are observed during care, and assessment of caregivers as part of care management for adults whose physical or cognitive status renders them incapable of independent living and dependent on another adult caregiver. Commenters cited that some examples of such individuals might include intellectually disabled adults, seriously disabled military veterans, and adults with significant musculoskeletal or central nervous system impairments (81 FR 80331).

We proposed that because the caregiver-focused health risk assessment may be furnished outside the patient's presence, the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the assessment. We also proposed that the definition of ''caregiver'' specified in the CY 2024 PFS final rule (88 FR 78917) will be the same for caregiver training services and the caregiver-focused health risk assessment.

We sought comment on these proposals and clarifications.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: Some commenters supported our clarifications that CPT code 96161 can be used to determine if caregiver training services are needed. Commenters were also supportive of our proposed consent requirements and proposed adoption of the definition of ''caregiver''.

Response: We thank commenters for their input. We clarify that a caregiver is not required to have a caregiver-focused health risk assessment to participate in caregiver training services.

After consideration of public comments, we are finalizing as proposed.

c. Proposals and New Coding

(A) Proposed Direct Care Caregiver Training Services

i. Coding

We proposed to establish new coding and payment for caregiver training for direct care services and supports. The topics of training could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. For example, in the direct care CTS codes, a caregiver could be taught how to properly change wound dressings to promote healing and prevent infection. This skill, among other direct care services, would not fall into the categories of CTS codes that currently exist (behavior management/modification or strategies and techniques to facilitate the patient's functional performance in the home or community) but is integral in effectuating the patient's treatment plan. Like other codes describing caregiver training services, these proposed new codes would reflect the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. We believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example, when the patient cannot follow through with the treatment plan for themselves.

We proposed three new HCPCS codes: G0541 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes*), G0542 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541)*), and G0543 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)*).

We continue to believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The medical or direct care CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example when the patient cannot follow through with the treatment plan for themselves. Direct care training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. Additionally, this would not be billable for caregiver training that is already being separately billed for patients under home health plan of care, receiving at-home therapy, or receiving DME services for involved medical equipment and supplies.

We sought additional information from commenters about potential service overlaps and potential examples of direct care services to receive caregiver training to inform our final policy. We solicited public comment on each of our proposals for direct care CTS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the creation of these codes.

Response: We thank commenters for their support.

Comment: One commenter requested to use the term ''pressure injury'' as opposed to ''decubitus ulcer'' in these code descriptors.

Response: We thank commenters for their input and would like to note that the term ''decubitus ulcer'' is included in the code descriptor only as an example, and caregiver training for the broader term ''pressure injuries'' would be permitted when reasonable and necessary, as CMS uses both terms.

Comment: One commenter requested that we specify that these direct care caregiver training services are ''not billable for patients receiving durable medical equipment (DME) services for medical equipment and supplies,'' although surgical dressings are part of DMEPOS equipment and related supplies. The commenter also requested that we clarify the definition of DME services and how wound dressings are involved in those services.

Response: We seek to avoid potentially duplicative payment for services that are already paid for as part of another Medicare benefit such as the Medicare Part B benefit for durable medical equipment (DME) or the Medicare Part B benefit for surgical dressings. Payment to suppliers of DME items such as drug infusion pumps includes payment for supplies associated with use of the pump, such as wound dressings at the catheter site. DME suppliers are required to train the beneficiary or caregiver on use of supplies necessary for the effective use of the infusion pump, such as the dressings at the catheter site. Likewise, payment to suppliers of dressings covered under the Part B benefit for surgical dressings includes payment related to training the beneficiary or caregiver on how to use the dressings, including how to change them correctly.

However, we would also like to clarify that the goal of paying for the

direct care CTS for beneficiaries with wounds includes training related to all aspects of wound care, such as how to properly change dressings, use of different ointments, turning the patient to prevent pressure. Therefore, we are revising the direct care CTS code descriptors to replace the words ''wound dressing changes'' with ''wound care.'' We are finalizing the direct care CTS code descriptors to read:

- G0541 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes*);
- G0542 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541)*); and
- G0543 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)*).

Comment: Some commenters requested that we remove the restriction for patients under home health plans of care, receiving at-home therapy, or receiving DME services for unrelated conditions.

Response: We agree with commenters that caregiver training may be appropriate for circumstances where a beneficiary's caregiver needs training, but the patient is under a home health plan of care, receiving at-home therapy, or receiving DME services for unrelated conditions. CTS would not be billable for caregiver training that is already being separately billed for patients under a home health plan of care, receiving at-home therapy, or receiving DME services for involved medical equipment and supplies. We seek to avoid potentially duplicative payment. We would not expect the caregiver population receiving these services on behalf of the patient to also receive CTS on behalf of the patient under another Medicare benefit category or Federal program.

Comment: Some commenters requested that we recognize that RDNs may provide CTS for special diet preparation.

Response: Registered dieticians (RDs) and nutrition professionals may only furnish direct care CTS when they identify a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered care plan for medical nutrition therapy (MNT) services. Medical nutrition therapy services are defined in section 1861(vv) of the Act as nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a RD or nutrition professional pursuant to a physician's referral. Under sections 1861(s)(2)(V) and 1861(vv) of the Act, RDs and nutrition professionals are limited to billing for MNT services they furnish to individuals with diabetes or a renal disease who meet certain specified criteria. This limitation would also apply to direct care CTS. In addition, because CTS are furnished outside the patient's presence, the RD or nutrition professional must obtain the patient's (or representative's) consent for the caregiver to receive the direct care CTS. Like other CTS, the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS must be documented in the patient's medical record.

Comment: Some commenters requested that these services would be designated as ''sometimes therapy'' services.

Response: We are designating direct care CTS as ''sometimes therapy'' services to facilitate payment for CTS under the PFS for outpatient physical therapy, occupational therapy, and speech-language pathology services when personally furnished by PTs and OTs, including those provided by their supervised assistants as appropriate, as well as the CTS personally furnished by SLPs. This means, as we stated in the CY 2024 PFS final rule (88 FR 78920) for the other CTS codes, that the services described by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care, that is, where the services are not integral to a therapy plan of care, they can be furnished under a treatment plan by physicians and NPPs.

Comment: Many commenters requested that we add examples, such as caregiver training for home dialysis and rare disease treatments, describing other types of direct care to these code descriptors. Commenters also recommended working with interested parties to develop further examples.

Response: The examples of health conditions for which direct care CTS might be appropriate were not intended to be exhaustive. We acknowledge that there are many circumstances under which direct care CTS may be reasonable and necessary to train a caregiver who assists in carrying out a treatment plan.

After consideration of public comments, we are finalizing the following code descriptors: G0541 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes), G0542 (Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0542 in conjunction with G0541)), and G0543 (Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers)). We are also finalizing that caregiver training may be appropriate for circumstances where a beneficiary's caregiver needs training, but the patient is under a home health plan of care, receiving at-home therapy, or receiving DME services for unrelated conditions. In addition, we are finalizing that G0541, G0542, and G0543 are designated as ''sometimes therapy'' services. All other details for these codes are being finalized as proposed.

ii. Valuation

For G0541, we proposed a direct crosswalk to CPT Code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing,*

feeding, problem-solving, safety practices) (without the patient present), face to face; initial 30 minutes), with a work RVU of 1.00 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0541. CPT code 97550 has an intraservice time of 30 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0541. Therefore, we proposed a work time of 30 minutes intraservice time (40 minutes of total time) for HCPCS code G0541 based on this same crosswalk to CPT 97550. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0541.

For G0542, we proposed a direct crosswalk to CPT Code 97551 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service)*), with a work RVU of 0.54 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0542. CPT code 97551 has an intraservice time of 17 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0542. Therefore, we proposed a work time of 17 minutes for HCPCS code G0542 based on this same crosswalk to CPT 97551. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0542.

For G0543, we proposed a direct crosswalk to CPT Code 97552 (*Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face with multiple sets of caregivers*), with a work RVU of 0.23 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0543. CPT code 97552 has an intraservice time of 9 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0541. Therefore, we proposed a work time of 9 minutes intraservice time (14 minutes total time) for HCPCS code G0543 based on this same crosswalk to CPT 97552. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0543.

We sought comment on supplies/equipment that would be typical for the newly created direct care strategies and techniques CTS codes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters pointed out that the proposed rule inadvertently referred to HCPCS codes GCTD1–3 in this section as GCTM1–3.

Response: We would like to thank commenters for pointing out this inadvertent drafting error. These codes are corrected above with the code descriptors for HCPCS codes G0541–G0543.

After consideration of public comments, we are finalizing the code descriptors for direct care caregiver training services, as described by HCPCS codes G0541–G0543.

Comment: Some commenters supported our valuation for HCPCS codes G0541–G0543. We did not receive comments discussing specific supplies and equipment that would be typical for these codes.

Response: We thank commenters for their input on the valuation of HCPCS codes G0541–G0543.

After consideration of public comments, we are finalizing as proposed.

We believe these services would largely involve contact between the billing practitioner and the caregiver through in-person interactions, which could be conducted via telecommunications, as appropriate. Therefore, we proposed to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth. Please see section II.D. for more information on Medicare Telehealth Services.

We sought comments on these proposals.

We received public comments on these proposals. Please refer to section II.D. for a summary of the comments we received and our responses.

(B) Individual Behavior Management/Modification Caregiver Training Services

i. Coding

We proposed to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. Current CPT coding (CPT 96202 and 96203) allows for ''multiple-family group behavior management/modification training services,'' meaning that this caregiver training service can only be furnished in a group setting with multiple sets of caregivers of multiple beneficiaries (please reference 88 FR 78818 for discussion of CPT 96202 and 96203). We proposed two new HCPCS codes: G0539 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes*) and G0540 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use G0540 in conjunction with G0539)*).

We continue to believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The behavior management/modification CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. We believe this is especially the case in medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient—for example when the patient cannot follow through with the treatment plan for themselves. Behavior management/modification training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. All other policies and procedures surrounding CPT 96202 and 96203 will also apply to these services (88 FR 78914–78920).

We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposals to establish HCPCS codes G0539 and G0540. We received some comments requesting the

creation of broader caregiver training codes in the future.

Response: We thank commenters for their input, and we may consider commenters' recommendations for future rulemaking.

After consideration of public comments, we are finalizing HCPCS codes G0539 and G0540 as proposed.

ii. Valuation

For HCPCS code G0539, we proposed a direct crosswalk to CPT Code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes*), with a work RVU of 1.00 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0539. CPT code 97550 has an intraservice time of 30 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0539. Therefore, we proposed a work time of 30 minutes intraservice time (40 minutes of total time) for HCPCS code G0539 based on this same crosswalk to CPT 97550. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0539. We sought comment on supplies/equipment that would be typical for the newly created individual behavior management/modification CTS codes.

For HCPCS code G0540, we proposed a direct crosswalk to CPT Code 97551 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; each additional 15 minutes (List separately in addition to code for primary service)*), with a work RVU of 0.54 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0540. CPT code 97551 has an intraservice time of 17 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0540. Therefore, we proposed a work time of 17 minutes for HCPCS code G0540 based on this same crosswalk to CPT 97551. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0540.

We sought comment on supplies/equipment that will be typical for the newly created individual behavior management/modification CTS codes.

We believe these services will largely involve contact between the billing practitioner and the caregiver through in-person interactions, which could be conducted via telecommunications as appropriate. Therefore, we proposed to add these codes to the Medicare Telehealth Services List to accommodate a scenario in which the practitioner completes the caregiver training service via telehealth. Please see section II.D. for more information on Medicare Telehealth Services.

We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our valuation for HCPCS codes G0539 and G0540. In addition, a few commenters supported a crosswalk to CPT code 90832 (*Psychotherapy, 30 minutes with patient*), as commenters stated this was a more analogous code. We did not receive comments discussing specific supplies and equipment that would be typical for these codes.

Response: We continue to believe that a crosswalk to CPT codes 97550 and 97551 are most appropriate for valuation of HCPCS codes G0539 and G0540, as these codes match closely in time and intensity. In an effort to maintain relativity within the caregiver training code family, we believe this crosswalk is appropriate.

After consideration of public comments, we are finalizing as proposed.

(C) Patient Consent

In the CY 2024 PFS final rule (88 FR 78916), we finalized a requirement that the treating practitioner must obtain the patient's (or representative's) consent for the caregiver to receive the CTS and that the identified need for CTS and the patient's (or representative's) consent for one or more specific caregivers to receive CTS be documented in the patient's medical record.

We proposed that consent for CTS can be provided verbally by the patient (or representative). This will align consent requirements with other services paid under the PFS that may be furnished without the patient present, such as certain care management services. This proposal will apply to CPT codes 97550, 97551, 97552, 96202, and 96203, as well as any caregiver training services HCPCS codes finalized in this year's rule, and any subsequently created caregiver training service codes. We sought comment on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of our proposal to allow verbal consent for caregiver training services.

Response: We appreciate commenters' input.

After consideration of public comments, we are finalizing as proposed.

(D) Addition to Telehealth List

Please see section II.D. of this final rule, Payment for Medicare Telehealth Services, for the outline related to proposals to add CTS to the Medicare Telehealth list.

(41) Request for Information for Services Addressing Health-Related Social Needs (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))

a. Background

In the CY 2024 PFS final rule (88 FR 78920), we finalized G-codes to reflect new coding and payment for services describing Community Health Integration (CHI), G0019 (Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month), and G0022 (Community health integration services, each additional 30 minutes per calendar month), which may include a community health worker (CHW), incident to the professional services and under the general supervision of the billing practitioner. We finalized a new stand-alone G code describing a SDOH Risk Assessment, G0136 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months). SDOH risk assessment refers to a review of the individual's SDOH or identified social risk factors that influence the diagnosis and treatment of medical conditions. We also finalized PIN services, described by HCPCS code G0023 (Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar

month) and G0024 (*Principal Illness Navigation services, additional 30 minutes per calendar month*); G0140 (*Principal Illness Navigation—Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month*) and G0146 (*Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month*), to better recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer support specialist, are involved in the patient's health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death.

b. Request for Information on Services Addressing Health-Related Social Needs

For CY 2025 we issued a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) (HPCCS codes G0019, G0022), Principal Illness Navigation (PIN) (HCPCS codes G0023, G0024), Principal Illness Navigation- Peer Support (PIN–PS) (HCPCS codes G0140, G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (HCPCS code G0136) services to engage interested parties on additional policy refinements for CMS to consider in future rulemaking.

We are interested in better addressing the social needs of beneficiaries and requesting information on the codes we created and finalized beginning in CY 2024 to fully encompass what interested parties and commenters believe should be included in the coding and payment we recently established. We sought comment on any related services that may not be described by the current coding that we finalized in the CY 2024 PFS final rule and that are medically reasonable and necessary ''for the diagnosis or treatment of illness or injury'' under section 1862(a)(1)(A) of the Act. We believe we can work within the current coding framework and explore additional opportunities to create codes that describe reasonable and necessary services furnished by billing practitioners and the auxiliary personnel under their general supervision. We are interested in feedback regarding any barriers to furnishing the services addressing health-related social needs, and if the service described by the codes we established are allowing practitioners to better address unmet social needs that interfere with the practitioners' ability to diagnose and treat the patient. This could include barriers specific to certain populations, including rural and tribal communities, residents of the U.S. Territories, individuals with disabilities, individuals with limited English proficiency, or other populations who experience specific unmet social needs.

In response to the CY 2024 PFS proposed rule, we heard from commenters that CSWs often connect individuals with community-based resources to address unmet social needs that affect the diagnosis and treatment of medical problems. CSWs can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness but are not authorized by statute to bill for services that are provided by auxiliary personnel incident to their professional services. Since CHI and PIN codes are typically provided by auxiliary personnel supervised by the billing practitioner, CSWs could serve as the auxiliary personnel. CSWs could not directly bill Medicare for CHI and PIN services if they were provided by auxiliary personnel, as they are not authorized to supervise, bill, and be paid directly by Medicare for services that are provided by auxiliary personnel incident to their professional services. We believe the current CHI and PIN coding accurately captures the services CSWs currently provide, including the work involved in connecting beneficiaries with community-based resources for unmet social needs that affect the diagnosis or treatment of medical problems. As we stated previously in the CY 2024 PFS final rule (88 FR 78926), ''the codes do not limit the types of other health care professionals, such as registered nurses and social workers, that can perform CHI services (and PIN services, as we discuss in the next section) incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1).'' We proposed to clarify that when we refer to ''certified or trained auxiliary personnel'' in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes CSWs.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported of this clarification.

Response: We thank commenters for their input.

We are finalizing our clarification as proposed.

We requested information if there are other types of auxiliary personnel, other certifications, and/or training requirements that are not adequately captured in current coding and payment for these services. We are also interested in hearing more about what types of auxiliary personnel are typically furnishing these services, including the certifications and/or licensure that they have. We are also interested in whether there are nuances or considerations that CMS should understand related to auxiliary personnel and training, certifications or licensure barriers or requirements that are specifically experienced by practitioners serving underserved communities. This could include settings such as community mental health centers, community health clinics including FQHCs and RHCs, tribal health centers, migrant farmworker clinics, or facilities located in and serving rural and geographically isolated communities including the U.S. Territories.

As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to community-based organizations, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. We stated that, generally, we believe such organizations know the populations and communities they serve and may have the infrastructure or systems in place to assist practitioners to provide CHI and PIN services. We stated that we understood that many community-based organizations (CBOs) provide social services and do other work that is beyond the scope of CHI and PIN

services, but we believed they are well-positioned to develop relationships with practitioners for providing reasonable and necessary CHI and PIN services.

We are interested in hearing more about CBOs and their collaborative relationships with billing practitioners. The new codes for CHI and PIN services recognized CBOs and their role in providing auxiliary personnel under the general supervision of the billing practitioners. We sought comment regarding the extent to which practitioners are contracting with CBOs (including current or planned contracting arrangements) for auxiliary personnel purposes, and if there is anything else CMS should do to clarify services where auxiliary personnel can be employed by the CBO, so long as they are under the general supervision of the billing practitioner. Given that the CHI and PIN services may be provided incident to the billing practitioner's professional services, we are also seeking comment on whether the incident to billing construct is appropriate for CBOs to supplement pre-existing staffing arrangements and the CBO/provider interface. We also sought comment on CBOs' roles, the extent to which practitioners are contracting with CBOs, incident to billing, and auxiliary personnel employed by CBOs under general supervision of practitioners serving and located in rural, tribal and geographically isolated communities, including the U.S. Territories.

We also solicited comments from interested parties across provider types and from practitioners in geographically isolated communities (for example, rural, tribal, and island communities) and otherwise underserved communities about coding Z codes on claims associated with billing for CHI, PIN, and SDOH risk assessment codes. We recognized that when screening for social needs, such needs may be identified and are interested in learning whether practitioners are also capturing unmet social needs on claims using Z codes for social risk factors or in some other way, and any barriers or opportunities to increase coding of Z codes when social risk factors screen positive.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care and addressing unmet social needs that affect the diagnosis and treatment of medical problems. Given the Agency's broader policy goals of increasing access to care, we are requesting information from interested parties and commenters on anything else that we should consider in the context of these codes and what else we could consider to be included in this newly established code set.

We sought comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high-value, potentially underutilized services by Medicare beneficiaries.

We sought public comment to understand more clearly how often evidence-based care for persons with fractures, for example, is not provided and the reasons for this, and how recent or new PFS codes, or their revaluation, might help resolve specific barriers to its provision. The PFS currently includes many codes that pay for various components of care to manage patients with fractures over a course of treatment, such as transitional care management (TCM) and other care management services, evaluation and management visits (including the inherent complexity add-on for office/outpatient visits), principal illness navigation services, community health integration services, and the social determinants of health risk assessment. We referred readers to our recent guidance on these services on the CMS website at *https://www.cms.gov/files/document/health-related-social-needs-faq.pdf.* Medicare also pays for bone mass measurement/density tests (*MLN006559—https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html#BONE_MASS*, and for outpatient osteoporosis medication under Part D and, in some cases, Part B (*https://www.medicare.gov/coverage/osteoporosis-drugs*). These services can be billed on their own, or in combination, where applicable. We note that in the CY 2020 PFS final rule (84 FR 62685) and CY 2021 PFS final rule (85 FR 84547), CMS indicated that TCM may be billed concurrently with other care management codes when relevant, medically necessary, and not duplicative.

We proposed new coding in other sections of this CY 2025 final rule that might be used to bill for managing fractures under a treatment plan, including the global post-operative add-on code, HCPCS code GPOC1, in section II.L. of this final rule and the advanced primary care management codes in section II.G.2 of this final rule. Interested parties have indicated that orthopedic surgeons, skilled nursing facilities (SNFs), and other practitioners and providers may not be providing comprehensive patient centered fracture management care for quality, payment, or administrative reasons, and that there is inadequate ''hand-off'' when post-discharge fracture care is transferred to practitioners in the community. They indicate a systemic disconnect on which provider and/or specialty is responsible for osteoporosis diagnosis and treatment, and that global surgical periods focus on acute fracture recovery rather than addressing osteoporosis. We are interested in hearing if the global postop add-on code could help resolve these issues.

We received public comments on this RFI. The following is a summary of the comments we received and our responses.

Comment: A few commenters responded to our RFI for fracture-related care. Overall, commenters agreed that care is commonly fragmented in osteoporosis and post-fracture care. Some commenters stated that services like APCM, GPOC1 (G0559), CHI, or PIN do not accurately describe fracture liaison services. Other commenters said that the initiating visits for CHI and PIN may be a barrier to care. Similar to general feedback we received for CHI and PIN, commenters requested that initiating visits be furnished retroactively, meaning that during care transitions, CHI or PIN services could begin, as long as the initiating visit occurs within 30 days of discharge.

Response: We thank commenters for their feedback and may consider these recommendations and requests for future rulemaking. We clarify that for billing PIN services, there are circumstances in which osteoporosis may be considered a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death.

Comment: Commenters provided many examples of services and service elements that may not be described in current coding, as well as information about how CBOs are currently working with practitioners to furnish these services.

Response: We thank commenters for providing further information about how CHI, PIN, and SDOH risk assessment services are currently being used and how these services could be improved in the future. We will consider this information for future rulemaking.

TABLE 17: CY 2025 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
15011	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less	NEW	C	C	Yes
15012	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	C	C	Yes
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	NEW	C	C	Yes
15014	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)	NEW	C	C	Yes
15015	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less	NEW	C	C	Yes
15016	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	C	C	Yes
15017	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less	NEW	C	C	Yes
15018	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)	NEW	C	C	Yes
25310	Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; each tendon	8.08	9.00	9.00	No
25447	Arthroplasty, intercarpal or carpometacarpal joints; interposition (eg, tendon)	11.14	10.50	10.50	No
25448	Arthroplasty, intercarpal or carpometacarpal joints; suspension, including transfer or transplant of tendon, with interposition, when performed	NEW	11.85	11.85	No
26480	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon	6.90	9.00	9.00	No
36514	Therapeutic apheresis; for plasma pheresis	1.81	1.81	1.81	No
36516	Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion	1.56	1.56	1.56	No
36522	Photopheresis, extracorporeal	1.75	1.75	1.75	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	NEW	1.94	B	No
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	NEW	0.79	B	No
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	NEW	0.80	B	No
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	NEW	3.00	3.00	No
49186	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5 cm or less	NEW	22.00	22.00	No
49187	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 5.1 to 10 cm	NEW	28.65	28.65	No
49188	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 10.1 to 20 cm	NEW	34.00	34.00	No
49189	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); 20.1 to 30 cm	NEW	40.00	40.00	No
49190	Excision or destruction, open, intra-abdominal (ie, peritoneal, mesenteric, retroperitoneal), primary or secondary tumor(s) or cyst(s), sum of the maximum length of tumor(s) or cyst(s); greater than 30 cm	NEW	50.00	50.00	No
51721	Insertion of transurethral ablation transducer for delivery of thermal ultrasound for prostate tissue ablation, including suprapubic tube placement during the same session and placement of an endorectal cooling device, when performed	NEW	4.05	4.05	No
53865	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NEW	3.10	3.10	No
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	NEW	1.48	1.48	No
55881	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation;	NEW	9.80	9.80	No
55882	Ablation of prostate tissue, transurethral, using thermal ultrasound, including magnetic resonance imaging guidance for, and monitoring of, tissue ablation; with insertion of transurethral ultrasound transducer for delivery of thermal ultrasound, including suprapubic tube placement and placement of an endorectal cooling device, when performed	NEW	11.50	11.50	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
59200	Insertion of cervical dilator (eg, laminaria, prostaglandin) (separate procedure)	0.79	1.20	1.20	No
60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	NEW	5.75	5.75	No
60661	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure)	NEW	4.25	4.25	No
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed	NEW	16.60	18.95	No
64466	Thoracic fascial plane block, unilateral; by injection(s), including imaging guidance, when performed	NEW	1.50	1.50	No
64467	Thoracic fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.74	1.74	No
64468	Thoracic fascial plane block, bilateral; by injection(s), including imaging guidance, when performed	NEW	1.67	1.67	No
64469	Thoracic fascial plane block, bilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.83	1.83	No
64473	Lower extremity fascial plane block, unilateral; by injection(s), including imaging guidance, when performed	NEW	1.34	1.34	No
64474	Lower extremity fascial plane block, unilateral; by continuous infusion(s), including imaging guidance, when performed	NEW	1.67	1.67	No
64486	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed)	1.27	1.20	1.20	No
64487	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)	1.48	1.39	1.39	No
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)	1.60	1.40	1.40	No
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)	1.80	1.75	1.75	No
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver	5.10	5.10	5.10	No
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array	3.79	3.79	3.79	No
66680	Repair of iris, ciliary body (as for iridodialysis)	6.39	7.97	7.97	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
66682	Suture of iris, ciliary body (separate procedure) with retrieval of suture through small incision (eg, McCannel suture)	7.33	8.74	8.74	No
66683	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed	NEW	10.67	10.67	No
76014	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (eg, surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; initial 15 minutes	NEW	0.00	0.00	No
76015	MR safety implant and/or foreign body assessment by trained clinical staff, including identification and verification of implant components from appropriate sources (eg, surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MR conditional status of individual components and systems, and consulting published professional guidance with written report; each additional 30 minutes (List separately in addition to code for primary procedure)	NEW	0.00	0.00	No
76016	MR safety determination by a physician or other qualified health care professional responsible for the safety of the MR procedure, including review of implant MR conditions for indicated MR examination, analysis of risk vs clinical benefit of performing MR examination, and determination of MR equipment, accessory equipment, and expertise required to perform examination, with written report	NEW	0.60	0.60	No
76017	MR safety medical physics examination customization, planning and performance monitoring by medical physicist or MR safety expert, with review and analysis by physician or other qualified health care professional to prioritize and select views and imaging sequences, to tailor MR acquisition specific to restrictive requirements or artifacts associated with MR conditional implants or to mitigate risk of non-conditional implants or foreign bodies, with written report	NEW	0.76	0.76	No
76018	MR safety implant electronics preparation under supervision of physician or other qualified health care professional, including MR-specific programming of pulse generator and/or transmitter to verify device integrity, protection of device internal circuitry from MR electromagnetic fields, and protection of patient from risks of unintended stimulation or heating while in the MR room, with written report	NEW	0.75	0.75	No
76019	MR safety implant positioning and/or immobilization under supervision of physician or other qualified health care professional, including application of physical protections to secure implanted medical device from MR-induced translational or vibrational forces,	NEW	0.60	0.60	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	magnetically induced functional changes, and/or prevention of radiofrequency burns from inadvertent tissue contact while in the MR room, with written report				
76981	Ultrasound, elastography; parenchyma (eg, organ)	0.59	0.59	0.59	No
76982	Ultrasound, elastography; first target lesion	0.59	0.59	0.59	No
76983	Ultrasound, elastography; each additional target lesion	0.50	0.47	0.47	No
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation	1.50	1.50	1.50	No
90480	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single dose	X	0.25	X	Yes
90832	Psychotherapy, 30 minutes with patient	1.78	1.86	1.86	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.57	1.64	1.64	No
90834	Psychotherapy, 45 minutes with patient	2.35	2.45	2.45	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	1.99	2.08	2.08	No
90837	Psychotherapy, 60 minutes with patient	3.47	3.63	3.63	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.62	2.74	2.74	No
90839	Psychotherapy for crisis; first 60 minutes	3.28	3.43	3.43	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.57	1.64	1.64	No
90845	Psychoanalysis	2.20	2.30	2.30	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.51	2.63	2.63	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.62	2.74	2.74	No
90849	Multiple-family group psychotherapy	0.62	0.65	0.65	No
90853	Group psychotherapy (other than of a multiple-family group)	0.62	0.65	0.65	No
92132	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), anterior segment, with interpretation and report, unilateral or bilateral	0.30	0.29	0.29	No
92133	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; optic nerve	0.40	0.31	0.31	No
92134	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina	0.45	0.32	0.32	No
92137	Computerized ophthalmic diagnostic imaging (eg, optical coherence tomography [OCT]), posterior segment, with interpretation and report, unilateral or bilateral; retina, including OCT angiography	NEW	0.64	0.64	No
93886	Transcranial Doppler study of the intracranial arteries; complete study	0.91	0.90	0.90	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
93888	Transcranial Doppler study of the intracranial arteries; limited study	0.50	0.73	0.73	No
93892	Transcranial Doppler study of the intracranial arteries; emboli detection without intravenous microbubble injection	1.15	1.15	1.15	No
93893	Transcranial Doppler study of the intracranial arteries; venous-arterial shunt detection with intravenous microbubble injection	1.15	1.15	1.15	No
93896	Vasoreactivity study performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.81	0.81	No
93897	Emboli detection without intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.73	0.73	No
93898	Venous-arterial shunt detection with intravenous microbubble injection performed with transcranial Doppler study of intracranial arteries, complete (List separately in addition to code for primary procedure)	NEW	0.85	0.85	No
96041	Medical genetics and genetic counseling services, each 30 minutes of total time provided by the genetic counselor on the date of the encounter	NEW	0.00	0.00	No
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	2.20	2.30	2.30	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.52	1.59	1.59	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.52	0.55	0.55	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.22	0.23	0.23	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.10	0.11	0.11	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.62	1.70	1.70	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.58	0.60	0.60	No
96380	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection, with counseling by physician or other qualified health care professional	0.24	0.24	0.24	No
96381	Administration of respiratory syncytial virus, monoclonal antibody, seasonal dose by intramuscular injection	0.17	0.17	0.17	No
96547	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)	C	6.53	6.53	No
96548	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes	C	3.00	3.00	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
96920	Excimer laser treatment for psoriasis; total area less than 250 sq cm	1.15	0.83	0.83	No
96921	Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm	1.30	0.90	0.90	No
96922	Excimer laser treatment for psoriasis; over 500 sq cm	2.10	1.15	1.15	No
97012	Application of a modality to 1 or more areas; traction, mechanical	0.25	0.25	0.25	No
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	0.18	0.18	0.18	No
97016	Application of a modality to 1 or more areas; vasopneumatic devices	0.18	0.18	0.18	No
97018	Application of a modality to 1 or more areas; paraffin bath	0.06	0.06	0.06	No
97022	Application of a modality to 1 or more areas; whirlpool	0.17	0.17	0.17	No
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	0.25	0.25	0.25	No
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	0.26	0.26	0.26	No
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	0.21	0.21	0.21	No
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	0.21	0.21	0.21	No
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	0.45	0.45	0.45	No
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	0.50	0.50	0.50	No
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises	0.48	0.48	0.48	No
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	0.45	0.45	0.45	No
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes	0.43	0.43	0.43	No
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	0.44	0.44	0.44	No
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes	0.48	0.48	0.48	No
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	0.45	0.45	0.45	No
97537	Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology	0.48	0.48	0.48	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	device/adaptive equipment), direct one-on-one contact, each 15 minutes				
97542	Wheelchair management (eg, assessment, fitting, training), each 15 minutes	0.48	0.48	0.48	No
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.60	0.61	0.61	No
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with insertion of needle(s) (List separately in addition to code for primary procedure)	0.50	0.46	0.46	No
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.65	0.74	0.74	No
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with insertion of needle(s) (List separately in addition to code for primary procedure)	0.55	0.47	0.47	No
98000	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	NEW	I	I	Yes
98001	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	I	I	Yes
98002	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	NEW	I	I	Yes
98003	Synchronous audio-video visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	NEW	I	I	Yes
98004	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.	NEW	I	I	Yes

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
98005	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	NEW	I	I	Yes
98006	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	I	I	Yes
98007	Synchronous audio-video visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	NEW	I	I	Yes
98008	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 15 minutes must be met or exceeded.	NEW	I	I	Yes
98009	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	I	I	Yes
98010	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.	NEW	I	I	Yes
98011	Synchronous audio-only visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded.	NEW	I	I	Yes
98012	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, straightforward medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 10 minutes must be exceeded.	NEW	I	I	Yes

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
98013	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, low medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.	NEW	I	I	Yes
98014	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, moderate medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.	NEW	I	I	Yes
98015	Synchronous audio-only visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination, high medical decision making, and more than 10 minutes of medical discussion. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.	NEW	I	I	Yes
98016	Brief communication technology-based service (eg, virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5-10 minutes of medical discussion	NEW	0.30	0.30	No
G0138	Intravenous infusion of cipaglucosidase alfaatga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga	C	0.21	0.21	Yes
G0168	Wound closure utilizing tissue adhesive(s) only	0.31	0.31	0.31	No
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care	0.18	0.18	0.18	No
G0442	Annual alcohol misuse screening, 5 to 15 minutes	0.18	0.18	0.18	No
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes	0.45	0.60	0.60	No
G0444	Annual depression screening, 5 to 15 minutes	0.18	0.18	0.18	No
G0445	High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes	0.45	0.45	0.60	No
G0446	Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes	0.45	0.45	0.60	No
G0447	Face-to-face behavioral counseling for obesity, 15 minutes	0.45	0.45	0.60	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
G0465	Autologous platelet rich plasma (prp) or other blood-derived product for diabetic chronic wounds/ulcers, using an fda-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	C	1.50	1.83	Yes
G0516	Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)	1.82	1.82	1.82	No
G0517	Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)	2.10	2.10	2.10	No
G0518	Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)	3.55	3.55	3.55	No
G0537	Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment, 5-15 minutes, not more often than every 12 months	NEW	0.18	0.18	No
G0538	Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at intermediate, medium, or high risk for CVD as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month	NEW	0.18	0.18	No
G0539	Caregiver training in behavior management/modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes	NEW	1.00	1.00	No
G0540	Caregiver training in behavior management/modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes	NEW	0.54	0.54	No
G0541	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes	NEW	1.00	1.00	No
G0542	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each	NEW	0.54	0.54	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	additional 15 minutes (List separately in addition to code for primary service)				
G0543	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers	NEW	0.23	0.23	No
G0544	Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, 4 calls per calendar month.	NEW	1.00	1.00	No
G0545	Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases specialist, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and/or complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, subsequent or discharge)	NEW	0.89	0.89	No
G0546	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5-10 minutes of medical consultative discussion and review	NEW	0.35	0.35	No
G0547	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11-20 minutes of medical consultative discussion and review	NEW	0.70	0.70	No
G0548	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21-30 minutes of medical consultative discussion and review	NEW	1.05	1.05	No
G0549	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting	NEW	1.40	1.40	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	practitioner; 31 or more minutes of medical consultative discussion and review				
G0550	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time	NEW	0.70	0.70	No
G0551	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes	NEW	0.70	0.70	No
G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan	NEW	C	C	No
G0553	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month	NEW	0.62	0.62	No
G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month. (List separately in addition to HCPCS code G0553)	NEW	0.61	0.61	No
G0555	Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring	NEW	C	C	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
G0556	Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate: ● Consent; ++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply. ++ Document in patient's medical record that consent was obtained. ● Initiation during a qualifying visit for new patients or patients not seen within 3 years; ● Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week; ● Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; ● Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours; ● Overall comprehensive care management; ++ Systematic needs assessment (medical and psychosocial). ++ System-based approaches to ensure receipt of preventive services. ++ Medication reconciliation, management and oversight of self-management. ● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan with typical care plan elements when clinically relevant; ++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver; ● Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable; ++ Ensure timely exchange of electronic health	NEW	0.17	0.25	Yes

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	information with other practitioners and providers to support continuity of care. ++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated. ● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record; ● Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate; ++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits). ● Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate; ● Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients; ● Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.				
G0557	Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate: ● Consent; ++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar	NEW	0.77	0.77	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	month); and that cost sharing may apply. ++ Document in patient's medical record that consent was obtained. ● Initiation during a qualifying visit for new patients or patients not seen within 3 years; ● Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week; ● Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; ● Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours; ● Overall comprehensive care management; ++ Systematic needs assessment (medical and psychosocial). ++ System-based approaches to ensure receipt of preventive services. ++ Medication reconciliation, management and oversight of self-management. ● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan; ++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver; ● Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable; ++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care. ++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated. ● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;				

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	• Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate; ++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits). • Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate; • Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients; • Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology				
G0558	Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate: • Consent; ++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply. ++ Document in patient's medical record that consent was obtained. • Initiation during a qualifying visit for new patients or patients not seen within 3 years; • Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week; • Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments; • Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;	NEW	1.67	1.67	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	● Overall comprehensive care management; ++ Systematic needs assessment (medical and psychosocial). ++ System-based approaches to ensure receipt of preventive services. ++ Medication reconciliation, management and oversight of self-management. ● Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan; ++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver; ● Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable; ++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care. ++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated. ● Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record; ● Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate; ++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits). ● Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;				

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
	• Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients; • Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology				
G0559	Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice) and is of the same or of a different specialty than the practitioner who performed the procedure, within the 90-day global period of the procedure(s), once per 90-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable: ++ Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation. ++ Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty). ++ Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately. ++ Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established	NEW	0.16	0.16	No
G0560	Safety planning interventions, each 20 minutes personally performed by the billing practitioner, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal or substance use-related crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts or risky substance use; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health or substance use disorder professionals or agencies; and making the environment safe	NEW	1.09	1.09	No
G0561	Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral (List separately in addition to 69433)	NEW	-	C	No
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	NEW	-	C	No

HCPCS	Descriptor	CY 2024 Work RVU	Proposed CY 2025 Work RVU	Final CY 2025 Work RVU	CMS Work Time Refinement
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	NEW	-	C	No
G0564	Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training	NEW	-	C	No
G0565	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation	NEW	-	C	No

TABLE 18: CY 2025 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64466	Thrc fascial pln blk uni njx	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27
64473	Lwr xtr fscl pln blk uni njx	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27
64486	Tap block unil by injection	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (67% of physician intra-service time)	7.5	7	L13: Refined to correct rounding error in clinical labor calculation	-0.27

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
76015	Mr sfty mplt&/fb asmt stf ea	ED050	Technologist PACS workstation	NF		45	39	E16: No equipment times were included; aligned equipment time with assist physician time	-0.13
76015	Mr sfty mplt&/fb asmt stf ea	L047A	MRI Technologist	NF	Perform procedure/service---NOT directly related to physician work time	27	21	G1: See preamble text	-4.56
76017	Mr sfty med physics xm cstmz	ED053	Professional PACS Workstation	F		13	0	G1: See preamble text	-0.80
76018	Mr safety implant elec prepj	L047A	MRI Technologist	NF	Clean room/equipment by clinical staff	2	1	G1: See preamble text	-0.76
76019	Mr safety implt pos&/immo blj	L047A	MRI Technologist	NF	Clean room/equipment by clinical staff	2	1	G1: See preamble text	-0.76
77012	Ct scan for needle biopsy	EL007	room, CT	NF		26	9	E11: Refined equipment time to conform with other codes in the family	-51.17
96920	Excimer lsr psriasis<250 sqcm	EQ161	laser, excimer	NF		0	38	E13: Equipment item replaces another	22.40

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								item; see preamble text	
96920	Excimer lsr psriasis<250 sqcm	SD363	laser, excimer, pay per use (under 250 cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-80.00
96921	Excimer lsr psriasis 250-500	EQ161	laser, excimer	NF		0	40	E13: Equipment item replaces another item; see preamble text	23.58
96921	Excimer lsr psriasis 250-500	SD364	laser, excimer, pay per use (250-500 cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-83.00
96922	Excimer lsr psriasis>500 sqcm	EQ161	laser, excimer	NF		0	46	E13: Equipment item replaces another item; see preamble text	27.12
96922	Excimer lsr psriasis>500 sqcm	SD365	laser, excimer, pay per use (> 500cm2)	NF		1	0	S7: Supply item replaced by another item; see preamble	-100.00
G0442	Annual alcohol	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT	5	15	G1: See preamble text	5.40

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	screen 15 min				directly related to physician work time				
G0444	Depression screen annual	L037D	RN/LPN/MTA	NF	Perform procedure/service---NOT directly related to physician work time	5	15	G1: See preamble text	5.40
G0445	High inten beh couns std 30m	EF023	table, exam	NF		17	20	G1: See preamble text	0.03
G0445	High inten beh couns std 30m	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0445	High inten beh couns std 30m	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40
G0446	Intens behave ther cardio dx	EF023	table, exam	NF		12	15	G1: See preamble text	0.03
G0446	Intens behave ther cardio dx	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0446	Intens behave ther cardio dx	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
G0447	Behavior counsel obesity 15m	EF023	table, exam	NF		17	15	G1: See preamble text	-0.02
G0447	Behavior counsel obesity 15m	SK057	paper, laser printing (each sheet)	NF		10	0	S7: Supply item replaced by another item; see preamble	-0.20
G0447	Behavior counsel obesity 15m	SK062	patient education booklet	NF		0	0.5	S8: Supply item replaces another item; see preamble	1.40

TABLE 19: CY 2025 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64466	Thrc fascial pln blk uni njx	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64466	Thrc fascial pln blk uni njx	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64473	Lwr xtr fscl pln blk uni njx	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64473	Lwr xtr fscl pln blk uni njx	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64486	Tap block unil by injection	EF018	stretcher	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64486	Tap block unil by injection	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		25.5	25	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
76018	Mr safety implant elec prepj	EL008	room, MR	NF		21	20	E15: Refined equipment time to conform to changes in clinical labor time	-3.28

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
76018	Mr safety implant elec prepj	EQ412	Vitals monitoring system (MR Conditional)	NF		21	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.32
76019	Mr safety implt pos&/immobl j	EL008	room, MR	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-3.28
76019	Mr safety implt pos&/immobl j	EQ412	Vitals monitoring system (MR Conditional)	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-0.32
G0442	Annual alcohol screen 15 min	EF023	table, exam	NF		10	15	E15: Refined equipment time to conform to changes in clinical labor time	0.05
G0444	Depression screen annual	EF023	table, exam	NF		10	15	E15: Refined equipment time to conform to changes in clinical labor time	0.05

TABLE 20: CY 2025 Invoices Received for Existing Direct PE Inputs

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
30140, 30901, 30903,30905, 30906, 31231, 31237, 31238, 43197, 43198	Atomizer tips (disposable)	SL464	$0.00	2.66	-	1	625,876
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring	SD248	$931.33	$1,149.00	23%	30	52,203
88341	Anti CD45 Monoclonal Antibody	SL495	$5.15	$8.73	70%	3	1,094,158
88341, 88342, 88344, 88360, 88361	Benchmark ULTRA automated slide preparation system	EP112	$125,040.59	$130,000.00	4%	2	2,683,605
88341, 88342, 88344, 88360, 88361	Reaction buffer 10X (Ventana 950-300)	SL478	$0.037	$0.045	22%	3	2,683,605
88341, 88342, 88344, 88360, 88361	Liquid coverslip (Ventana 650-010)	SL479	$0.051	$0.084	65%	3	2,683,605
88341, 88342, 88344, 88360, 88361	SSC (10X) (Ventana 950-110)	SL480	$0.051	$0.069	35%	2	2,683,605
88341, 88342, 88344, 88360, 88361	Cell Conditioning 1 (Ventana 950-124)	SL482	$0.560	$0.937	67%	3	2,683,605
88342	Confirm anti-CD15 Mouse Monoclonal Antibody (Ventana 760-2504)	SL474	$4.90	$9.24	89%	3	1,157,793
92240, 92242	indocyanine green (25ml uou)	SL083	$76.94	$125.11	63%	8	36,974

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$260.35	$292.50	12%	20	510,943
97810, 97811, 97813, 97814	needle, acupuncture	SC075	$0.10	$0.199	99%	1	263,591
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$19.43	31.29	61%	2	-
7 codes	pack, drapes, cystoscopy	SA045	$17.33	$14.99	-14%	2	-
Deleted from all codes	pack, drapes, laparotomy (chest-abdomen)	SA046	$7.26	-	-	-	-
67221	pack, ocular photodynamic therapy	SA049	$16.35	$26.35	61%	2	1,062
38 codes	pack, urology cystoscopy visit	SA058	$113.70	$37.63	-67%	2	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.91	$2.33	-40%	1	-

TABLE 21: CY 2025 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
51721, 55881, 55882	TULSA-PRO TDC Cart	EQ410	1,638.60	1	2,300
53865	iTIND device	SD366	2,972.50	4	295
55881, 55882	TULSA-PRO Disposable Kit	SA136	8,967.00	2	847
60660	RF Electrodes 18 Gauge 70 mm Length	SD368	1,995.00	3	10
60660, 60661	RF Ablation System V1000 and RF Pump	EQ411	49,950.00	2	11
76018, 76019	Disposable oximeter probe and clip (MR Conditional)	SD369	6.40	1	19,215
76018, 76019	Vitals monitoring system (MR Conditional)	EQ412	85,182.60	1	19,215
76019	Thermoplastic splint material 6”x9” (MR Safe)	SG100	21.75	1	76
92137	tomographic device, optical coherence angiography (OCTA)	EQ409	164,500.00	2	360,890
96920, 96921, 96922	Mupirocin 2% Topical Ointment 22 grams	SJ095	0.139	1	108,634
96920	laser, excimer, pay per use (under 250 cm2)	SD363	80.00	5	73,369
96921	laser, excimer, pay per use (250-500 cm2)	SD364	83.00	4	21,696
96922	laser, excimer, pay per use (> 500cm2)	SD365	100.00	3	13,569
G0138	Opfolda (65 mg capsule)	SH111	33.00	0	3,955
No codes	inFlow Measuring Device	SD370	140.00	1	-
No codes	inFlow Valve-Pump Device	SD371	495.00	1	-
No codes	inFlow Activator Kit	SD372	1,250.00	1	-
306 codes (component of SA042)	ortho-phthalaldehyde 0.55% (eg, Cidex OPA)	SM030	0.554	1	-
306 codes (component of SA042)	ortho-phthalaldehyde test strips	SM031	1.556	1	-
7 codes (component of SA045)	drape, surgical, legging	SB057	3.284	1	-
7 codes (component of SA045)	drape, surgical, split, impervious, absorbent	SB058	8.424	1	-
22510, 22511, 22513, 22514	Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in)	SB056	8.049	1	12,721
67221 (component of SA049)	kit, ocular photodynamic therapy (PDT)	SA137	26.00	1	1,062
67221 (component of SA049)	y-adapter cap	SD367	0.352	1	1,062
145 codes (component of SA082)	post-mydriatic spectacles	SB059	0.328	1	-

TABLE 22: CY 2025 No PE Refinements

HCPCS	Description
15011	Hrv skn cll ssp agrft 1st 25
15012	Hrv skn cll ssp agrft ea add
15013	Prepj skn cll ssp agrft 1st
15014	Prepj skn cll ssp agrft ea
15015	App skn cl ssp agrft t/a/l 1
15016	App skn cl ssp agrf t/a/l ea
15017	App skn cll ssp f/n/g/hf 1st
15018	App skn cll ssp f/n/g/hf ea
25310	Transplant forearm tendon
25447	Repair wrist joints
25448	Arthrp ntrcrpl/crp/mtcrp ssp
26480	Transplant hand tendon
36514	Apheresis plasma
36516	Apheresis immunoads slctv
36522	Photopheresis
38225	Car-t hrv bld-drv t lymphcyt
38226	Car-t prep t lymphcyt f/trns
38227	Car-t receipt&prepj admn
38228	Car-t admn autologous
49186	Opn exc/dstr ntra-abd 5 cm/<
49187	Opn exc/dstr ntra-abd 5.1-10
49188	Opn exc/dst ntra-abd 10.1-20
49189	Opn exc/dst ntra-abd 20.1-30
49190	Opn exc/dstr ntra-abd >30 cm
51721	Ins trurl ablt trnsdc thr us
53865	Cysto insj dev ischmc rmdlg
53866	Cathj rmvl dev ischmc rmdlg
55881	Ablt trurl prst8 tis thrm us
55882	Ablt trurl prst8 tis trnsdcr
59200	Insert cervical dilator
60660	Abltj 1/+thyr ndul 1lobe prq
60661	Abltj 1/+thyr ndul addl prq
61715	Mrgfus strtctc ablt trgt icr
64467	Thrc fascial pln blk uni nfs
64468	Thrc fascial pln blk bi njx
64469	Thrc fascial pln blk bi nfs
64474	Lwr xtr fscl pln blk uni nfs
64487	Tap block uni by infusion
64488	Tap block bi injection
64489	Tap block bi by infusion
64590	Ins/rpl prph sac/gstr npg/r
64595	Rev/rmv prph sac/gstr npg/r
66680	Repair iris & ciliary body
66682	Repair iris & ciliary body
66683	Implantation iris prosthesis
76014	Mr sfty implt&/fb asmt stf 1
76016	Mr safety deter phys/qhp
76981	Use parenchyma
76982	Use 1st target lesion
76983	Use ea addl target lesion
92132	Cmptr ophth dx img ant segmt
92133	Cmptr ophth img optic nerve
92134	Cptr ophth dx img post segmt
92137	Cptrz oph img pst sg rta oct

HCPCS	Description
93886	Intracranial complete study
93888	Intracranial limited study
93892	Tcd emboli detect w/o inj
93893	Tcd emboli detect w/inj
93896	Vsrctv std tcd icr art compl
93897	Emboli detcj wo iv mbubb njx
93898	Ven-artl shunt det mbubb njx
96041	Genetic counseling svc ea 30
96380	Admn rsv monoc antb im cnsl
96381	Admn rsv monoc antb im njx
97012	Mechanical traction therapy
97014	Electric stimulation therapy
97016	Vasopneumatic device therapy
97018	Paraffin bath therapy
97022	Whirlpool therapy
97032	Appl modality 1+estim ea 15
97033	App mdlty 1+iontphrsis ea 15
97034	App mdlty 1+cntrst bth ea 15
97035	App mdlty 1+ultrasound ea 15
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/> regions
97530	Therapeutic activities
97533	Sensory integration
97535	Self care mngment training
97537	Community/work reintegration
97542	Wheelchair mngment training
97810	Acupunct w/o stimul 15 min
97811	Acupunct w/o stimul addl 15m
97813	Acupunct w/stimul 15 min
97814	Acupunct w/stimul addl 15m
98000	Synch audio-video new sf 15
98001	Synch audio-video new low 30
98002	Synch audio-video new mod 45
98003	Synch audio-video new hi 60
98004	Synch audio-video est sf 10
98005	Synch audio-video est low 20
98006	Synch audio-video est mod 30
98007	Synch audio-video est hi 40
98008	Synch audio-only new sf 15
98009	Synch audio-only new low 30
98010	Synch audio-only new mod 45
98011	Synch audio-only new high 60
98012	Synch audio-only est sf 10
98013	Synch audio-only est low 20
98014	Synch audio-only est mod 30
98015	Synch audio-only est high 40
98016	Brief comunicaj tech-bsd svc
G0168	Wound closure by adhesive
G0283	Elec stim other than wound
G0443	Brief alcohol misuse counsel
G0516	Insert drug del implant, >=4
G0517	Remove drug implant
G0518	Remove w insert drug implant

F. Evaluation and Management (E/M) Visits

1. Office/Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-On

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the O/O E/M visit complexity add-on code. The full descriptor for the O/O E/M visit complexity add-on code, HCPCS code G2211, is (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*).

The O/O E/M visit complexity add-on code ''reflects the time, intensity, and PE resources involved when practitioners furnish the kinds of O/O E/M visit services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high-risk disease) and to address the majority of a patient's health care needs with consistency and continuity over longer periods of time.'' (88 FR 78970 through 78971). We explained in the CY 2024 PFS final rule that it is the relationship between the patient and the practitioner that is the determining factor for when the add-on code should be billed. The add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship. The first part of the code descriptor, the ''continuing focal point for all needed health care services,'' describes a relationship between the patient and the practitioner when the practitioner is the continuing focal point for all health care services that the patient needs. The second part of the add-on code also describes a relationship involving medical services that are part of ongoing care related to a patient's single, serious condition or a complex condition. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship in making a diagnosis, developing a treatment plan, and weighing the factors that affect a longitudinal doctor-patient relationship. The practitioner must decide what course of action and choice of words in the visit itself would lead to the best health outcome in the single visit while simultaneously building up an effective, trusting longitudinal relationship with the patient. Weighing these various factors, even for a seemingly simple condition, makes the entire visit inherently complex, which is what this add-on code is intended to capture (88 FR 78973 through 78974).

We responded to concerns raised by commenters about potential duplicative payment and potential misreporting of the code, noting that when procedures or other services are reported on the same day by the same billing practitioner as a significant, separately identifiable O/O E/M visit (the base codes that the visit complexity add-on code can be billed with), we believed that the services involve resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant a different payment policy (88 FR 78971). We finalized our proposal that the O/O E/M visit complexity add-on code is not payable when the O/O E/M visit is reported with CPT Modifier -25, which denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service (88 FR 78974).

Some commenters expressed concern about our proposal to exclude payment for the visit complexity add-on code when the O/O E/M base code is reported with Modifier -25 because some preventive services such as the annual wellness visit (AWV) or a preventive vaccine are often provided on the same day as a separately identifiable O/O E/M visit, appropriately billed with Modifier -25. The commenters were concerned that practitioners might avoid the policy by not providing a preventive service on the same day as another O/O E/M service. We acknowledged that immunizations and AWVs were sometimes furnished on the same day as an O/O E/M visit and that our policy would prevent payment of the add-on code with such office visits billed with Modifier -25 and indicated that we would monitor utilization of the visit complexity add-on code and continue engagement with interested parties as the policy is implemented (88 FR 78975).

We have begun to monitor utilization of HCPCS code G2211 and are continuing to engage with interested parties. We continue to hear from some practitioners that our non-payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported on the same day as a preventive immunization or other Medicare preventive service is disruptive to the way such care is usually furnished and contrary to our policy objective for establishing the add-on payment. An early analysis of practitioner claims from the first few months of 2024 shows relatively few Medicare preventive services being billed on the day preceding or following an O/O E/M visit. We cannot conclude from this analysis that our policy to deny payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported on the same day as a preventive immunization or other Medicare preventive service is disruptive to the way such care is usually furnished. However, we do agree with practitioners expressing concerns that the current policy is not well-aligned with our policy objective for establishing the add-on payment.

In response to these concerns, we proposed to refine our current policy for services furnished beginning in CY 2025. We proposed to allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an AWV, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. Allowing payment for the O/O E/M visit complexity add-on code in this scenario as proposed would support our policy aims, which include paying for previously unaccounted resources inherent in the complexity of all longitudinal primary care office visits. In part, the O/O E/M visit complexity add-on code recognizes the inherent costs of building trust in the practitioner-patient relationship. We believe that trust-building in the longitudinal relationship is more significant than ever in making decisions about the administration of immunizations and other Medicare Part B preventive services. We welcomed comments on this proposal.

We received many public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal and encouraged CMS to finalize as proposed. They stated that there are inherent costs of building trust in the practitioner-patient relationship, which is particularly important when making decisions about administering immunizations and other Medicare Part B preventive services, and that these inherent costs are reflected in the valuation of the O/O E/M visit complexity add-on code.

Response: We agree and thank commenters for their support of this proposal.

Comment: A few commenters opposed our proposal and questioned

the need for the O/O E/M visit complexity add-on code based on arguments similar to those made in prior years. Those in opposition stated that our proposed policy would result in unnecessary payments if finalized because the O/O E/M visit complexity add-on code itself is ill defined and the O/O E/M visit code set is appropriately valued.

Response: We refer the commenters to the CY 2024 PFS final rule (88 FR 78972) where we discussed similar concerns regarding duplicative payment when the O/O E/M visit complexity add-on code (HCPCS code G2211) is billed with an O/O E/M visit. We continue to believe that the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule did not fully account for the resource costs associated with primary care and certain types of specialty visits (85 FR 84569). However, those values were finalized in concert with separate payment for HCPCS code G2211 which accounted for the resource costs associated with those types of visits (87 FR 69588).

Comment: A few commenters recommended that CMS allow the O/O E/M visit complexity add-on code (HCPCS code G2211) to be reported alongside other CPT codes, such as those describing other E/M visits furnished to beneficiaries in other settings of care including nursing facilities, assisted living facilities and the patient's home. Commenters explained that home-based primary care practices provide access to primary care services for patients who otherwise would not be able to leave the house to see a primary care practitioner, and include the development of longitudinal, ''high-touch'' relationships with their patients.

Response: We appreciate that practitioners who provide home-based primary care services may furnish E/M visits in an individual's home or residence that contribute to the development of longitudinal relationships with those patients. Commenters focused on how practitioners who furnish E/M visits to patients in homes or residences, nursing facilities, and assisted living facilities develop longitudinal relationships with their patients just as practitioners do in the office or outpatient setting. Whereas the values we established for the revised O/O E/M CPT codes in the CY 2021 PFS final rule were finalized in concert with separate payment for HCPCS code G2211 (85 FR 84569, 87 FR 69588), we finalized work RVUs for the nursing facility E/M visit codes (87 FR 69604 through 69606) and the home or residence services code family (87 FR 69608 and 69609) subsequently in the CY 2023 final rule. Nevertheless, we may consider in future rulemaking whether home or residence evaluation and management services bear unrecognized resource costs and whether HCPCS code G2211 should be applicable to home or residence E/M visits.

Comment: Many commenters recommended that in addition to the AWV, immunizations and preventive services, we finalize that payment for the O/O E/M visit complexity add-on code (HCPCS code G2211) can be made when the following services are reported by the same billing practitioner on the same day as HCPCS code G2211: an echocardiogram or other cardiovascular imaging procedure, occipital nerve block via injection, nebulizer treatment, ambulatory continuous glucose monitoring (CGM), Transitional Care Management (TCM), and spirometry or inhalation device education. These commenters stated that as these services are part of long-term, longitudinal relationships with patients who are often extremely complex and require extensive evaluation, HCPCS code G2211 captures the additional work of treating these patients. Other commenters stated that certain specialists, such as endocrinologists, typically see sicker patients than primary care practitioners and to the extent that other services (beyond O/O E/M visits and preventive services) are furnished to these patients they should also be billable alongside HCPCS code G2211.

Other commenters stated that we should continue to explore the appropriateness of restricting billing of HCPCS code G2211 to O/O E/M visits not billed with the payment modifier -25. These commenters stated that even if the visit is being reported in conjunction with another service, there still may be resource costs associated with longitudinal care that are not reflected in the payment for the O/O E/M visit or the other service.

Other commenters recommended that, rather than refine our billing policies to allow HCPCS code G2211 to be billable alongside O/O E/M visits with modifier -25, that we prohibit concurrent billing with codes in the surgical section of the CPT Codebook (CPT codes 10000–69999), or allow billing of HCPCS code G2211 with O/O E/M visits reported with modifier -25 during a global period if the global period has >0% designated to pre or post operative care.

Many commenters also requested clarification as to whether HCPCS code G0402 (*Initial Preventive Physical Exam (IPPE))* was included as a preventive service billable alongside HCPCS code G2211.

Response: We note that the application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs), but rather the relationship between the patient and the practitioner (88 FR 78973). In part, HCPCS code G2211 recognizes the inherent costs of building trust in the practitioner-patient relationship that are not reflected in the valuation of the O/O E/M code set. As we discussed in the proposed rule, building trust as part of a longitudinal practitioner-patient relationship may be particularly significant in the context of preventive services, and for this reason, we believe it is appropriate to limit billing of HCPCS code G2211 to preventive services at this time. However, we do acknowledge the points raised by commenters about other similar services and may consider broadening the applicability of HCPCS code G2211 through future rulemaking.

Regarding reporting HCPCS code G2211 alongside O/O E/M visits with modifier -25, we continue to believe as we stated in the CY 2024 PFS final rule, that separately identifiable O/O E/M visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone O/O E/M visits to warrant a different payment policy, and as such, we finalized that the O/O E/M visit complexity add-on code, HCPCS code G2211, is not payable when the O/O E/M visit is reported with payment modifier -25 (88 FR 78971). We may consider additional changes to this policy for future rulemaking. We responded to comments that suggested alternative policies and that suggested exemptions for specific codes, including codes that would fall within the range of CPT codes 10000–69999 referenced by one of the commenters on the CY 2025 PFS proposed rule. We believed the alternatives offered by commenters could increase administrative burden with minimal benefit gained and unnecessarily delay reactivation of the complexity add-on code and payment (88 FR 78974–78975). We would need more time to evaluate the potential policy implications and systems changes associated with a prohibition on concurrently billing HCPCS code G2211 with codes in the surgical section of the CPT Codebook (CPT codes 10000–69999) or allow billing of HCPCS code G2211 with O/O E/M visits

reported with modifier -25 during a global period if the global period has >0% designated to pre or post operative care.

We appreciate commenters' recommendations for additional services to be included in the refined policy for the O/O E/M visit complexity add-on code that we proposed to apply for the AWV, vaccine administration, and Part B preventive services furnished in the office or outpatient setting. While we did not propose and are not adding other services to our refined policy for the O/O E/M visit complexity add-on code in this final rule, we are confirming that the IPPE, also known as the ''Welcome to Medicare'' preventive visit is included in our proposed policy because it is a Part B preventive service furnished in the office or outpatient setting.

Comment: Several commenters requested that we provide detailed medical necessity requirements and documentation guidelines related to reporting HCPCS code G2211.

Response: In response to interested party feedback requesting guidance about medical necessity and documentation requirements, we posted frequently asked questions at *https://www.cms.gov/files/document/hcpcs-g2211-faq.pdf*. As we stated in this document, we have not specified any additional medical record documentation requirements for reporting HCPCS code G2211. Our medical reviewers may use the medical record documentation to confirm the medical necessity of the visit and the patient care relationship as appropriate. We would expect that information included in the medical record or in the claims history for a patient/practitioner combination, such as diagnoses, the practitioner's assessment and medical plan of care, and/or other codes reported could serve as supporting documentation for billing HCPCS code G2211. Practitioners should consult their Medicare Administrative Contractor (MAC) regarding documentation requirements related to the underlying O/O E/M visit.

After consideration of public comments, we are finalizing as proposed to allow payment of the O/O E/M visit complexity add-on code (HCPCS code G2211) when the O/O E/M base code (CPT 99202–99205, 99211–99215) is reported by the same practitioner on the same day as an AWV, vaccine administration, or any Medicare Part B preventive service.

G. Enhanced Care Management

1. Background

As described in the CY 2025 Medicare Physician Fee Schedule (PFS) proposed rule, the CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center) tests innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care. CMS Innovation Center models are assessed for their impact on quality of care and expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) and the scope and duration of the model test may be expanded through rulemaking if expected to either reduce spending without compromising quality of care or enhance quality of care without increasing spending (section 1115A of the Act). After more than a decade of testing over 50 innovative payment and service delivery models, the CMS Innovation Center has enabled broad transformative changes to service delivery and payment in the Medicare, Medicaid, and CHIP programs which inspire additional transformation throughout the health care delivery system. Participants in CMS Innovation Center models have demonstrated improvements in care delivery and patient experience. The CMS Innovation Center undertook a retrospective review and synthesis of select model evaluations where care delivery changes have been observed, and the review indicated demonstrable evidence of enhanced care delivery in several areas, such as care coordination, team-based care, and leveraging data to risk-stratify patients.[24]

Under the PFS statute at section 1848 of the Act, we establish payment amounts for covered physicians' services, and update our payment policies to address changes, including changes in medical practice. In the CY 2025 PFS proposed rule, we proposed to incorporate key payment and service delivery elements from CMS Innovation Center models tested and evaluated over the prior decade into permanent coding and payment under the PFS (89 FR 61596). Specifically, we proposed to recognize a primary care practice delivery model trend which we will refer to as ''advanced primary care'' and which we propose to define using the 2021 National Academies of Sciences, Engineering, and Medicine (NASEM) report on Implementing High-Quality Care as: ''whole-person, integrated, accessible, and equitable health care by interprofessional teams that are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities.'' [25] Using this definition, we proposed to recognize the resources involved in furnishing services using an ''advanced primary care'' approach to care under the PFS [26] (89 FR 61596). Under this approach, the delivery of care is supported by a team-based care structure and involves a restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices. This restructuring creates several advantages for patients, and provides more broad accessibility and alternative methods for patients to communicate with their care team/practitioner about their care outside of in-person visits (for example, virtual, asynchronous interactions, such as online chat), which can lead to more timely and efficient identification of, and responses to, health care needs (for example, practitioners can route patients to the optimal clinician and setting—to a synchronous visit, an asynchronous chat, or a direct referral to the optimal site of care).[27] Practitioners using an advanced primary care delivery model can more easily collaborate across clinical disciplines through remote interprofessional consultations with specialists as well as standardize condition management into evidence-based clinical workflows, which allow for closed-loop follow-up and more real-time management for

[24] Fowler, Ph.D., JD, E., Rudolph, MPH, N., Davidson, LCSW, MSW, K., Finke, MD, B., Flood, S., Bernheim, MD, Ph.D., S. M., & Rawal, Ph.D., P. (2023). Accelerating Care Delivery Transformation—The CMS Innovation Center's Role in the Next Decade. *New England Journal of Medicine, 4*(11). *https://doi.org/10.1056/cat.23.0228*. CMS. Synthesis of Evaluation Results across 21 Medicare Models, 2012–2020. Fowler, Ph.D. 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/wp-eval-synthesis-21models*.

[25] National Academies of Sciences, Engineering, and Medicine. 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25983*.

[26] Team-based approaches to care can achieve improved provider and care team satisfaction, improved team communication, improved patient safety, and improved patient and family engagement in care. Coleman, M. Dexter. D., & Nankivill, N. (2015, August). Factors affecting physician satisfaction and Wisconsin Medical Society strategies to drive change. Wisconsin Medical Journal. 114(4), 135–142. Retrieved from *https://www.wisconsinmedicalsociety.org/professional/wmj/archives/volume-114-issue-4-august-2015/*.

[27] Ellner, A., Basu, N. & Phillips, R.S. From Revolution to Evolution: Early Experience with Virtual-First, Outcomes-Based Primary Care. J GEN INTERN MED 38, 1975–1979 (2023). *https://doi.org/10.1007/s11606-023-08151-1*.

patients with acute or evolving complex issues. Practitioners can then use synchronous interactions to build rapport with patients and families, partner on complex decisions, and personalize their patients' care plans.

Specifically, we proposed to adopt coding and payment policies to recognize advanced primary care management (APCM) services for use by practitioners who are providing services under this specific model of advanced primary care, when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services for a patient. This new coding and payment makes use of lessons learned from the CMS Innovation Center's testing of a series of advanced primary care models, such as Comprehensive Primary Care (CPC),[28] Comprehensive Primary Care Plus (CPC+),[29] and Primary Care First (PCF)[30] [31] to inform the elements upon which the delivery of APCM services under an advanced primary care delivery model depend. As detailed in this final rule, this coding and payment will incorporate elements of several specific, existing care management and communication technology-based services (CTBS) into a bundle of services, that reflects the essential elements of the delivery of advanced primary care, for payment under the PFS starting in 2025.

In the context of the proposal, we were also interested in feedback on other related policies for our consideration in future rulemaking. To gather information from interested parties to inform potential future proposals, we included an Advanced Primary Care Hybrid Payment Request for Information (RFI) (Advanced Primary Care RFI) in the proposed rule. The Advanced Primary Care RFI sought feedback on whether and how we should consider additional payment policies that reflect our efforts to recognize the delivery of advanced primary care, including bundling of additional individual services, which may currently be furnished together as primary care services but paid separately. This focused approach to seeking feedback on advanced primary care payment policies is an important step in our ongoing efforts to emphasize accountable care and supports our goal of having 100 percent of Traditional Medicare beneficiaries in accountable care relationships by 2030.[32]

In addition to recognizing advanced primary care, this final rule also recognizes physician and practitioner work that draws from evidence generated by the CMS Innovation Center's Million Hearts® model.[33] The Million Hearts® model found that quantitative assessment of patients' atherosclerotic cardiovascular disease (ASCVD) risk and providing high-risk beneficiaries with cardiovascular-focused care management services improved quality of care, including mortality.[34] We proposed to establish coding and PFS payment for these services based in part on the evidence generated by the Million Hearts® model.

2. Advanced Primary Care Management (APCM) Services (HCPCS Codes G0556, G0557, and G0558)

a. Background

We described in the CY 2025 PFS proposed rule that we have been analyzing opportunities to strengthen and invest in primary care in alignment with the goals of the U.S. Department of Health and Human Services (HHS) Initiative to Strengthen Primary Care.[35] Research has demonstrated that greater primary care physician supply is associated with improved population-level mortality and reduced disparities,[36] and also, that establishing a long-term relationship with a primary care provider leads to reduced emergency department (ED) visits,[37] improved care coordination, and increased patient satisfaction.[38] HHS recognizes that effective primary care is essential for improving access to healthcare, for the health and wellbeing of individuals, families, and communities, and for achieving health equity. The first coordinated set of HHS-wide actions to strengthen primary care, as part of the Initiative, is in primary care payment; for example, adjusting payment to ensure it supports delivery of advanced primary care. CMS Innovation Center models, described in section II.G.2.a.(1) in this final rule, reflect the ongoing work within HHS and the unified, comprehensive approach to HHS primary care activities that we are accomplishing through our current statutory authorities and funding.

Over the last decade, we have updated PFS payment policies as appropriate, and we remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services that encompass aspects of advanced primary care furnished by interprofessional care teams and typically concentrating on the delivery of appropriate preventive care to patients and the management of individuals' chronic conditions as they progress over time. As part of the CY 2014 PFS final rule, we reaffirmed our support of primary care and recognized care management as one of the critical components of primary care that contributes to better health outcomes for individuals and reduced expenditure growth, and explained our prioritization of the development and implementation of several initiatives (such as those discussed in section II.G.2.a.(1) in this final rule) (77 FR 68978). Since then, we have implemented coding and payment for many care management services to better recognize the resources involved in furnishing medically necessary care management activities that generally are performed outside the context of a face-to-face, in-person visit—most often by the billing practitioner's clinical staff on behalf of patients with complex health care needs, including transitional care management in the CY 2013 PFS final rule (77 FR 68979); non-complex and complex chronic care management (CCM) in the CY 2015, 2017, and 2019

[28] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-initiative.*

[29] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

[30] *https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.*

[31] Finke, Bruce, et al. ''Addressing Challenges in Primary Care—Lessons to Guide Innovation.'' *JAMA Health Forum,* vol. 3, no. 8, 19 Aug. 2022, p. e222690, *https://doi.org/10.1001/jamahealthforum.2022.2690.*

[32] CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade (*https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper*).

[33] *https://www.cms.gov/priorities/innovation/innovation-models/million-hearts-cvdrrm.*

[34] Peterson G, Steiner A, Powell R, et al. Evaluation of the Million Hearts® Cardiovascular Disease Risk Reduction Model: Fourth Annual Report. Mathematica. February 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mhcvdrrm-fourthannevalrpt.*

[35] U.S. Department of Health and Human Services. (2023). Primary Care: Our First Line of Defense. *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf.*

[36] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005–2015. *JAMA Intern Med.* 2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624. *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393.*

[37] Willemijn L.A. Schäfer et al, ''Are People's Health Care Needs Better Met When Primary Care Is Strong? A Synthesis of the Results of the QUALICOPC Study in 34 Countries,'' Primary Health Care Research and Development 20 (2019): e104. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609545/.*

[38] Michael J. van den Berg, Tessa van Loenen, and Gert P Westert, ''Accessible and Continuous Primary Care May Help Reduce Rates of Emergency Department Use: An International Survey in 34 Countries,'' Family Practice 33, no. 1 (Feb. 2016): 42–50. *https://academic.oup.com/fampra/article/33/1/42/2450446.*

PFS final rules (78 FR 74414, 83 FR 58577, and 81 FR 80244); and principal care management (PCM) in the CY 2020 PFS final rule (84 FR 62962). The CCM and PCM code families now include 5 sets of codes which are reported monthly on a timed basis, each set with a base code of 20 to 60 minutes and an add-on code for each additional 30 minutes. The code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing.

Additionally, we have established coding and payment for certain services where a medical professional evaluates a patient's medical information remotely using communication technology. As discussed in the CY 2019 PFS final rule, this set of services is defined by and inherently involves the use of communications technology, and includes certain remote patient monitoring services, virtual check-in services, remote evaluation of pre-recorded patient information, remote interpretations of diagnostic imaging tests, and interprofessional consultations. We recognize that technological advances have changed and continue to change the practitioner-patient care delivery interaction. We have recognized these technology-enabled interactions through separately billable CTBS over the last several years. However, we acknowledge, as we learn more about how advanced primary care services are furnished to patients, that in some clinical care delivery scenarios, practitioners furnishing the type of care highlighted in this discussion may furnish certain aspects of the CTBS services in complement to care management services (for example, by allowing interprofessional care teams to answer patient questions, refer patients to higher levels of care, view and interpret patient images, order needed treatments, and offer reassurance or advice), in an effort to more efficiently manage the quantity and quality of medical information that is necessary to support effective patient-centered treatment plans.

Despite these important steps to pay separately for these care management services, there has been limited uptake of care management services and Medicare still overwhelmingly pays for primary care through traditional office/outpatient (O/O) Evaluation and Management (E/M) visit codes, which describe a broad range of physicians' services but do not fully distinguish and account for the resources associated with primary care and other longitudinal care. As we stated in the CY 2024 PFS final rule, because E/M visit codes are intended to be used very broadly, the complexity of services required to provide this type of care is not fully incorporated as part of the valuation of the work RVUs when the E/M code itself is used as the primary way to report the work of the professional (88 FR 78972). In the CY 2024 PFS final rule, we took steps to better recognize the inherent complexity of visits associated with primary and longitudinal care of patients by finalizing a new add-on code (HCPCS code G2211, *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition*) for use by practitioners furnishing services as the continuing focal point for all the patient's needed health care services, such as a primary care practitioner (88 FR 78969). When furnishing primary and longitudinal care, practitioners must be attuned to the factors that develop and maintain trusting practitioner-patient relationships that enable effective diagnosis, management, and treatment on an ongoing basis. In finalizing the O/O E/M visit complexity add-on code, we recognized the feedback from interested parties indicating that the care management codes alone may not have mitigated the deficiencies in the ability of existing E/M codes to reflect the time and resources involved in furnishing visits in the context of longitudinal care—of which, advanced primary care is one model. Many commenters responded, as reflected in the CY 2024 PFS final rule, that they did not view the coding and payment currently available under the PFS as capable of recognizing the broad range of elements that define primary care (88 FR 52326). Other commenters responded that they did not believe that the existing E/M service codes alone reflect the work and resources involved in furnishing non-procedural care to Medicare beneficiaries (88 FR 78976).

Over the years, interested parties have focused attention on the ongoing need to improve how practitioners are paid, in and outside of payment bundles, including but not limited to the possibility of E/M codes designed specifically to be billed in conjunction with care management codes and the elimination of multiple disparities between the payment for E/M services in global periods and those furnished individually. Based on feedback from the physician and practitioner community, we understand that advanced primary care encompasses the work of interprofessional teams who are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships, which necessarily involves time spent by primary care practitioners and their clinical staff outside of individual E/M visits.

As with many services paid under the PFS, we balance making payment that recognizes and supports technological developments in healthcare and the resources involved in evolving medical practice to allow for appropriate and expanded access to innovative technologies and newer services with promoting stability and efficiency in coding and billing rules for practitioners and institutions. We recognize the important role of gathering input and information from the CMS Innovation Center models (described in more detail in section II.G.2.a.(1) in this final rule), comment solicitations, research from other public and private entities, the work of all parties involved in furnishing primary care, and from the public at large. As previously noted, interested parties have given ample feedback over the years to inform our recognition of care management services; for example, as part of the CY 2022 PFS rulemaking, interested parties specifically requested our consideration of a ''30-day global period bundling care management services'' and we responded that we would consider this suggestion for future rulemaking (86 FR 65118). We have continued to incorporate feedback into our rulemaking and strengthen our care management code sets with the goal of better recognizing the elements of advanced primary care as part of a multi-year strategy. Based on this feedback, we proposed to establish a set of codes to better describe advanced primary care management services broadly, to provide more stability in payment and coding for practitioners in the context of continued evolution in advanced primary care, as well as to provide us with a mechanism for continued and intentional improvements to advanced primary care payment.

(1) Key Care Delivery Methods in Select CMS Innovation Center Models

We described in the CY 2025 PFS proposed rule that we have prioritized

the implementation or testing of a series of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. By supporting enhanced care management and coordination, these initiatives contributed to the growing practice of advanced primary care and have also provided valuable lessons learned that we have incorporated into our policies.

Several CMS Innovation Center models address payment for care management services and CTBS. The CPC initiative,[39] the CPC+ model,[40] and the PCF model [41] all included payments for care management services that closely aligned with the care management services included in the PFS. In these initiatives and models, primary care practices received risk-adjusted, per beneficiary per month (PBPM) payments for care management services furnished to Medicare FFS beneficiaries attributed to their practices. These model payments were designed to offer practices a stable, predictable revenue stream that supported required infrastructure and appropriately compensated practices for the enhanced services they would provide. Practices participating in the CPC+ consistently cited these payments as the most useful type of model payment support they received; these stable, prospectively paid payments typically served as the main funding source for compensating care managers, behavioral health providers, and other staff hired to improve care delivery.[42] Because these payments were paid prospectively and could be used to support a range of care management and coordination activities, they provided participants with greater financial stability and flexibility to develop and expand capabilities to meet patients' care needs.[43] Table 23 identifies a number of CMS Innovation Center models and key care delivery methods from each.[44]

[39] *https://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdf.*

[40] *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[41] *Evaluation of the Primary Care First Model.* February 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[42] O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[43] O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[44] For more information on how the Innovation Center is supporting primary care, *https://www.cms.gov/files/document/primary-care-infographic.pdf.*

TABLE 23: Key Care Delivery Methods from Select CMS Innovation Center Models

Model	Key Care Delivery Methods	Citation
ACO Investment Model (AIM)	AIM provided an opportunity for participants to invest in care transformation activities. Specifically, AIM was an opportunity for independent primary care practices in rural communities to hire population health staff, such as care managers or outreach coordinators. Care managers conducted outreach, scheduling, and patient education. Care managers did this through a variety of mechanisms including phone, in the physician office, and via home visits.	Evaluation of the Accountable Care Organization Investment Model, Final Report, September 2020, available at: https://www.cms.gov/priorities/innovation/data-and-reports/2020/aim-final-annrpt
Comprehensive Primary Care (CPC)	CPC practices provided longitudinal and episodic care management services for patients at high or rapidly increasing risk whom the practices believed were most likely to benefit from intensive support. By 2016, CPC practices risk stratified 95% of their empaneled patients, and provided care management to 20% of those patients. CPC practices also greatly increased their use of dedicated care managers over time. By 2016, 89% of practices reported that, "care managers who were members of the [primary care] practice team systematically provided care management services to high-risk patients" – an increase from 20% in 2012. Beneficiaries attributed to CPC practices had slower growth in hospitalizations and emergency department (ED) visits than those being managed by practices not in the model.	Evaluation of the Comprehensive Primary Care Initiative, Fourth Annual Report, May 2018, available at: *https://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdfhttps://downloads.cms.gov/files/cmmi/CPC-initiative-fourth-annual-report.pdf* Long-Term Effects of the Comprehensive Primary Care Model on Health Care Spending and Utilization. May 2022. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9130381/.*
Comprehensive Primary Care Plus (CPC+)	CPC+ practices used data and team-based care to proactively identify the needs of their patients and efficiently manage their care. Additionally, by the final year of the model, about 97% of physicians in CPC+ and comparison practices reported the use of scheduled phone, video, or e-visits for at least some of their patients. Finally, CPC+ had small favorable effects on some claims-based, quality-of-care	Evaluation of Comprehensive Primary Care Plus. Final Report, December 2023, available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

Model	Key Care Delivery Methods	Citation
	measures of planned care and population health and patient and caregiver engagement.	
Primary Care First (PCF)	All PCF practices provide 24/7 access to a care team practitioner with real-time access to an electronic health record (EHR). Practices also provide risk-stratified care management for all empaneled patients and ensure beneficiaries receive timely follow-up contact from the practice after ED visits and hospitalizations. Practices commonly report expanding their practice care team by hiring additional clinical and non-clinical staff to bolster longitudinal care management services.	Evaluation of the Primary Care First Model, Second Annual Report, February 2024, available at: *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported the proposed coding and payment policies to recognize APCM services under this specific model of advanced primary care, making use of lessons learned from the CMS Innovation Center's testing of advanced primary care models. Most commenters expressed gratitude that separate payment could be available for services they had already been furnishing, and many commenters appreciated our goal to address the perceived gap in payment for care management and coordination for patients without multiple chronic conditions. Many commenters appreciated the proposed shift away from time-based payment and thanked us for acknowledging that primary care needs often change month to month. Several commenters supported our proposals' emphasis on technology integration and commitment to the evolving healthcare landscape, highlighting the importance of virtual interactions for better patient-centered care. A few commenters were concerned that our proposed APCM coding and payment would duplicate work described by the existing CCM and PCM codes, potentially creating confusion and administrative burden. One commenter suggested we collaborate with the AMA's CPT Editorial Panel on coding or revise existing CCM and PCM codes to reduce burden and simplify requirements.

Many commenters recommended that cost sharing be eliminated for the proposed APCM services, indicating that any amount of cost sharing could be prohibitive to receiving beneficiary consent, ultimately limiting the uptake of and billing for APCM services. A few commenters suggested that APCM services are preventive services that should be exempt from beneficiary cost sharing. Several commenters indicated that cost sharing had limited their ability to bill for other care management services, resulting in their underutilization. A few commenters stressed that it can be difficult to educate beneficiaries on the value of care management services and the associated cost sharing because the patient is not ordinarily present when APCM services are performed. Finally, one commenter believed that the application of cost sharing could exacerbate existing health inequities.

Response: We thank the commenters for their support and feedback. We anticipate that these services will fill a need in primary care and care management, and result in more accurate payment for advanced primary care under the PFS. While we recognize concerns about potential confusion with CCM and PCM, APCM codes are essential for improving payment accuracy and enabling practitioners to spend more time with patients. We look forward to reviewing and considering, including through potential future rulemaking, any recommendations from the AMA's CPT Editorial Panel and RUC if they consider developing CPT codes and recommending valuations for these or similar services.

In response to the comments regarding elimination of beneficiary cost sharing for APCM services, most services covered under Medicare Part B carry cost sharing obligations (deductible and co-payment) unless the statute specifies that they do not apply. As for considering APCM services to be ''preventive services'' to which cost sharing does not apply, we do not see how APCM services would fit within any of the benefit categories for preventive services under the Act at this time. In particular, the Secretary has the authority to add ''additional preventive services'' that, among other things, have been assigned an ''A'' or ''B'' rating by the United States Preventive Services Task Force. But APCM services have not earned such a rating at this time. Since APCM services do not currently meet the criteria for ''additional preventive services,'' we cannot designate them as such under section 1861(s)(2)(BB) of the Act or remove coinsurance obligations on that basis at this time. Further, we do not have other statutory authority that would allow us to remove or waive the applicable cost sharing for APCM services.

b. Proposed HCPCS G-Codes for Advanced Primary Care Management (APCM)

We proposed in the CY 2025 PFS proposed rule to establish coding and make payment under the PFS for a newly defined set of APCM services described and defined by three new

HCPCS G-codes. To recognize the resource costs associated with furnishing APCM services to Medicare beneficiaries, we proposed to establish and pay for three new G-codes that describe a set of care management services and CTBS furnished under a broader application of advanced primary care. This new coding and payment would reflect the recognized effectiveness and growing adoption of the advanced primary care approach to care.[45] It will also encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management and CTBS codes, for clinicians who care for their patients using an advanced primary care model. We recognize that there are primary care physicians, practitioners, and practices beyond those that have participated in CMS Innovation Center primary care models (such as those outlined in section II.G.2.a.(1) in this final rule), that may incur resource costs associated with their treatment of patients based on the advanced primary care delivery model. Providing care using an advanced primary care delivery model involves resource costs associated with maintaining certain practice capabilities and continuous readiness and monitoring activities to support a team-based approach to care, where significant resources are used on virtual, asynchronous patient interactions, collaboration across clinical disciplines, and real-time management of patients with acute and complex concerns, that are not fully recognized or paid for by the existing care management codes. We have observed medical practice trends in primary care for several years. We note that in prior rulemaking, for example, in the CY 2013 PFS final rule, we stated, ''we further consider[ed] how advanced primary care practices can fit within a fee-for-service model'' (77 FR 68987), and in the CY 2015 PFS final rule, we stated our commitment ''to supporting advanced primary care, including the recognition of care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth'' (79 FR 67715). In the CY 2017 PFS final rule, we discussed changes to retain elements of the CCM service that are ''most characteristic of the changes in medical practice toward advanced primary care'' (81 FR 80251). As the delivery of primary care has evolved to embrace advanced primary care more fully, it is prudent to now adopt specific coding and payment policy to better recognize the resources involved in care management under an advanced primary care delivery model.

In the CY 2025 PFS proposed rule, we explained the proposed new codes and their descriptors (89 FR 61596), we proposed to define the elements of the scope of service for APCM that will be required for a practitioner to bill Medicare for the APCM service, and we explained the standards for practices that furnish APCM services to ensure that the physicians and practitioners who bill for these services have the capability to fully furnish advanced primary care, including APCM services (see section II.G.2.c. of this final rule). We proposed to identify specific care management and CTBS services that are a part of advanced primary care delivery and would be bundled into the PFS payment for the APCM services. As such, we identified the services that we proposed will overlap substantially with the new codes and which will not be separately billable with the APCM codes under our proposal (see section II.G.2.d. of this final rule). Finally, we proposed to establish relative values for these codes for purposes of payment under the PFS (see section II.G.2.e. of this final rule).

We proposed the following G-codes and descriptors for APCM services, and as explained in section II.G.2.d. of this final rule, due to the similar scope of APCM and other care management and CTBS services, we proposed to include some of the same language from the CCM and PCM service elements in the APCM code descriptors, as well as emphasized that certain practice capabilities and requirements are inherent in these elements and must be met in order to bill for APCM services:

HCPCS code G0556 (*Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

- *Consent;*

++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.*

++ *Document in patient's medical record that consent was obtained.*

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*
- *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*
- *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*
- *Overall comprehensive care management;*

++ *Systematic needs assessment (medical and psychosocial).*

++ *System-based approaches to ensure receipt of preventive services.*

++ *Medication reconciliation, management and oversight of self-management.*

- *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;*

- *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ *Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.*

++ *Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.*

[45] National Academies of Sciences, Engineering, and Medicine (NASEM). 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25983*; Maeng DD et al. Reducing long-term cost by transforming primary care: evidence from Geisinger's medical home model. Am J Manag Care. 2012 Mar;18(3):149–55. PMID: 22435908. Available here: *https://pubmed.ncbi.nlm.nih.gov/22435908/*; Jones C et al. Vermont's Community-Oriented All-Payer Medical Home Model Reduces Expenditures and Utilization While Delivering High-Quality Care. Popul Health Manag. 2016;19(3):196–205. Available here: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4913508/*.

• *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*

• *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ *Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).*

• *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*

• *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*

• *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology).*

HCPCS code G0557 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in G0556, as appropriate*) and HCPCS code G0557 (*Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in G0556, as appropriate*).

We proposed that HCPCS codes G0556 through G0558 would describe APCM services furnished per calendar month, following the initial qualifying visit (see section II.G.2.c.(1) for more on the initiating visit). Physicians and NPPs, including nurse practitioners (NPs), physician assistants (PAs), certified nurse midwives (CNMs) and clinical nurse specialists (CNSs), could bill for APCM services. As we describe in more detail in section II.G.2.c., within the code descriptors for HCPCS codes G0556, G0557, and G0558, we proposed to include the elements of the scope of service for APCM as well as the practice capabilities and requirements that are inherent to care delivery by the care team/practitioner who is billing under a practice using an advanced primary care delivery model, and necessary to fully furnish and, therefore, bill for APCM services.

As described in more detail in section II.G.2.e.(1) of this final rule, within the code descriptors for HCPCS codes G0556, G0557, and G0558, we proposed that the practitioner who bills for APCM services intends to be responsible for the patient's primary care and serves as the continuing focal point for all needed health care services. We anticipated that most practitioners furnishing APCM services will be managing all the patient's health care services over the month and have either already been providing ongoing care for the beneficiary or have the intention of being responsible for the patient's primary care and serving as the continuing focal point for all the patient's health care services. We anticipate that these codes will mostly be used by the primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics, but we are also aware that, in some instances, certain specialists function as primary care practitioners—for example, an OB/GYN or a cardiologist. In contrast to situations where the patient's overall, ongoing care is being managed, monitored, and/or observed by a practitioner, there are situations when care is provided by a practitioner who would not serve as ''the continuing focal point for all needed health care services.'' Similarly, there are some time- or condition-limited practitioner-patient relationships that are clearly not indicative of the ongoing care that we anticipate practitioners would be responsible for when furnishing APCM services. As we stated in the CY 2021 PFS proposed rule and CY 2024 PFS final rule in the context of our policies for the O/O E/M visit complexity add-on code (HCPCS code G2211), a practitioner whose ''relationship with the patient is of a discrete, routine, or time-limited nature; such as, but not limited to, a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus, for counseling related to seasonal allergies, initial onset of gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time'' (85 FR 84570 and 84571, 88 FR 78971). For example, a patient who spends one month of the year in another location could require physicians' services in that location if they experience exacerbation of one of their chronic conditions, but the practitioner who treats them would not intend to manage or monitor that patient's overall, ongoing care. Finally, HCPCS code G2211 can also be billed when medical services are ''part of ongoing care related to a patient's single, serious condition or complex condition,'' but this is different from the APCM requirement. A practitioner's management of one or more serious conditions (as is often the case with specialty care), without more, does not mean that the practitioner is also responsible for all primary care services and the focal point for all needed care (the requirement for APCM), and thus would not necessarily mean that the practitioner could bill for APCM.

As is our current policy for other care management services, and consistent with both CPT guidance and Medicare rules for CPT codes 99487, 99489, 99490, we proposed that HCPCS codes G0556, G0557, and G0558 may only be reported once per service period (calendar month) and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period (89 FR 61596). That is, based on a patient's status, a physician or practitioner would identify the patient to receive Level 1, Level 2, or Level 3 APCM services

during a given service period (calendar month), and we would make payment for only one claim for APCM services for that service period. At this time, we do not see the need or value of implementing restrictions or complex operational mechanisms to identify a single physician or NPP who may bill for APCM services for a specific beneficiary. However, we recognize that other initiatives, such as the Medicare Shared Savings Program, have operational mechanisms in place to attribute patients to certain ACOs (§ 425.400). While a similar approach could be used to attribute patients for APCM services, we are reluctant to introduce unnecessary complexity for these services. As we continue to develop our policies in this area, we sought feedback from interested parties on methodologies that could allow for identification of the beneficiary's primary care practitioner. We also sought comment on whether there should be additional requirements to prevent potential care fragmentation or service duplication.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments regarding the types of practitioners that can furnish and be paid for APCM services. These interested parties thanked us for including advanced practice nurses such as nurse practitioners, certified nurse midwives, and clinical nurse specialists. Several commenters encouraged us to add additional types of health care professionals to those who can furnish APCM, such as registered nurses and pharmacists.

Response: We thank the commenters for their feedback. We appreciate the value of interdisciplinary teams, which can include registered nurses and pharmacists. As discussed later in this rule, APCM services can be furnished by the types of Medicare-enrolled practitioners that are authorized under the statute to furnish and be paid for services performed by auxiliary personnel (which can include registered nurses and pharmacists) incident to their own professional services. We proposed to add APCM services as designated care management services under § 410.26(b)(5), which means that these services can be performed by auxiliary personnel under the general supervision of the billing physician or other practitioner. As defined under § 410.26(a)(3), general supervision means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service, whereas direct supervision in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service.

Comment: A few commenters asked how to identify the practitioner responsible for the patient's primary care, giving an example of a patient who has a primary care practitioner and a geriatrician. Other commenters supported our proposed definition of primary care practitioner as the individual responsible for the patient's primary care and who serves as the continuing focal point for all needed health care services, with one stating that such a practitioner would understand the history and context of each patient. Another commenter agreed with our proposed approach to identifying the appropriate practitioner for purposes of billing for APCM services, as it is tailored toward those practitioners who provide consistent, longitudinal care rather than those who provide more time-limited, discrete services. We did not receive any comments about patient-practitioner relationships not indicative of a primary care relationship.

Response: We appreciate the commenters' support for our proposed approach to identifying the primary care practitioner responsible for the patient's care. We recognize that a patient may regularly see multiple practitioners, and that more than one of them may be in a specialty that is generally considered to furnish primary care, as in the example provided by the commenter of a patient who sees their primary care practitioner and a geriatrician. While more than one practitioner may have an ongoing relationship with the patient, there ordinarily would be only one of them who serves as the continuing focal point for all needed health care services. We proposed that the patient must be informed as part of the required beneficiary consent before receiving APCM services that only one practitioner can furnish and be paid for these services during a calendar month. We believe that any lack of clarity as to which practitioner serves as the continuing focal point for all care can be resolved through the beneficiary consent process and with clear and comprehensive patient education.

Comment: A few commenters indicated it may be useful to use a beneficiary's attestation of their main health care practitioner on *Medicare.gov* to identify who could bill for APCM services. Additionally, some commenters suggested that we should develop a claims-based attribution method similar to that used by the Shared Savings Program or CMS Innovation Center models to determine the responsible primary care practitioner.

Response: We thank the commenter for this suggestion. We acknowledge that an attribution method that uses historical claims data and/or beneficiary attestations made through *Medicare.gov* could be useful to reduce the administrative burden on practitioners in determining whether they are the appropriate primary care practitioner for purposes of APCM services. Given that these are new services, we believe it would be more appropriate to refrain from implementing additional requirements so that we may consider feedback from interested parties as they gain experience billing for these services. We may consider additional guardrails to prevent the submission of APCM claims from more than one practitioner through possible future rulemaking. Finally, as we discussed in the CY 2021 final rule related to monitoring appropriate use of the E/M visit complexity add-on code (HCPCS code G2211), we believe that information included in the patient's medical record or claims history could serve as supporting documentation to help us determine whether the billing physician or practitioner is the appropriate primary care practitioner for purposes of APCM services (85 FR 84571). We would like to remind commenters that only one practitioner can bill for APCM services per month, which should be discussed when obtaining the patient's consent for these services.

Comment: We received many comments about the specialties of the practitioners we would expect to furnish and bill for APCM services. A few commenters were split on whether specialists should be permitted to bill for the APCM codes, with some commenters recommending that specialists who might tend to serve in the role of primary care practitioner, such as cardiologists, endocrinologists, and pulmonologists should be allowed to bill for APCM services. Other commenters stated that even specialists who have long-term relationships with patients are unlikely to provide advanced primary care services as envisioned in our proposed APCM codes, and expressed concern that allowing them to bill for APCM services could lead to fragmented care.

Response: We understand the commenters' concerns about fragmented care, especially across specialists and primary care practitioners. Our aim in developing proposals to identify the appropriate practitioner to furnish and bill for APCM services was to retain flexibility to allow for the specific circumstances of individual practitioners and beneficiaries. We reiterate as described before that a specialist who manages one or more of a patient's serious conditions is not necessarily the practitioner who is responsible for all of the patient's primary care and the focal point for all needed health care, which is specified in the code descriptors as the basis for a practitioner to furnish and bill for APCM services. In the event that a specialist and a primary care practitioner both intend to be responsible for all primary care services and serve as the focal point of all needed care for the same patient, we note that we proposed to make payment to only one practitioner for APCM services in any single month. Further, we proposed that the patient must be informed of this as part of the required patient consent before receiving APCM services. We believe that the question of which practitioner should furnish and bill for APCM services for a patient can be resolved through clear and comprehensive patient education, as well as communication between practitioners if needed.

Comment: Several commenters agreed with our proposed coding structure of monthly billing for APCM. A few other commenters agreed that a monthly billing cycle strikes a balance between the number of times these services are furnished annually and monthly payment.

Response: We thank commenters for their support. We continue to believe that billing APCM each calendar month is the most appropriate billing cadence.

After consideration of public comments, we are finalizing our proposals without modification to create three G-codes to describe APCM services effective January 1, 2025, which can be billed monthly following the initiating qualifying visit (see section II.G.2.c.(1) for more on the initiating visit) by the physician or practitioner (nurse practitioner, physician assistant, certified nurse midwife, or clinical nurse specialist) who intends to be responsible for the patient's primary care and serve as the continuing focal point for all needed health care services. We are not limiting APCM services to practitioners in specific specialties, but we remain open to feedback about these policies from interested parties.

We anticipate that APCM services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26. We proposed that APCM services will be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of our proposal to include APCM as a designated care management service, including support for our proposal to allow general supervision of auxiliary personnel for these services.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing our proposal to add APCM services as a ''designated care management service'' under § 410.26(b)(5) and, as such, these services can be provided by auxiliary personnel under the general supervision of the billing practitioner.

Unlike the other coding to describe care management services, we further proposed that the code descriptors for HCPCS codes G0556, G0557, and G0558 would not be time-based (89 FR 61596). Based on feedback from the physician and practitioner community, we understand that ongoing care management and coordination services are standard parts of advanced primary care, even in months when documented clinical staff or billing professional minutes may not reach the required thresholds for billing or the patient's condition does not meet the clinical conditions for care management services under the existing code set. In consideration of the extensive feedback from interested parties, we have learned that practitioners who currently furnish monthly care management services may already be providing APCM services in a variety of clinical circumstances, documenting all necessary aspects of the patient-centered care furnished monthly to the patient without meeting the requirements to bill for care management services, such as satisfying the administrative requirement to count clinical staff minutes to reach specific time-based thresholds. As we stated in the CY 2024 PFS final rule in the context of the O/O E/M visit complexity add-on code (HCPCS code G2211), physicians and practitioners may diagnose and treat a condition in an O/O E/M visit that is not expected to last as long as three months or would not reasonably be expected to result in a risk of hospitalization, and the practitioner's clinical staff may provide significant care management and coordination services relating to that condition. For example, COVID–19 cases are clinical circumstances that generally do not last three months but may require significant acute management, care coordination, and follow-up within a given month, particularly for patients with comorbidities (88 FR 78973). Practitioners may also provide care management and coordination services to a patient whose condition meets the criteria in one or more care management codes, but the documented minutes of service may not reach the minimum time threshold to bill for a care management service. For example, the practitioner might provide care coordination for a month that includes 20 minutes of consulting with the patient's other healthcare providers and modifying medications to address an acute exacerbation of hypertension but will not meet the requirements for billing the PCM service. We also noted that, unlike the current coding to describe certain CTBS services, we proposed that the code descriptors for HCPCS codes G0556, G0557, and G0558 will not include the timeframe restrictions for billing certain CTBS (for example, the restriction for virtual check-in services that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment). As addressed in the CY 2019 PFS final rule, we have heard from interested parties that the timeframe restrictions for billing certain CTBS are administratively burdensome (83 FR 59686).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters were overwhelmingly supportive of our proposal to not require the counting of clinical staff minutes spent furnishing APCM services to reach specific time-based thresholds for billing the proposed APCM codes, noting that doing so is both administratively burdensome and often results in practitioners providing services that they are unable to bill and be paid for because they do not reach the required minimum time threshold to bill for a service. One commenter applauded this proposal and asserted that, in time-based billing scenarios, the need to

maintain a certain rate of billable units across the patient population to keep the program financially tenable may directly or indirectly incentivize care managers to prioritize activities that fulfill billing requirements and deprioritize needed activities for patients who may need intervention but have already fulfilled the billing requirements or are unlikely to fulfill the billing requirements. A few commenters expressed concern that removing the time-based thresholds may inadvertently incentivize over-billing of the proposed APCM codes, in which a practitioner bills the APCM codes for beneficiaries whether or not they are performing any of the APCM service elements, such as care coordination.

Response: We agree with the commenters who suggested that practitioners delivering care using an advanced primary care approach are providing ongoing care management and coordination services for their patients. While these activities should be documented in the patient's medical record, we agree that the need to document clinical staff minutes spent providing these services is unnecessarily administratively burdensome in the context of advanced primary care, and that the requirement to meet time-based thresholds is not necessary to bill the APCM codes (HCPCS codes G0556, G0557, and G0558) as we proposed to define them. While we appreciate the concern about over-billing, we believe that practitioners that meet all of the other requirements to bill HCPCS codes G0556, G0557, and G0558, and are documenting the care management and coordination services they are furnishing to patients in the medical record without recording the clinical staff minutes spent on each activity, are providing medically necessary advanced primary care management services. We reiterate that, while only one physician or practitioner may furnish and be paid for APCM services for a patient in a single month, a patient's other health care providers can furnish and bill for other care management services, such as TCM, CCM, PCM, CHI, PIN, and certain CTBS, when medically necessary. Additionally, we recognize that there may be some practitioners who do not furnish care using the advanced primary care model or prefer to bill using other care management codes rather than the new APCM codes. We note that, like all other physicians' services billed under the PFS, each of these services must be medically reasonable and necessary to be paid by Medicare.

Comment: Most commenters were supportive of not including the same time-based restrictions on billing other services that apply for CTBS in the code descriptors for HCPCS codes G0556, G0557, and G0558. Commenters also suggested that it is not always possible to adhere to the current restrictions on billing for certain CTBS services, including for virtual check-in services that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment, despite a practitioner's best efforts to do so.

Response: We agree that the time-related billing restrictions that apply for certain CTBS services (for example, virtual check-in services) are not necessary for HCPCS codes G0556, G0557, and G0558. We adopted the limitations on when certain CTBS can be billed with other codes to avoid duplicative payment. For example, in the case of virtual check-in services, which are a brief exchange with a practitioner to determine whether the patient needs to be seen or the problem can be addressed in a different way, payment for a contemporaneous E/M service would already reflect the resources involved in furnishing the virtual check-in service. However, in the case of virtual check-ins provided as part of APCM services, there is no need for such limitations because the APCM codes describe a broad set of advanced primary care services—not all of which will be provided in any particular month.

After consideration of public comments, we are finalizing our proposal without modification to establish APCM codes and descriptors that reflect all elements of service furnished during a month without specifying the amount of time that must be spent furnishing the services during the month; and without including time-related billing restrictions for the elements of the services.

We also proposed that not all elements included in the code descriptors for APCM services must be furnished during any given calendar month for which the service is billed (89 FR 61596). APCM services are largely designed to be person-centered and focused on the individual patient, such that the elements that are provided depend on medical necessity and individual patient need. Therefore, we anticipate that all the APCM scope of service elements (for example, comprehensive care management and care coordination) will be routinely provided, as deemed appropriate for each patient, acknowledging that not all elements may be necessary for every patient during each month (for example, the beneficiary may have no hospital admissions that month, so there is no management of a care transition after hospital discharge). We also anticipate that there may be some months where it may be appropriate for some service elements to be performed more than once for the patient. For example, in one month a patient with heart failure and chronic kidney disease receiving APCM Level 2 services (G0557) may be on a stable medication regimen, receive communication about their care plan, but no virtual check-ins. The next month, the patient may experience a heart failure exacerbation requiring inpatient admission, and then receive as part of their APCM service timely communication and follow-up with new labs ordered, multiple virtual check-ins ensuring that the patient understands their new medications, a phone call to help the patient understand the lab results, and an interprofessional consultation with the patient's cardiologist to help decide if the patient's diuretic dosage should be changed.

However, even if not all elements of the APCM service are furnished each month for which APCM is billed, we proposed that billing practitioners and auxiliary personnel must have the ability to furnish every service element and furnish these elements as is appropriate for any individual patient during any calendar month. As described in more detail in the CY 2025 PFS proposed rule (89 FR 61707), maintaining certain advanced primary care practice capabilities and requirements is inherent in these elements and must be met to fully furnish and bill APCM. For example, using our previous example of the patient with heart failure and chronic kidney disease receiving Level 2 APCM services, if the patient experiences swollen legs, the patient should be able to submit a photo or video to the practitioner via a secure communications system, and the practitioner must be able to interpret and communicate remotely with the patient about those images.

While we proposed that specific minutes spent furnishing APCM services for purposes of billing HCPCS codes G0556–G0558 need not be documented in the patient's medical record, we will expect that any actions or communications that fall within the APCM elements of service will be described in the medical record and, as appropriate, their relationship to the clinical problem(s) they are intended to resolve and the treatment plan, just as

all clinical care is documented in the medical record.

We sought feedback on these service descriptions as part of the CY 2025 PFS proposed rule, on whether there are elements of other care management services that should be removed or altered for purposes of APCM services. We have summarized comments on our proposed service descriptions on section II.G.2.c. for Level 1, Level 2, and Level 3 APCM. Finally, while the service descriptors above are consistent across all three APCM levels because the scope of service elements are consistent across all levels of APCM and the elements that are provided depend on medical necessity and individual patient need, we proposed that the APCM codes will be stratified into three levels based on certain patient characteristics that are broadly indicative of patient complexity and the consequent resource intensity involved in the provision of these services in the context of advanced primary care. We proposed that the new APCM coding schema will be stratified based on APCM services being furnished using the advanced primary care model to patients with one or fewer chronic conditions (''Level 1''); patients with two or more chronic conditions (''Level 2''); and Qualified Medicare Beneficiaries (QMBs)[46] with two or more chronic conditions (''Level 3'') (see Table 24 for the three APCM code levels). This stratification of APCM into three levels allows us to distinguish among different levels of patient complexity and more accurately reflect the resources required to furnish APCM services for certain categories of beneficiaries. We anticipate that a practitioner using the advanced primary care model will bill for APCM services for all or nearly all the patients for whom they intend to assume responsibility for primary care.

Furthermore, we recognized the ways in which this new APCM coding intersects with current care management codes around number of chronic conditions (89 FR 61596). We note that the current care management codes are generally stratified in a similar, though more granular way, by the degree of complexity of care based on the presence of chronic conditions and complexity of medical decision making, who directly performs the service, and the time spent furnishing the service. In establishing separate payment for CCM services in the CY 2014 PFS final rule, we recognized that the resources involved in furnishing comprehensive, coordinated care management services to patients with multiple (two or more) chronic conditions were greater than those included in a typical non-face-to-face care management service, which we continued to consider as bundled into the payment for face-to-face E/M visits (78 FR 43337). In the CY 2017 PFS final rule, based on robust feedback from interested parties indicating that the new CCM codes did not fully capture the service time required to furnish care to beneficiaries with more complex conditions, we finalized new codes for patients with complex care management needs. In the CY 2016 PFS final rule, in considering how to improve the accuracy of our payments for care coordination, particularly for patients requiring more extensive care management, we stated that the care coordination and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or certain behavioral health conditions often requires extensive discussion, information-sharing, and planning between a primary care physician and a specialist (for example, with a neurologist for a patient with Alzheimer's disease plus other chronic diseases) (80 FR 70919).

TABLE 24: Patient-Centered Risk Stratification for Billing APCM Codes

Level 1 [G0556]	Level 2 [G0557]	Level 3 [G0558]
Patients with one or fewer chronic conditions.	Patients with two or more chronic conditions.	Patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many public comments on our proposed APCM service code levels, some of which we have summarized in section II.G.2.e(1) where we discuss Level 1, Level 2, and Level 3 APCM services. In general, the majority of commenters appreciated our efforts to stratify the APCM codes based on patient complexity and resource intensity, recognizing the importance of addressing the needs of patients with varying levels of chronic conditions. Furthermore, many commenters were supportive of the proposal not to require all elements of the APCM services to be furnished each month in which APCM is billed, expressing appreciation for our acknowledgment that beneficiaries' needs will vary from month to month.

However, several commenters generally believed the proposed stratification may not fully account for the severity of individual conditions or appropriately account for the resource costs for beneficiaries with multiple complex conditions and recommended various alternatives for stratification. Several commenters suggested that our proposed APCM levels are inappropriately weighted towards uncomplicated, lower-risk patients and were concerned that the proposed stratification does not reflect the additive impact of multiple chronic conditions, or the increased resources associated with furnishing APCM services to higher-risk patients with complex illness. Some of these commenters suggested that there are a significant number of Medicare beneficiaries with more than two chronic conditions and, as the number of chronic condition increases, the types of support and time needed to manage these patients increases. Specifically, several commenters encouraged us to add an additional level to the APCM service codes to account for patients with significant clinical complexity and healthcare needs that do not meet QMB criteria, but who still require intensive resource utilization. A few commenters suggested that six chronic conditions would be an appropriate threshold. Other commenters recommended that a fourth tier be added to the APCM

[46] See 42 CFR 435.123. The proposal includes both individuals in the QMB eligibility group who also have full scope Medicaid coverage (''QMB-plus'') and individuals in the QMB eligibility group who do not have Medicaid eligibility under any other Medicaid coverage group (''QMB-only''). However, this proposal would not include those QMBs who are in the Medicare Part B Immunosuppressive Drug benefit, which provides coverage of immunosuppressive drugs based on eligibility requirements described in § 407.55, because such individuals would not qualify for Medicare coverage of the services described in this rulemaking. See 42 CFR 435.123(c)(2).

service code levels based on the high needs beneficiary criteria from the High Needs track of the ACO REACH Model to account for the resources needed to support patients with complex illness. These commenters suggested that this criterion has been effective at identifying high-cost, high-needs patients and would allow us to incorporate another successful element of value-based care into traditional Medicare payment policy.

Response: We thank all commenters for their careful consideration of the proposed approach to stratify the APCM codes, and we appreciate commenters' suggestions for specific types of beneficiaries who may require intensive care management resource utilization and warrant an additional APCM code level, including beneficiaries with complex illness. We appreciate commenters' suggestion to consider the high needs beneficiary criteria from the High Needs track of the ACO REACH model. The model's eligibility criteria for alignment to a High Needs Population ACO includes beneficiaries with one or more conditions that impair mobility or neurological condition, significant chronic or other serious illness reflected by risk score and unplanned hospital admissions, or signs of frailty (who may also be dually eligible or at risk of becoming dually eligible).[47] We also acknowledge commenters' concerns that patients with two chronic conditions may require additional time and more complex care than a patient with two chronic conditions and QMB status. However, we believe that beneficiaries who are QMBs face unique challenges outside chronic condition management that may impact their care, requiring additional care management resources. We believe that our proposed APCM code stratification recognizes that individual beneficiaries have unique and varying resource needs, and strikes a balance between being overly specific in the creation of many categories, which could increase confusion and administrative burden, and being overly simplistic, which could inadequately differentiate between variations in the resources involved in furnishing APCM services. We believe that our proposal does this in an appropriate way and, as such, are finalizing the code stratification as proposed. However, we continue to welcome feedback to help us consider possible future changes to our policy and will take commenters' suggestions into consideration as we consider the development of proposals for future rulemaking.

Comment: A few commenters recommended that we review the AMA RUC Medical Home Workgroup's valuation recommendations from 2008 where they described services defined in the Medicare Medical Home demonstration project.[48] For context, in 2008, pursuant to the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432), we conducted a three-year demonstration project to evaluate the medical home model of patient care. We drafted a three-tiered system to categorize medical homes based on the capabilities of the physician practices serving in that capacity for purposes of conducting the demonstration project. We asked the RUC for their assistance in creating possible valuations for these three tiers, including costs associated with physician work, direct practice expense, and professional liability insurance. These requirements ranged from entry-level practices to fully integrated, complex health systems, and which took into consideration varying practice-level capabilities, such as electronic prescribing capabilities, documentation of referral histories, and maintenance/service contract for hardware, internet, etc. These commenters suggested that we adopt the RUC's 2008 valuation recommendations as a framework for APCM services and establish APCM levels based on these medical home practice tiers.

Response: We have reviewed the RUC's 2008 recommendations for code descriptors, physician work, direct practice expense inputs, and professional liability insurance crosswalks for each of the three tiers of medical homes and found that the recommended tier system and payment based on practice-level capabilities would not fully capture the policy goals of the proposed APCM coding and payment. The proposed APCM codes were built on a presumed set of practice capabilities that reflect the use of an advanced primary care model of care delivery, which has been increasingly common in medical practice, and valued to more accurately account for the resources involved in furnishing care using an advanced primary care model. While we have never addressed in rulemaking the AMA RUC's findings and recommendations for the medical home practice tiers and associated valuations, we acknowledge that several practice-level capabilities described by the RUC are similar to the proposed APCM service elements, including but not limited to obtaining consent, care planning, acting as the primary focal point of care, and 24/7 access. However, our proposal to adopt coding for APCM was to recognize the shift in medical practice toward care delivery using an advanced primary care model and improve payment for care management services delivered by practitioners who have adopted an advanced primary care approach, which involves a specific set of practice-level capabilities. Stratifying coding for APCM services based on practice-level capabilities would not be helpful to that purpose. And there is other available coding that recognizes the resources involved in care management services furnished by practitioners outside of an advanced primary care model. We are also concerned that stratifying levels of payment for APCM services based on practice-level capabilities, rather than patient-level characteristics, could further exacerbate inequities in health systems, including smaller or rural practices who may furnish care to equally complex patients as compared to larger, more established health systems and clinics.

Finally, we do not believe the valuation proposed in the RUC's recommendation can be appropriately applied to the proposed APCM code levels. The RUC suggested a work RVU per patient per month of 0.35 for Tier 3 in the medical home model, which was intended for ''very sick'' patients. The recommended 0.35 RVU is lower than the highest valuation for APCM. If we had adopted the RUC's recommended RVUs for the three tiers, we would have reduced our proposed values for the APCM codes, which would not have appropriately reflected the resources involved in furnishing these services.

After consideration of public comments, we are finalizing as proposed the APCM service code levels.

(*1*) Level 1 APCM

We proposed the Level 1 APCM code for patients with one or fewer chronic conditions because of the increased import and use of non-face-to-face

[47] For PY2025, CMS expanded these criteria to include beneficiaries that have at least 90 Medicare-covered days of Home Health services utilization or at least 45 Medicare-covered days in a Skilled Nursing Facility within the previous 12 months. The revised eligibility criteria were expected to more effectively identify beneficiaries with complex needs that would benefit from participation in a High Needs Population ACO. More information available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa* and *https://www.cms.gov/priorities/innovation/innovation-models/reach-py24-model-perf#:~:text=The%20model's%20eligibility%20criteria%20for,admissions%2C%20or%20signs%20of%20frailty*.

[48] *American Medical Association. (n.d.). Medical home model of care: Recommendations (Publication No. 0). AMA. https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/rbrvs/medicalhomerecommend_0.pdf*.

interactions in advanced primary care even for patients with relatively fewer health needs, which has increased over time for several observable reasons, including broad evolution in information and communication technology in everyday life, diffusion of practices first adopted for higher-acuity patients, and continuing practices widely adopted during the COVID–19 pandemic that reduce reliance on in-person interactions (89 FR 61596). APCM services for a patient diagnosed with one or fewer chronic conditions will require significantly less time and resources than one with two or more chronic conditions since, in general, there would be fewer ongoing health needs and other health care resources to coordinate, a lower risk of drug interactions, and less complicated physiology. Based on CY 2010 Medicare claims data, the difference in annual expenditures per beneficiary between patients with one or fewer chronic conditions and those with two or three chronic conditions was $3,673.[49] Our current care management coding similarly delineates patient complexity between patients with a single serious chronic condition (PCM codes) and those with two or more serious chronic conditions (CCM codes). We anticipate that practitioners who would furnish APCM services may have already had experience with care management services coding and payment for much of this population. The Level 1 APCM code would also address the current gap in coding and payment for care management services furnished using an advanced primary care model for patients without multiple chronic conditions.

We received many public comments on our proposed APCM service code levels. The following is a summary of the comments we received and our responses.

Comment: Most of the commenters recommended that we adopt additional codes to provide differential payment for more and less complex beneficiaries. Many commenters were concerned that the proposed stratification is heavily weighted towards uncomplicated, lower-risk patients. A few commenters pointed out that some patients with a single, but very serious condition, may require significantly more resources than patients with multiple chronic conditions that are stable or less severe. By focusing solely on the number of chronic conditions, commenters suggested that this stratification could overlook the nuanced differences in resource needs based on condition severity and complexity. Many commenters recommended that we further evaluate and refine the stratification scheme to more accurately reflect the resource intensity required for effective advanced primary care delivery by incorporating additional factors, such as the severity of individual conditions, social risk factors beyond QMB status, and other indicators of medical complexity. Several commenters recommended that we create an add-on code for QMBs that could be reported with any of the APCM levels, including Level 1. These commenters stated that it is likely that there are many beneficiaries with two or fewer chronic conditions that have social risk factors that may impact their care. These commenters provided the example of an otherwise healthy beneficiary who has found themselves newly homeless, leaving them at greater risk for contracting infections and illnesses, which impacts their overall care.

Response: We believe that all beneficiaries, even with a small number of chronic conditions, can benefit from care coordination and access to advanced primary care services. We also recognize that a patient's health conditions may change rapidly, and having established ongoing care can mitigate and reduce negative health outcomes. We appreciate that the number of chronic conditions a beneficiary has may not correlate perfectly to the severity or complexity of illness. However, as noted earlier in this discussion, we are aiming to strike a balance between coding specificity and administrative simplicity to appropriately stratify APCM services based on how chronic medical conditions interact with increased risk associated with social determinants of health (SDOH) factors. We understand that there will always be beneficiaries within a particular APCM code level whose needs for APCM services are greater or less than other beneficiaries. We expect the adoption of coding and payment policies for APCM services to be an iterative process, informed by ongoing feedback from interested parties that we will take into consideration for future rulemaking.

Comment: One commenter stated that the code descriptor for HCPCS code G0556 does not mention the presence of a chronic condition, while the risk stratification for billing the code states ''patients with one or fewer chronic conditions.'' This commenter therefore requested that we include ''patients with one or fewer chronic conditions'' in the code descriptor for enhanced clarity. Another commenter asked us to clarify what constitutes a ''chronic condition'' for purposes of APCM service level selection, and whether we would use an approach similar to CCM in which we do not enumerate an exhaustive list of conditions that qualify for CCM payment, instead defining a qualifying condition as one that is ''expected to last at least 12 months or until the patient's death and or that place them at significant risk of death, acute exacerbation and or decompensation, or functional decline.''

Response: We agreed with the commenters that we should add clarifying language to the code descriptor for Level 1 APCM services. We are finalizing modifications to our proposed code descriptor for Level 1 APCM services to indicate the presence of one or fewer chronic conditions that are ''expected to last at least 12 months or until the patient's death and or that place them at significant risk of death, acute exacerbation and or decompensation, or functional decline.'' We point out to commenters that we had already included this definition of ''chronic condition'' for Level 2 and Level 3 APCM services.

After consideration of public comments, we are finalizing the code descriptor for HCPCS code G0556 as: HCPCS code G0556 (*Advanced primary care management services for a patient with one chronic condition [expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline], or fewer, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

- *Consent*;

++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.*

++ *Document in patient's medical record that consent was obtained.*

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner,*

[49] *Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.*

including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;

• *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*

• *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*

• *Overall comprehensive care management;*

++ Systematic needs assessment (medical and psychosocial).

++ System-based approaches to ensure receipt of preventive services.

++ Medication reconciliation, management and oversight of self-management.

• *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan with typical care plan elements when clinically relevant;*

++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;

• *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

• *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*

• *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

• *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*

• *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*

• *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).

(*2*) Level 2 APCM

We proposed the Level 2 APCM code for patients with two or more chronic conditions because of the frequency of chronic conditions in the Medicare population. In fact, nearly four in five Medicare beneficiaries have two or more chronic conditions.[50] Furthermore, as noted previously, our current care management coding delineates patient complexity for the CCM codes for patients with two or more serious chronic conditions, and we anticipate that practitioners who will furnish APCM services may have already had experience with care management services coding and payment for much of this population.

For example, someone with chronic kidney disease and heart failure requires regular check-ins, coordination with specialty care, follow-up after hospital admissions for heart failure exacerbations, regular modifications of the care plan, and more. These services are typically described by the existing CCM services. The patient may also typically need to reach out more often to their primary care practitioner with questions or new symptoms via the patient portal. For instance, the person sends a message through the patient portal to ask whether or not they should come into the primary care office after gaining ten pounds in the last week—which could be a sign of increased fluid retention and the need for increased diuretic dosages to avoid pleural edema (an accumulation of fluid in the lungs). The primary care team books the patient for a same-day urgent care appointment to assess for signs of swelling and pleural edema. Again, this on-demand access to their primary care team can help treat the patient's chronic conditions in a patient-centered way and avoid unnecessary complications.

Comment: One commenter recommended that we add a modifier to be reported with the Level 2 APCM code to reflect social complexity and/or additional medical complexity for non-QMB beneficiaries.

Response: We thank commenters for their consideration of the proposed Level 2 APCM service, and we appreciate the commenter's suggestion for potential ways to recognize that non-QMB beneficiaries may also have increased needs associated with social and/or medical complexity and therefore require more resources regardless of their QMB status. However, we believe that our proposed coding approach appropriately balances coding specificity with administrative simplicity. We continue to welcome feedback to help us evaluate the appropriateness of the APCM service levels, coding structure, and our social risk adjustment methodology, and we will consider possible changes to our policy in future rulemaking.

After consideration of public comments, we are finalizing as proposed the code descriptor for HCPCS code G0557:

HCPCS code G0557 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

• *Consent*;

++ Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of

[50] Lochner, K., Goodman, R., Posner, S., & Parekh, A. (n.d.). *Multiple Chronic Conditions Among Medicare Beneficiaries.* CMS. *https://www.cms.gov/mmrr/Downloads/MMRR2013_003_03_b02.pdf.*

the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.

++ Document in patient's medical record that consent was obtained.

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*
- *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*
- *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*
- *Overall comprehensive care management;*

++ Systematic needs assessment (medical and psychosocial).

++ System-based approaches to ensure receipt of preventive services.

++ Medication reconciliation, management and oversight of self-management.

- *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;

- *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

- *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*
- *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

- *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*
- *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*
- *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).

(*3*) Level 3 APCM

We proposed the Level 3 APCM code for patients with QMB status and two or more chronic conditions based on our understanding that people with both multiple chronic conditions and social risk factors generally require more time and resources from primary care practitioners and their teams to ensure that the patient's chronic conditions are managed appropriately and effectively. We proposed to use a patient's QMB status as a method to identify beneficiaries with social risk factors that generally necessitate relatively greater resource requirements to effectively furnish advanced primary care than people without such risk factors. There is significant evidence that such dually eligible beneficiaries, on average, are more medically complex and have higher healthcare needs;[51] for example, dually eligible beneficiaries are more likely to have poor functional status[52] and recent expenditure data found that the difference in Medicare spending on a per person per year basis between dually eligible and non-dually eligible Medicare beneficiaries was $13,198 in CY 2021.[53]

QMBs are the largest eligibility group within the Medicare-Medicaid dually eligible enrollee population, comprising of 66 percent of the 12.8 million individuals per the most recent available data.[54] For the approximately 8.5 million dually eligible beneficiaries who are QMBs, Medicaid covers Medicare's cost sharing requirements. The QMB eligibility group helps to ensure full access to the Medicare benefit for the lowest income enrollees by covering these costs. Individuals can qualify for QMB status if their income is below 100 percent of the Federal Poverty Level ($15,300/year in 2024) and assets are no more than $9,430/$14,130 (one person/married couple in 2024), although States can request our approval to disregard certain income and assets.[55] Beneficiaries apply for this benefit with their State's Medicaid program and must be redetermined eligible at least annually.

There is growing recognition that social risk factors—such as income, education, access to food and housing, and employment status—play a major role in health,[56] such that social risk

[51] *Kaiser Family Foundation. (n.d.). A primer on Medicare: What is the role of Medicare for dual-eligible beneficiaries?* Retrieved June 24, 2024, from *https://www.kff.org/report-section/a-primer-on-medicare-what-is-the-role-of-medicare-for-dual-eligible-beneficiaries/#:~:text=A%20larger%20share%20of%20dual,beneficiaries%3B%20and%20more%20than%20half%20(.*

[52] *ASPE. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. December 2016. https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[53] *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_Duals DataBook-508.pdf.*

[54] *Beneficiaries Dually Eligible for Medicare and Medicaid. Data from CY 2021.* (January 2024). MedPAC and MACPAC. *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf.*

[55] *Access to Care Issues Among Qualified Medicare Beneficiaries (QMB).* (2015). Centers for Medicare & Medicaid Services. *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.*

[56] Long P, Abrams M, Milstein A, Anderson G, Apton KL, Dahlberg M, Whicher D. Effective care for high-need patients. Washington, DC: National Academy of Medicine. 2017. *https://nam.edu/wp-content/uploads/2017/06/Effective-Care-for-High-Need-Patients.pdf*; Schroeder, S. (2007, September 20). We Can Do Better—Improving the Health of the American People. New England Journal of Medicine, 357(12), 1221–1228. *https://www.nejm.org/doi/full/10.1056/NEJMsa073350.*

factors may affect a person's ability to reach their health goals, as well as the diagnosis and treatment of their medical problems. A report submitted to Congress by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in response to the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185) found that dual Medicare-Medicaid enrollment as a marker for low income was typically the most powerful predictor of poor outcomes on quality measures among social risk factors examined.[57] Beneficiaries with social risk factors may have worse health outcomes due to a host of factors, including higher levels of medical risk, worse living environments (for example, availability of community services, pollution, safety), greater challenges in adherence to medication regimens and medical recommendations (for example, diet/lifestyle), and/or bias or discrimination. Evidence suggests that many health outcomes are related more to social, environmental, and economic factors (which may be beyond practitioners' control) than to clinical interventions.[58] Dual enrollees, and more specifically, QMBs, are therefore a category of Medicare beneficiaries who are the most socially at-risk of poorer clinical outcomes. As stated in the ASPE report, ''Some of the observed relationship between social risk factors and outcomes may be the result of underlying differences in medical complexity, frailty, disability, and/or functional status. For example, dually-enrolled beneficiaries are more likely to have poor functional status, and therefore, may be more likely to be readmitted after a hospitalization.'' As another example, a patient with diabetes, heart failure, and QMB status may experience food, transportation, or housing insecurity that contributes to difficulty maintaining blood glucose control which can contribute to medical complications including potentially preventable heart failure exacerbations. The primary care practitioner's team may need to check-in regularly to ensure, for example, that the patient gets needed specialty care such as an ophthalmologic examination to avoid the ocular manifestations of diabetes; and consider the availability of transportation vouchers so the patient can attend the ophthalmology appointment. We proposed the Level 3 APCM code to recognize the unique characteristics of QMBs as beneficiaries with social risk factors for whom significantly more resources are involved in comprehensive care management by practitioners that furnish advanced primary care services to them.

Additionally, we note that patients with QMB status are not responsible for the Medicare cost sharing associated with covered Medicare Part A or B services, including for any APCM services. Generally, States cover such cost sharing on behalf of QMBs, although many States use a ''lesser-of'' policy through which States pay less than the full cost sharing amounts.[59] We solicited comments from States on how they would cover cost sharing for the proposed APCM bundle, considering lesser-of policies.

We also sought feedback on the use of QMB status and multiple (two or more) chronic conditions as the basis to bill for APCM Level 3 (G0558), whether QMB status is an appropriate indicator to identify beneficiaries with added social risk, and whether there is an equivalent marker of social deprivation for use in commercial markets that might be a possible alternative identifier.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters appreciated our recognition of social risk as a factor in health outcomes and healthcare delivery and agreed that beneficiaries with higher social risk have higher healthcare needs but were concerned about our proposed use of QMB status as a proxy indicator for patients with added social risk. A few commenters stated that there is currently not a widely adopted or universal approach to social risk adjustment and asserted that research has not shown dual eligibility status to be sufficiently sensitive to capture all at-risk beneficiaries. Multiple commenters encouraged us to broaden the criteria to identify and address social risk for Level 3 and suggested that we use additional data sources, including for example residence in areas with high Area Deprivation Index scores, dual eligibility status, and presence of unmet SDOH needs, to identify social risk.

Several commenters recommended that the requirements for Level 3 APCM include beneficiaries with at least one chronic condition and one unmet SDOH need, regardless of their dual eligibility or QMB status. Another commenter urged us to adjust payments to practitioners caring for patients who experience not only greater medical complexity but also greater social-emotional complexity, asserting that it is critical that risk adjustment criteria account for health-related social needs (HRSNs), including economic stability, education, social and community life, one's neighborhood and access to high-quality health care.

A few commenters were concerned about practitioners' ability to determine a patient's QMB status and were concerned about additional operational burden. These commenters asserted that this will be a significant obstacle to billing G0558 and were concerned that many practices may have to bill G0557 if they cannot confirm a patient's QMB status. Several commenters recommended that we use more readily identifiable criteria, such as dual eligibility status. One commenter stated that we should determine what level of APCM a beneficiary qualifies for to reduce practitioner burden. A few commenters recommended that we make use of existing Z-codes for SDOH (Z55–65) as standard identifiers and make payment to practitioners when they ask their patients about their SDOH to determine their patients' eligibility for APCM Level 3.

Many other commenters supported the use of QMB status as an appropriate indicator to identify beneficiaries with added social risk and called it a ''good first approach'' for us and advanced primary care practices to stratify the risk of Medicare beneficiaries to whom they provide APCM services. One of these commenters suggested that future risk stratification should identify other people in need of more intensive APCM services, such as those with disabilities, those with serious mental and other chronic illnesses, or those with disproportionate use of potentially preventable acute care services. Other commenters encouraged us to review findings of methodologies tested in Innovation Center models, as well as to engage with payers and policymakers to align on a common framework that incorporates a broader understanding of social risk using validated data and methodologies, and then incorporate their learnings into the APCM framework.

[57] ASPE. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. December 2016. *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[58] World Health Organization. (2018). Health Impact Assessment (HIA): The determinants of health. *http://www.who.int/hia/evidence/doh/en/.*

[59] Under the ''lesser of'' policy, a State caps its payment of Medicare cost sharing at the Medicaid rate for a particular service. For example, if the Medicare rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment.

Response: We thank commenters for their feedback. We reiterate our view that QMB status is a good indicator for patients with higher SDOH needs. As described in the CY 2025 PFS proposed rule (89 FR 61596), we chose QMB status as the method to identify beneficiaries with SDOH factors who may require relatively greater resources from practitioners that furnish advanced primary care services due to the strong evidence associated with dual eligibility for Medicare and Medicaid with poorer outcomes in Medicare Value-Based Purchasing (VBP) programs, in addition to the fact that we have QMB status in our administrative data (in contrast to other SDOH data elements) as well as the lack of cost sharing for QMBs.[60] However, we acknowledge that there may be other ways to identify patients with higher SDOH needs, including for example residence in areas with high Area Deprivation Index scores, dual eligibility status, and presence of unmet SDOH needs, and we intend to consider possible additional or alternative methods through future rulemaking, as appropriate.

We also appreciate the concerns some commenters raised about practitioners' ability to use QMB status to determine patient eligibility for Level 3 APCM services. However, we continue to believe practitioners have access to this information when verifying a patient's Medicare eligibility. Because all Medicare providers and suppliers are prohibited from billing QMBs for Medicare cost sharing, we have established mechanisms in place to help practitioners identify QMB patients. The Medicare 270/271 HIPAA Eligibility Transaction System (HETS) became effective in November 2017. Through HETS, health care providers can determine QMB status for each patient prior to billing. We also include QMB information in the Medicare Remittance Advice (RA) for fee-for-service claims after claims processing. Practitioners should consider asking their third-party eligibility-verification vendors how their products reflect the QMB information in HETS. We also recognize that, in some larger practices or practices that are part of larger health systems, there may be administrative staff or billing departments that have access to this information. For practitioners who furnish services to QMBs, including those who plan to bill for Level 3 APCM services, it would be important to establish internal workflows to ensure proper identification of patients with QMB status. Additional information can be found at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1128.pdf*. Practitioners can also learn a patient's QMB status directly through State Medicaid agencies. While States may use different methods for verification, such as telephonic or electronic systems, the Medicaid eligibility verification systems will confirm whether an individual is covered as a QMB.

While we acknowledge the opportunities raised by several commenters to use additional data sources to identify patients with likely social risk, we believe that our proposal to use QMB status is evidence-based, operationally feasible, and sufficiently sensitive to capture at-risk beneficiaries that require additional resources. As such, are finalizing the use of QMB status as proposed. However, as health services research continues to evolve in identifying social risk, we will continue to explore possible additional or alternative methods to identify patients with social risk and modify coding and payment for APCM services through future rulemaking as appropriate.

Comment: Several commenters recommended that we adopt a higher intensity APCM code for seriously ill/high needs beneficiaries and value this code to account for the higher resource costs involved in delivering advanced primary care to patients with complex illness. These commenters asserted that an additional APCM code level would capture non-QMB patients with significant clinical complexity and healthcare needs who require intensive APCM services and resource utilization.

Response: We appreciate commenters' suggestion for potential ways to recognize that non-QMB beneficiaries who are seriously ill may have increased needs associated with medical complexity and therefore require more resources. As we stated in response to comments on the Level 1 and Level 2 APCM service levels, we believe that our proposed coding approach and the specific recognition of QMBs in one code level appropriately balances coding specificity with administrative simplicity. We will continue to engage with interested parties to assess the appropriate level of code stratification and will address any potential refinements through future rulemaking.

After consideration of public comments, we are finalizing our proposal to define Level 3 APCM services based on QMB status and two or more chronic conditions. We will continue to evaluate the appropriateness of the APCM service levels, coding structure, and recognition of social risk. We are finalizing as proposed the code descriptor for HCPCS code G0558: HCPCS code G0558 *(Advanced primary care management services for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

- *Consent*;

++ *Inform the patient of the availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.*

++ *Document in patient's medical record that consent was obtained.*

- *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*
- *Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*
- *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*
- *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours;*
- *Overall comprehensive care management;*

++ *Systematic needs assessment (medical and psychosocial).*

++ *System-based approaches to ensure receipt of preventive services.*

++ *Medication reconciliation, management and oversight of self-management.*

- *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be*

[60] ASPE. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. December 2016. *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver;

• *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.

++ Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.

• *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*

• *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

• *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*

• *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients;*

• *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*).

c. APCM Service Elements and Practice-Level Capabilities

All the elements within the scope of APCM services are included in the service descriptors for G0556, G0557, and G0558, listed in Table 26, and described in this section. We proposed in the CY 2025 PFS proposed rule that APCM services will include nearly the same scope of service elements and conditions we established for CCM and PCM services (including elements of 24/7 access and care continuity, care management and care plan, care coordination, management of care transitions, and enhanced communication). This is appropriate because care management is a key component of care delivery using an advanced primary care model. The phrasing in the code descriptors for APCM services generally tracks the code descriptors for CCM and PCM services, except for references to ''time spent'' or ''minutes'' of service.

We sought to ensure that the APCM codes will fully and appropriately capture the care management services and CTBS that are characteristic of the changes in medical practice toward advanced primary care, as demonstrated in select CMS Innovation Center models. As we do for CCM and PCM services, we proposed to require for APCM services that the practitioner provide an initiating visit and obtain beneficiary consent (see section II.G.2.c.(1) and II.G.2.c.(2) of this final rule). As described in more detail in this section, we proposed to incorporate as elements of APCM services ''Management of Care Transitions'' and ''Enhanced Communications Opportunities.'' For the ''Management of Care Transitions'' APCM service element, we proposed to specify timely follow-up during care transitions (see section II.G.2.c.(6) of this final rule). For the ''Enhanced Communications Opportunities'' APCM service element, we proposed to incorporate access to CTBS services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with the patient, as well as access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits) (see section II.G.2.c.(8) of this final rule).

We also proposed to specify for APCM services the practice-level characteristics and capabilities that are inherent to, and necessarily present when a practitioner is providing covered services using an advanced primary care delivery model. As described in more detail below, included in the service descriptors for G0556, G0557, and G0558, and listed in Table 26, are practice-level capabilities that reflect care delivery using an advanced primary care model and are focused around 24/7 access and continuity of care (see section II.G.2.c.(3) of this final rule), patient population-level management (see section II.G.2.c.(9) of this final rule), and performance measurement (see section II.G.2.c.(10) of this final rule). These practice capabilities are indicative of, and necessary to, care delivery using an advanced primary care model. Further, APCM services, as we proposed to define them, could not be fully performed in the absence of these practice capabilities; and, in such cases, APCM services should not be billed.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters agreed that the proposed elements and requirements reflect the services consistent with effective APCM and these standards are consistent with current CMS primary care models and demonstration projects. Several commenters supported aspects of the proposal that crossed multiple APCM service elements—for example, commenters expressed appreciation for the reference to caregivers in four of the proposed elements (24/7 access and continuity of care, patient-centered comprehensive care plan, management of care transitions, and enhanced communications opportunities). Some commenters suggested modifications, and several were concerned about the volume and burden of requirements.

Other commenters were concerned that, while most practices may be set up to deliver these services, certain primary care practices may find it challenging to meet some of the proposed service elements. Some commenters raised concerns that the practice-level capabilities will be difficult for small or independent practices (and in some cases, health centers) to meet and requested that that we modify certain practice-level capabilities and APCM levels to account for varying levels of practice infrastructure.

One commenter was particularly concerned about the inability of low resource safety net providers—settings in which lower income individuals and QMBs may receive their primary care, to meet these standards, which could

potentially exacerbate disparities in care and payment for patients at the highest risk. They asserted that without the ability to bill for APCM services, safety net clinics will continue to face underpayment for the important care they provide. The commenters stated that clinics that do not meet the requirements to bill for APCM services, but still deliver substantial care coordination, management, and advanced primary care services to chronically ill beneficiaries with social risk—often with limited resources to expand their capacity—are particularly vulnerable to underpayment. For these reasons, some commenters suggested that implementing tiered practice capability requirements could address the current ''all or nothing'' approach, where there are some practices that invest significant time and resources in infrastructure to provide chronic care management but fall short of the requirements to bill for APCM services, and then are ineligible for payment for their currently uncompensated services.

Response: We appreciate commenters' feedback about the proposed APCM service elements and practice-level requirements which are reflective of the services consistent with care management in advanced primary care. As we do for other care management services, we continue to recognize the involvement of caregivers in health care for some patients.

We also appreciate commenters' suggested modifications to certain service elements and practice-level capabilities, and we acknowledge several commenters' concerns about the volume and burden of requirements. We welcome information on these issues from interested parties and may consider revisions in future rulemaking.

We remain interested in the use of APCM services in settings such as small practices and in rural and underserved areas, and we are committed to identifying ways to increase access to primary care in underserved communications. We also encourage practitioners who may not meet all of the requirements to bill for APCM services to consider whether the care coordination and management services they are delivering would meet the requirements to bill for other care management services such as TCM, CCM, PCM, CHI, PIN, or certain CTBS. We will continue to identify and evaluate ways to encourage providers to make APCM services available to all their patients in order to support care improvement for underserved, high-risk beneficiaries.

We proposed that practitioners participating in the ACO REACH Model, the Making Care Primary model, and the Primary Care First model will satisfy the initiating visit, Patient Population-Level Management, and performance measurement APCM service elements and practice-level capabilities by virtue of their model participation. These CMS Innovation Center models promote advanced primary care delivery consistent with the proposed APCM service elements and practice-level capabilities described in Table 25. The models all utilize attribution methods that review the most recently available two years of Medicare claims to identify whether a model participant is responsible for a Medicare beneficiary's primary care, aligning with the initiating visit requirements for APCM services. Additionally, these three models include risk stratification and quality and cost performance metrics that are aligned or overlap with the ''Value in Primary Care'' Merit-based Incentive Payment System (MIPS) Value Pathway (MVP).[61] Around-the-clock access and continuity of care, Patient Population-Level Management, and performance measurement are indicative of, and necessary to, care delivery using an advanced primary care model. We also considered whether certain practitioners in other types of CMS Innovation Center models also satisfy the service elements and requirements and sought comments on this question.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A number of commenters requested that we deem all ACO or alternative payment model (APM) participants as satisfying all service elements and requirements to bill the APCM codes by nature of their participation in such a program. A few commenters questioned why practitioners in ACOs would need to bill the APCM codes given that the proposed service elements may overlap with ACO functions.

Response: We clarify that practitioners participating in the ACO REACH Model, the Making Care Primary model, and the Primary Care First model would satisfy the proposed initiating visit, patient population-level management, and performance measurement APCM service elements and practice-level capabilities by virtue of meeting requirements of their model participation, and that we are not waiving any of the APCM service elements or requirements for practitioners in these models or the Shared Savings Program.

The one proposed practice-level requirement for APCM services that is slightly different for these model participants and Shared Savings Program participants than for other practitioners is the performance measurement requirement. Because these models and the Shared Savings Program require their participating practitioners to report on quality and cost performance metrics that are aligned or overlap with the Value in Primary Care MVP, we proposed that requiring these practitioners to report the Value in Primary Care MVP for purposes of billing for APCM services would be substantially duplicative. Our proposal would require all other APCM service elements and practice-level capabilities to be met and maintained in order for the model participants to bill for APCM services. We simply noted that, for practitioners participating in the ACO REACH Model, the Making Care Primary model, or the Primary Care First model, many of the APCM service elements and practice-level requirements would be met by meeting model participation requirements. Similarly, practitioners participating in other APMs may, by meeting requirements of their participation in the APM, meet some or all of the APCM service elements and practice-level requirements; however, not all APMs require reporting on quality and cost measures that align or overlap with the Value in Primary Care MVP.

[61] See, for example, ACO Realizing Equity, Access, and Community Health (REACH) Model Request for Applications. Available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa,* ACO Realizing Equity, Access, and Community Health (REACH) Model PY 2024 Quality Measurement Methodology. Available at *https://www.cms.gov/files/document/aco-reach-quality-msr-meth-py24.pdf;* Making Care Primary Payment and Attribution Methodologies. Available at *https://www.cms.gov/files/document/mcp-pymt-att-methodologies.pdf,* Primary Care First Payment and Attribution Methodologies PY 2024. Available at *https://www.cms.gov/files/document/pcf-py24-payment-meth.pdf.*

TABLE 25: APCM Service Elements* and Practice-Level Capabilities

Consent • Inform the patient of the availability of APCM services; that only one practitioner can furnish and be paid for these services during a calendar month; of the right to stop services at any time (effective at the end of the calendar month); and that cost sharing may apply* (may be covered by supplemental health coverage) • Document in patient's medical record that consent was obtained
Initiating Visit for New Patients (separately paid) • Initiation during a qualifying visit for new patients • An initiating visit is not needed: (1) if the beneficiary is not a new patient (has been seen by the practitioner or another practitioner in the same practice within the past three years) or (2) if the beneficiary received another care management service (APCM, CCM, or PCM) within the previous year with the practitioner or another practitioner in the same practice.
24/7 Access to Care and Care Continuity • Provide 24/7 access for urgent needs to care team/practitioner, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week. In the event of afterhours communication with a beneficiary, whoever is responsive to the patient's concerns must document and communicate their interaction with the beneficiary to the primary care team/practitioner. • Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments • Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits and/or expanded hours, as appropriate
Comprehensive Care Management • Overall comprehensive care management may include, as applicable • Systematic needs assessment (medical and psychosocial) • System-based approaches to ensure receipt of preventive services • Medication reconciliation, management and oversight of self-management
Patient-Centered Comprehensive Care Plan • Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan which is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver
Management of Care Transitions (for example, discharges, ED visit follow-up, referrals, as applicable) • Coordination of care transitions between and among health care providers and settings, including transitions involving referrals to other clinicians, follow-up after an emergency department visit, or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities, as applicable • Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care. • Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after ED visits and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated

Practitioner, Home-, and Community-Based Care Coordination • Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), as applicable, and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors in the patient's medical record
Enhanced Communication Opportunities • Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate • Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits)
Patient Population-Level Management • Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate • Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients • A practitioners who is participating in a Shared Savings Program ACO, REACH ACO, Making Care Primary, or Primary Care First satisfies this requirement
Performance Measurement Be assessed on primary care quality, total cost of care, and meaningful use of CEHRT, which can be met in several ways: • For practitioners who are MIPS eligible clinicians, by registering for and reporting the Value in Primary Care MVP** • A practitioner who is part of a TIN participating in a Shared Savings Program ACO satisfies this requirement through the ACO's reporting of the APM Performance Pathway*** • A practitioner who is participating in a REACH ACO, a Making Care Primary, or a Primary Care First practice satisfies this requirement by virtual of meeting requirements under the CMS Innovation Center ACO REACH, Making Primary Care Primary, or Primary Care First models.

* Medicare beneficiaries who are enrolled in the QMB eligibility group do not have any Medicare cost sharing responsibility for copays, deductibles, and coinsurance.

** See discussion in section II.G.2.c.(10) of the CY 2025 PFS proposed rule for a description of the timeline of MIPS reporting, and information for eligible clinicians who are not MIPS eligible or QPs. MIPS eligible clinicians who furnish APCM services in 2025 who intend to report on for the CY performance year/2027 MIPS payment year must register to report the Value in Primary Care MVP as described under § 414.1365(b). For more details, see the 2024 MIPS Quick Start Guide, available at *https://qpp.cms.gov/mips/reporting-options-overview*.

*** See requirement in section III.G. of the CY 2025 PFS final rule for practitioners in Shared Savings Program ACOs to report the APP Plus quality measure set.

We sought comment on whether the proposed service elements and practice-level requirements are appropriately reflective of care management services for advanced primary care, and whether there are elements of APCM services or practice capabilities that should be modified or removed.

We also sought feedback on ways to align the APCM services with other Medicare programs and initiatives, such as the Shared Savings Program, the ACO REACH Model, and advanced primary care models, and the Quality Payment Program, including MIPS and Advanced Alternative Payment Models (Advanced APMs). We sought to create a low burden way for practitioners to furnish APCM services by appropriately recognizing ways in which they may meet APCM billing requirements as part of these programs and initiatives. We noted that under the Quality Payment Program, practitioners who are MIPS eligible clinicians will report measures and activities as specified by us under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. To report to MIPS for a performance period (§ 414.1320(i)) for the Promoting Interoperability performance category, a MIPS eligible clinician must use Certified EHR Technology (CEHRT), as defined at paragraph (2) under CEHRT at § 414.1305, report on the objectives and associated measures as specified by us and submit required attestations as specified in § 414.1375(b)(3). Eligible clinicians who participate in Advanced APMs under the Quality Payment Program are required under the terms of those APMs to use CEHRT as specified in § 414.1415(a)(1)(iii); and are paid under the terms of those APMs based on MIPS-comparable quality measures as specified in § 414.1415(b).

As described as part of this final rule, we proposed that a billing practitioner who is part of a Shared Saving Program ACO, or CMS Innovation Center ACO or participating in Making Care Primary or Primary Care First will already satisfy the APCM practice-level requirements for Patient Population-Level Management (see section II.G.2.c.(9) of this final rule), and performance measurement (see section II.G.2.c.(10) of this final rule) by meeting separately applicable participation requirements within the Shared Savings Program and these APMs. As noted previously, we considered whether practitioners in

other types of CMS Innovation Center models might also satisfy certain APCM service elements and practice-level requirements through their participation in the models and sought comments on this question. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments recognizing our desire to minimize duplicative reporting and the associated burdens, but no specific suggestions to achieve this goal. Commenters did not directly address the ways in which we may better align with other programs and initiatives. Finally, commenters sought confirmation that practices participating in either a Shared Savings Program ACO or Innovation Center model will satisfy the performance measurement requirements.

Response: We thank commenters for their feedback and the request for clarification. As described in the CY 2025 proposed rule and in this final rule, we considered the burden associated with potentially duplicative reporting requirements. Practitioners in practices participating in a Shared Savings Program ACO or in certain Innovation Center models (ACO REACH, Making Care Primary, Primary Care First) will satisfy the performance measurement element of the APCM services by meeting their respective program and model requirements.

(1) Beneficiary Consent

Consistent with other care management services, we proposed in the CY 2025 PFS proposed rule that the beneficiary's consent to receive APCM services must be documented in the medical record as a condition of payment for APCM services, as not all Medicare beneficiaries for whom APCM services would be medically necessary may want to receive these services. As we do for CCM and PCM services, we proposed to require billing practitioners to inform the beneficiary of the availability of APCM services, and ensure the beneficiary is aware that Medicare cost sharing usually applies (though these costs may be covered through supplemental health coverage). The practitioner should also inform the beneficiary that, by providing APCM services, they intend to assume responsibility for all of the patient's primary care services and serve as the continuing focal point for all needed health care services; and that only one practitioner can furnish and be paid for APCM services during a calendar month, but that their consent to receive APCM services does not limit their option to receive Medicare covered health care services from other practitioners. The practitioner should inform the beneficiary that APCM is an ongoing, monthly service and of their right to stop APCM services at any time (effective at the end of the calendar month), and that they only need to provide consent once to receive APCM services from the practitioner. We proposed that the practitioner would document in the beneficiary's medical record that this information was explained and note whether the beneficiary accepted or declined APCM services. We noted that practitioners can still elect to obtain written consent rather than verbal consent.

Practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of similar care management services, such as CCM services. The patient consent requirement is intended to ensure that patients do not incur unexpected expenses for care that is largely, or in significant part, non-face-to-face in nature. The requirement for patient consent would also help to avoid duplicative practitioner billing, as the patient would understand that the practitioner intends to serve as the focal point for all their care, and that only one practitioner can furnish and be paid for APCM services in any particular month.

We sought feedback on these requirements, including how best to effectively educate both practitioners and beneficiaries on the benefits of APCM, especially as it reflects a new bundle of services that may have previously been separately billed, and whether it would be helpful if we provided a template to facilitate patient consent.

We also sought feedback on whether we should require practitioners to revisit consent for APCM services on an ongoing basis with patients.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters were generally supportive of our proposal to require consent. Many commenters felt that consent is important for beneficiaries so they understand that cost sharing may apply for these services on an ongoing basis. Several commenters requested clarification on the frequency in which consent should be obtained, and some commenters stated it should be obtained no more than once a year. One commenter sought clarification if patients with an existing consent for CCM would require a new consent for APCM. Commenters disagreed on how consent should be obtained, with some requesting written consent to be required, while others requested verbal consent to be allowed, citing administrative burden of obtaining written documents. Another commenter requested that we create a standardized consent form to be used for APCM services. Others criticized consent requirements as an administrative burden and stated that this burden is a substantial barrier to uptake of current CCM and PCM codes.

Response: We thank commenters for their feedback. We appreciate commenters' feedback about the potential operational difficulty of obtaining and documenting consent. However, as discussed in the CY 2014 PFS final rule (78 FR 74424), we continue to believe that consent is important to ensure beneficiaries understand their potential cost sharing responsibilities, especially for non-face-to-face services. We also encourage practitioners and practices to view the consent process as an opportunity to educate the beneficiary about the new coding Medicare has created for APCM services and discuss the service elements and capabilities that make a practice qualified to perform these services. This is also an opportunity to ensure that the beneficiary is not receiving APCM services elsewhere, and as discussed in greater detail later in this final rule, to ensure that the beneficiary acknowledges and understands that this practitioner will serve as the focal point of all primary care services until the beneficiary is no longer receiving this type of care with this practitioner or practice. For these reasons, we do not believe that a patient's previous consent for CCM would be sufficient for purposes of the new APCM services, and a beneficiary transitioning from CCM to APCM would require a new consent.

After consideration of public comments, we are finalizing as proposed that patient consent needs to be obtained at initiation of APCM services and documented in the medical record. Written consent is not necessary; however, practitioners may obtain written consent if they wish. We are also clarifying that the patient consent must be obtained to receive APCM services from the billing practitioner—which would be the practitioner who intends to be responsible for all primary care services and serve as the continuing focal point for all needed health care services. A new consent to receive APCM services is required if there is a change in the practitioner who furnishes and bills for the APCM services, which is in line with consent

requirements for other care management services.

(2) Initiating Visit

Consistent with CCM services (CPT codes 99437, 99439, 99487, and 99489—99491) and PCM services (CPT codes 99424—99427), we proposed in the CY 2025 PFS proposed rule to require an initiating visit for APCM services only for new patients instead of for all beneficiaries receiving APCM services. Consistent with the definition of ''new patient'' as described in the CPT® 2024 Professional Edition Code Book on page 4, we proposed to define a ''new patient'' as a person who did not receive any professional services from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years.[62] The initiating visit furnished in advance of APCM services establishes the beneficiary's relationship with the billing practitioner, ensures the billing practitioner assesses the beneficiary prior to initiating APCM services, facilitates collection of comprehensive health information to inform the care plan, and provides an opportunity to obtain beneficiary consent (although beneficiary consent can be obtained outside of the initiating visit). We proposed that the same services that can serve as the initiating visit for CCM services could serve as the initiating visit for APCM, including a Level 2 through 5 E/M visit, initial preventive physician exam (IPPE), or TCM service, and we proposed that the initiating visit could be provided in person or as a Medicare telehealth service.

We proposed that an initiating visit would not be required for ''established patients'' based on certain circumstances that demonstrate an established patient-practitioner relationship in advance of furnishing APCM services: (1) if the beneficiary is not a new patient (has been seen by the practitioner or another practitioner in the same practice within the past three years) or (2) if the beneficiary received another care management service (including an APCM service, non-complex or complex CCM service (CPT codes 99487, 99489, 99490, 99491, 99439, 99437), or PCM service (CPT codes 99424, 99425, 99426, 99427)) within the previous year with the practitioner or another practitioner in the same practice. For patients with whom the practitioner (or another in the same practice) has an established relationship, there is not necessarily a need for an initiating visit for APCM services; and we would not want to require an initiating visit under circumstances where a visit may not be medically necessary. The policy not to require an initiating visit for beneficiaries who have received any professional service from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years is consistent with CPT's definition of the term ''established patient,'' such that this captures patients who have been seen relatively recently and who have an existing relationship with the practice. In the case of beneficiaries who have received care management services from a practitioner within the practice in the past year, this indicates that the patient is also an ''established patient'' in that the patient has an existing relationship with the practice, and the patient previously has consented to the receipt of care management services, which have overlapping service elements with APCM services.

We noted that these standards would be consistent with applicable Shared Savings Program and CMS Innovation Center patient attribution standards in the ACO REACH Model, Making Care Primary, and Primary Care First. Any beneficiary eligible to be assigned to an ACO because of an established care relationship between the beneficiary and a billing practitioner who will be billing for APCM services under the ACO participant's TIN, including beneficiaries who voluntarily aligned to a practitioner in the ACO, would not be considered a new patient and would not require an initiating visit. Medicare rules governing patient attribution to an ACO on the basis of care provided by an ACO-participating clinician similarly establish where an existing care relationship exists. Similarly, beneficiaries eligible to be assigned to a REACH ACO, or a Making Care Primary or Primary Care First practice because of an established care relationship between the beneficiary and a billing practitioner who will be billing for APCM services under the model participant's TIN, including beneficiaries who voluntarily aligned to a practitioner participating in one of these three models would not be considered a new patient and would not require an initiating visit. While we proposed certain exceptions to the initiating visit requirement for APCM services, we noted that an initiating visit may still be needed even when not required, and the billing practitioner can always furnish and bill for medically necessary visits, including before initiating APCM services.

We sought feedback on these requirements, including whether additional services could serve as the initiating visit and whether a different period of time (for example, patients not seen within one or 2 years) would be more appropriate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly in favor of our proposals not to require initiating visits for established patients, and commenters agreed with the definitions proposed for established patients. Commenters were also supportive of our proposal to include Medicare telehealth visits or in-person visits as initiating visits. One commenter suggested that including other specialist visits would expedite patients into APCM. A few other commenters agreed with our inclusion of the IPPE and stated that we should also include the Medicare Annual Wellness Visit (AWV). We did not receive any comments about the proposed inclusion of ACO and CMMI model participants as established patients.

Response: We agree that initiating APCM services expeditiously is important, but we disagree that an initiating visit could be provided by a different practitioner than the practitioner furnishing APCM. APCM coding describes services furnished by the specific practitioner who is serving as the focal point of all health care for a patient, and we continue to believe that the practitioner furnishing the initiating visit should be the practitioner who will be furnishing the APCM services. We thank the commenters for noticing that we did not include the AWV in our proposal. This was an oversight, and we agree that the AWV could serve as an initiating visit, so long as the practitioner furnishing the AWV is a physician or other qualified health professional such as a nurse practitioner, physician assistant, clinical nurse specialist, or certified nurse midwife, as discussed earlier in this final rule, and will be the same practitioner who will furnish the APCM services.

After consideration of public comments, we are finalizing as proposed that an initiating visit is required before a new patient receives APCM services. We are finalizing our definition of a ''new patient'' for this purpose as described in the CPT® 2024 Professional Edition Code Book on page 4, as a person who did not receive any

[62] American Medical Association. CPT Professional 2024. American Medical Association, 2023.

professional services from the physician or other qualified health care professional or another practitioner in the same group practice within the previous 3 years.[63] We are also finalizing that an initiating visit is not required for established patients. We are finalizing our definition of an ''established patient'' as (1) a beneficiary who has been seen by the practitioner or another practitioner in the same practice within the past three years or (2) a beneficiary who has received another care management service (including an APCM service, non-complex or complex CCM service (CPT codes 99487, 99489, 99490, 99491, 99439, 99437), or PCM service (CPT codes 99424, 99425, 99426, 99427)) within the previous year from the practitioner or another practitioner in the same practice. We are also finalizing that beneficiaries who are eligible to be assigned to an ACO because of an established care relationship between the beneficiary and the billing practitioner who will bill for APCM services and beneficiaries assigned to a REACH ACO, or a Making Care Primary or Primary Care First practice because of a similarly established care relationship are considered established patients.

We are finalizing a modification to our proposal to specify that, in addition to the initiating visit services we identified in the proposed rule, the Medicare AWV can serve as an initiating visit, so long as it is furnished by the practitioner who will furnish the APCM services.

(3) 24/7 Access and Continuity of Care

Access and continuity build on the patient-practitioner relationship to ensure patients receive the right care at the right time from the right care team member. We proposed in the CY 2025 PFS proposed rule to include for APCM services the same scope of service elements we established for CCM and PCM services for 24/7 Access and Continuity of Care with some modifications. For 24/7 Access to Care, the scope of the service element we proposed for APCM services would be to provide 24/7 access for urgent needs to the care team/practitioner with real-time access to patient's medical records, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week.

As described in the CY 2017 PFS final rule, this accurately reflects the potential role of clinical staff or call-sharing services in addressing after-hours care needs, and that after-hours services typically would and should address any urgent needs and not only those explicitly related to the beneficiary's chronic conditions (79 FR 67722). In advanced primary care models of care, primary care practices should be at the center of that care—providing an effective ''first contact'' for patients, supporting patients in their management of care, and coordinating across different settings of care. Achieving this level of access to primary care requires timeliness and an effective relationship with those in the practice who are providing that care. True access is fully informed by knowledge about the patient and their care, which is only possible through real-time access to the patient's electronic health information. Access to primary care, informed by health information technology (IT), makes the right care at the right time possible, potentially avoiding costly urgent and emergent care. Practices can achieve 24/7 access to care informed by health IT through call coverage by a practitioner with health IT system access. This can be a practitioner from the practice or a covering practitioner who has system access. Many practices and systems use nurse call lines or answering services working with standard protocols to provide the initial point of contact after hours and effectively address common problems. In this situation, an escalation protocol will engage a practitioner with system access when needed for decision making. Other successful practices expand hours, add urgent care services or partner with other practices to provide these services, or contract with existing urgent care providers to manage and coordinate care after regular office hours.

For Continuity of Care, the scope of service element would be to provide continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments. Continuity of care refers to the ability of patients to receive care from practitioners who know them and are known by them. This continuity builds and reinforces a relationship based in trust and shared experience that is highly valued by both practitioners and patients. Practice focus on continuity of care can translate to improved preventive and chronic care, patient and practitioner satisfaction, lower hospital utilization, and lower costs.[64] Depending on the type and setting of care, there are three components of continuity that improve patient outcomes and experience:[65] relational continuity (defined as the ''ongoing therapeutic relationship between a patient (and often their family/caregiver)'' which is foundational in advanced primary care), informational continuity (where practitioners have access to information on patients' past events and personal circumstances to inform current care decisions); and longitudinal continuity (which refers to ongoing patterns of healthcare visits that occur with the same practice over time). A key strategy to optimize continuity is ensuring that all practitioners and/or the care team have access to the same patient information to guide care within health IT, and successful practices start with a review and discussion of the practice-level data developed through measurement of continuity.[66] Practices can develop the capability to measure continuity of care between the patient and the practitioner/care team using health IT, practice management software, or other tracking mechanisms, allowing them to track improvements over time.

As included in the APCM code descriptors, we proposed to specify for the ''24/7 Access to Care'' APCM service element that the practice would maintain the capability to deliver care in alternative ways to traditional office

[63] American Medical Association. CPT Professional 2024. American Medical Association, 2023.

[64] Hussey, P.S., Schneider, E.C., Rudin, R.S., Fox, D.S., Lai, J., & Pollack, C.E. (2014). Continuity and the costs of care for chronic disease. JAMA Internal Medicine, 174(5), 742–748.; Bayliss, E.A., Ellis, J.L., Shoup, J.A., Zeng, C., McQuillan, D.B., & Steiner, J.F. (2015). Effect of continuity of care on hospital utilization for seniors with multiple medical conditions in an integrated health care system. The Annals of Family Medicine, 13(2), 123–129.; Nyweide, D.J., Anthony, D.L., Bynum, J.P., Strawderman, R.L., Weeks, W.B., Casalino, L.P., & Fisher E.S. (2013). Continuity of care and the risk of preventable hospitalization in older adults. JAMA Internal Medicine, 173(20), 1879–1885.; Haggerty, J.L., Reid, R.J., Freeman, G.K., Starfield, B.H., & Adair, C.E. (2003). Continuity of care: a multidisciplinary review. BMJ, 327, 1219. *doi:10.1136/bmj.327.7425.1219;* Gupta, R., & Bodenheimer, T. (2013). How primary care practices can improve continuity of care. JAMA Internal Medicine, 173(20), 1885–1886. doi:10.1001/jamainternmed.2013.7341.; Willard R., & Bodenheimer T. (2012, April). The building blocks of high-performing primary care: Lessons from the field. California Healthcare Foundation. *http://www.chcf.org/publications/2012/04/building-blocks-primary-care.*

[65] Haggerty, J.L., Reid, R.J., Freeman, G.K., Starfield, B.H., & Adair, C.E. (2003). Continuity of care: a multidisciplinary review. *BMJ, 327,* 1219. *doi:10.1136/bmj.327.7425.1219.*

[66] Gupta, R., & Bodenheimer, T. (2013). How primary care practices can improve continuity of care. *JAMA Internal Medicine, 173*(20), 1885–1886. doi:10.1001/jamainternmed.2013.7341.; Willard R., & Bodenheimer T. (2012, April). *The building blocks of high-performing primary care: Lessons from the field.* California Healthcare Foundation. *http://www.chcf.org/publications/2012/04/building-blocks-primary-care.*

visits to best meet the patient population's needs, such as e-visits, phone visits, home visits, and/or expanded hours. This standard for alternatives to office visits is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices regularly offer at least one alternative to traditional office visits [67]) and reflects the understanding that providing alternatives to traditional office visits is an essential element of the delivery of care under an advanced primary care model of care. Moving care out of traditional office visits can reduce demand and open supply for prioritized visits. By changing where and how care is delivered, practices may have increased availability for patients with complex needs who may be better served by more time-intensive visits in the office, at home, or in a nursing home. We did not propose that a practice will need to regularly deliver care in all these alternative ways—for example, a practice may routinely offer e-visits and phone visits, but not regularly furnish home visits, and still demonstrate this primary care practice capability. Another practice might offer extended hours on certain days to help patients who may find it hard to take off work to see their clinician, and this would satisfy this practice requirement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our 24/7 access to care requirement for APCM services. One commenter stated that most practices currently have this capability, reflected by the fact that physicians with hospital privileges generally must demonstrate they have continuous coverage for urgent patient needs. Several commenters requested clarification on the 24/7 access to care requirement for APCM services. A few commenters stated that providing 24/7 access to care is very difficult due to physician shortage and burnout, as well as certain practice arrangements that may limit real-time access to the patient's electronic health information—for example, practices that rely on a third party to provide after-hours call coverage. One commenter urged us to support improvements in data-sharing infrastructures, such as health information exchanges, which may help alleviate some of these barriers.

[67] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

Another commenter suggested that we should modify the requirement for 24/7 availability. This commenter stated that depending on the hour of the day, a reasonable amount of time should be allotted to respond to patients, such as overnight when the practitioner should have time to review the patient's charts before speaking to them. If this is not possible, then a previously agreed-upon alternate should be allowed to respond to the patient. Another commenter raised concerns about small and independent practices in under-resourced settings that might not be able to guarantee 24/7 access.

Commenters generally supported our continuity of care requirement for APCM services and acknowledged the alignment of this requirement with our proposal that APCM services are to be billed only by the practitioner who intends to be the focal point for all needed health care for the patient. One commenter was concerned about the lack of a measure of continuity for accountability or evaluation as it relates to the performance measurement requirement for APCM services and recommended that we assess continuity as a measured outcome. This commenter asserted that, with continuity, patient health outcomes are improved across a wide range of chronic disease areas, including diabetes, asthma, cancer, and dementia. Several commenters requested clarification on the alternative visit requirement for APCM services, including one commenter who asked whether the practitioner/care team is required to offer home visits to bill for APCM services.

Response: We emphasize that our intent with this proposal was to ensure that practices have flexibility in how they satisfy the requirements, including how they ensure 24/7 access for urgent patient needs. While we continue to believe that real-time access to patient medical records is best for addressing after-hours care needs, we understand this may not always be feasible, especially for smaller practices that may rely on third parties for after-hours coverage. Furthermore, we would like to reiterate that we did not propose to require that a practice would need to regularly deliver care in all of the alternative ways we mentioned, but instead that the practice would provide care by some alternative means to traditional office visits as appropriate to best meet their patient population's needs, including but not limited to e-visits, phone visits, home visits, and/or expanded in-person patient care hours.

Comment: Several commenters requested clarification on how to document that a practice meets the 24/7 access to care requirement if a patient receiving APCM services does not use after-hours care in a given month, and asked if they would need to document in each patient's medical record that the practice has 24/7 access to care.

Response: We do not expect that the practice level requirements like 24/7 access to care would be documented in each patient's medical records for each month for which APCM services are furnished, but we would expect that if the patient had an interaction with a care team member after hours, this would be documented in the patient's medical record. By billing for APCM services, the practice is attesting that it meets the requirements included in the code descriptor.

After consideration of public comments, we are finalizing the 24/7 access and continuity of care requirement as proposed, but with clarification that 24/7 access for urgent needs means reasonable after-hours care, when necessary, and with a modification that there need not be real-time 24/7 access to the patient's medical record. Instead, we will require that the after-hours responder must document and communicate their interaction with the patient to the primary care team/practitioner, and that interaction must be documented in the patient's medical record. We are modifying the 24/7 access to care requirement because we understand that real-time access to patient medical records may not always be feasible, especially for smaller practices that may rely on third parties for after-hours coverage. We would like to reiterate that real-time access to the patient's medical record is a key component of advanced primary care, and we may revisit this issue in future rulemaking.

(4) Comprehensive Care Management

We proposed in the CY 2025 PFS proposed rule to adopt for APCM services the ''Comprehensive Care Management'' service element we established for CCM and PCM services with some modifications. Rather than ''care management for chronic conditions,'' the APCM service element would be ''overall comprehensive care management'' which, like the element for CCM and PCM services, may include, as applicable, ''systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of

medications.'' This care management standard is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices provide targeted, proactive, relationship-based care management to all patients identified as at increased risk and likely to benefit from intensive care management and provide short-term care management, including medication reconciliation, to patients following hospital admission/discharge/transfer, including observation stays, and, as appropriate, following an ED discharge)[68] and is an essential element of the delivery of care under an advanced primary care model of care. Care management is a resource-intensive process of working with patients, generally outside of face-to-face office visits, to help them understand and manage their health, navigate the health system, and meet their health goals. Practices working with patients who have complex care needs have found care management to be an effective and necessary strategy for mitigating risk and improving health outcomes. Practices have found it valuable to think in terms of two broad types of patients who might benefit from different approaches to care management: patients with some combination of multiple comorbidities, complex treatment regimens, frailty and functional impairment, behavioral and social risks, and serious mental illness who would often benefit from long-term, proactive, and relationship-based longitudinal care management; and patients who are otherwise stable and will benefit from short-term, goal-oriented episodic care management during periods of increased risk like transitions of care; diagnosis of a new, serious illness or injury involving complex treatment regimens; or newly unstable chronic illness.

Successful practices use on-site, non-physician, practice-based, or integrated shared care managers to provide longitudinal care management for the highest risk cohort of patients, with assistance from other practice staff, as needed. Multiple team members may engage in care management, but each patient identified as eligible should have a clinically trained individual in the practice who is accountable for active, ongoing care management that goes beyond office-based clinical diagnosis and treatment.[69] Longitudinal care management is captured in health IT and includes providing proactive care that moves beyond traditional office visits or crisis-driven care (for example, ED care or hospitalization) and is not primarily visit-based. Although office visits are opportunities to define goals, plan patient care, engage in shared decision making, and build a trusting relationship, most care management activities take place by phone, patient portal, email, mail, or home visits (and through visits to skilled nursing facilities or hospitals to support transitional care).

Practices use the concept of episodic care management to identify patients who have acute or urgent needs using ''triggering events'' (for example, hospital discharge, new diagnoses, medical crisis, major life event, decompensation in otherwise controlled chronic condition) for short-term, problem-focused care management services. Episodic care management is generally time-limited and problem focused and most often includes coordination of services and follow-up, patient education and support for self-management, and medication reconciliation.

We sought feedback on these requirements.

Comment: We received a few comments on this proposal, which were overwhelmingly supportive. In particular, several commenters expressed appreciation for our efforts to recognize that practices furnish comprehensive care management by acknowledging the team-based aspect of APCM which may help a patient navigate their complex health conditions.

Response: We thank the commenters for their support and are finalizing the comprehensive care management service element as proposed.

(5) Patient-Centered Comprehensive Care Plan

We proposed in the CY 2025 PFS proposed rule to adopt for APCM services the ''Comprehensive Electronic Care Plan'' service element we established for CCM and PCM services with some modifications. As included in the APCM code descriptors, we proposed to specify that the care plan is ''patient-centered'' which, as for CCM and PCM services, ''is available timely within and outside the billing practice'' as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and ''copy of care plan to patient/caregiver.''

Providing longitudinal care management, which is an essential element of the delivery of care under an advanced primary care model of care, includes the process of personalized care planning. The personalized care planning process helps practices engage and collaborate with patients to ensure that their care aligns with patient preferences, goals, and values.[70] A care plan is a mutually agreed-upon document that outlines the patient's health goals, needs, and self-management activities and is accessible to all team members providing care for the patient. The care plan should be patient-friendly, accessible to the patient, and should limit use of unfamiliar medical jargon and acronyms. The care plan should also be structured and standardized, documented in health IT to enable sharing among patient, caregivers, and care team members. All high-risk patients receiving longitudinal care management should have a personalized care plan developed in a joint, open-ended conversation between the patient and care team. Personalized care planning is a dynamic process; therefore, the care plan document should be updated at when applicable by the care team and patient. In addition, when patients' health status, preferences, goals, and values change, their plans of care should, too.

As described in the CY 2020 final rule, we proposed language to describe the ''typical'' care plan elements which do not comprise a set of strict requirements that must be included in a care plan for purpose of billing but are intended to reflect those that are typically included in a care plan as medically appropriate for a particular beneficiary. The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements: problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; interaction and coordination with outside resources and practitioners and providers; requirements for periodic

[68] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

[69] Taylor, E. F., Machta, R. M., Meyers, D. S., Genevro, J., & Peikes, D. N. (2013). Enhancing the primary care team to provide redesigned care: The roles of practice facilitators and care managers. *Annals of Family Medicine, 11*(1), 80–83. *doi:10.1370/afm.1462.*

[70] Coulter A., Entwistle, V. A., Eccles, A., Ryan, S., Shepperd, S., & Perera, R. (2015). Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database System Review, 3,* CD010523.; Edwards, S. T., Dorr, D. A., & Landon, B. E. (2017). Can personalized care planning improve primary care? *JAMA, 318*(1), 25–26.

review; and when applicable, revision of the care plan (84 FR 62691).

We sought feedback on these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposed patient-centered comprehensive care plan requirement for APCM services. Several commenters requested clarification on the care plan requirement, including whether existing CCM care plans meet the service requirements and what our expectations are regarding updating the care plan at ''regularly defined intervals.'' One commenter also asked us to clarify whether a member of the care team could initiate the care plan if they sent it to the primary practitioner to edit and approve. One commenter requested that we embed into the care plan the same requirements for cultural and linguistic factors that we proposed in the practitioner, home-, and community-based care coordination requirement for APCM services. Another commenter requested that we create an additional code for updating the care plan (in addition to HCPCS G0506, *Comprehensive assessment and care plan for patients with chronic conditions*), with a limit on billing it three times per year. One commenter encouraged us to work with other agencies, stakeholders, and physicians to establish clear, minimum requirements for EHR vendors that improve the process to create, share, reconcile, and integrate multiple plans of care into a comprehensive care plan. Other commenters agreed that all the required care elements in the plans are necessary elements for care and should be included in any final policy.

Response: We thank the commenters for their feedback. We are clarifying that a member of the care team could draft the care plan, as appropriate, and send to the practitioner for review and approval. We appreciate the recommendation that cultural and linguistic factors be included as a care plan requirement and remind commenters that the typical care plan elements which are based on the those finalized in the CY 2020 PFS final rule (84 FR 62691), are not limited to that list. In the instance it is beneficial to the patient to include cultural and linguistic factors in the care plan, the practitioner should be empowered to add them. We intended that our definition of ''regularly defined intervals'' match similar requirements for other care management services, and thus are clarifying that the care plan should be updated ''when applicable'' to match current requirements for CCM. While it may be preferable, when feasible, to update the care plan on an annual basis or more frequently, if there are relevant clinical changes within that time, we believe that the need and frequency for care plan revision should be considered as medically appropriate for a particular beneficiary. We emphasize that our intent is to ensure that practitioners have flexibility in how they can satisfy the care plan requirement, and we do not wish to impose additional administrative burden.

Comment: Some commenters stated that a ''comprehensive care plan'' is not needed when a practitioner is engaged in Level 1 APCM services for a beneficiary with only one or no chronic conditions, and instead suggested that the care plan requirement would be satisfied if the practitioner maintains an up-to-date problem and medication list for the patient, including the status of preventive services. A few commenters recommended that care plans developed as part of the AWV should satisfy the care plan requirement for APCM services. One commenter was concerned about specific elements of the care plan that might be too subjective—for example, expected outcome and prognosis.

Response: We emphasize that our intent is to ensure that practitioners have flexibility in how they satisfy the care plan requirement, including who drafts the care plan, what elements are included, and as mentioned above, at what frequency they are updated. We are sympathetic to commenters' concerns about this element, especially in terms of current clinical practice and medical necessity for less complex beneficiaries. While we are not requiring a specific format for the care plan and, as described above, we provide a series of typical care plan elements; we would like to emphasize that the need for specific care plan elements should be considered as medically appropriate for a particular beneficiary, which we also believe speaks to the commenters' questions about the care plan for a level 1 beneficiary. We also agree with commenters that care plans developed as part of the AWV by the same practitioner who furnishes APCM services may be used to satisfy this requirement, as appropriate considering the particular patient's clinical circumstances.

After consideration of public comments, we are finalizing the patient-centered comprehensive care plan service element for APCM services as proposed.

(6) Management of Care Transitions

We proposed in the CY 2025 PFS proposed rule to adopt for APCM services the ''Management of Care Transitions'' service element we established for CCM and PCM services with some modifications. Rather than requiring that the practice must facilitate communication of relevant patient information through electronic exchange of continuity of care documents with other health care providers regarding these transitions, we proposed more simply to require the billing practitioner to ''ensure timely exchange of electronic health information'' with other practitioners and providers. As included in the APCM code descriptors, we also proposed to specify for the ''Management of Care Transitions'' APCM service element that the care team/practitioner will follow up with the patient and/or caregiver within 7 days after each ED visit and hospital discharge. This timely follow-up standard is similar to several requirements tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices ensure patients with ED visits received a follow-up interaction within one week of discharge [71] and the MCP model's requirement that participating practices implement episodic care management to provide timely follow-ups for high-risk patients post ED visit and hospitalization [72]), and we patterned the timely follow-up element after our policy for TCM services which requires, for example, ''communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge'' and a ''face-to-face visit within 7 calendar days of discharge.'' Providing timely follow-ups for patients is an essential element of the delivery of care under an advanced primary care model of care, and this will help achieve timely, seamless care across settings especially after discharge from a facility. Key aspects of follow-up after ED visits and hospitalizations include identifying and partnering with target hospitals and EDs where the majority of a practice's patients receive services to achieve timely notification and transfer of information following hospital discharge and ED visits.[73]

[71] *https://www.cms.gov/priorities/innovation/files/x/cpcplus-practicecaredlvreqs.pdf.*

[72] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

[73] Carrier, E., Yee, T., & Holzwart, R. A. (2011). Coordination Between Emergency and Primary Care Physicians (NIHCR Research Brief No. 3). National Institute for Health Care Reform. *http://nihcr.org/analysis/improving-care-delivery/prevention-*

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When developing a standardized process for data exchange and timely follow-up, successful practices include the following processes: information and data exchange about patients seen in an ED or admitted to/discharged from a hospital (for example, via HIE, hospital portal, hospital-generated report, EHR, or additional health IT system); definition for ''timely'' follow-up after discharge (for example, no later than within 2 days of discharge from hospital admission or observation stay and within 1 week of discharge from the ED); protocols for when follow-up will be done (for example, before discharge or following a standardized follow-up protocol); process of incorporating into the patient's medical record so the information is available at the time of the follow-up visit or other patient contact; and standardized processes and protocols for data exchange and formalized partnerships to develop an efficient workflow to ensure timely follow-up and facilitate efficient and safe transitions of care.

Practices use a variety of scheduling strategies to prioritize same-day or next-day access for acutely ill patients and to provide timely follow-up for patients experiencing care transitions. Successful practices are those that can strike the right balance between timely access to visits and the offering patients a provider of their choice (Continuity of Care). Establishing standardized protocols and pathways to improve and ensure responsiveness and timely callbacks to patients is an effective way to impact patient–practitioner/care team communication and to ensure a safeguard for addressing emergent and urgent patient phone calls. Successful practices routinely evaluate the degree to which patients' phone calls are answered promptly or returned within a practices' established guidelines (for example, non-urgent, emergent, urgent) and routed to the appropriate practitioner or care team member, incorporating patients' clinical needs and preferences.[74] Such strategies are paramount for practices whose patients may be contacting the practice with care needs that require care team prioritization and urgent reply. We sought feedback on these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters were concerned about our proposed management of care transitions requirement for APCM services, and particularly the requirement for timely follow-up communication within 7 days of an ED visit or hospital discharge. A few commenters suggested that we should modify the requirement for timely follow-up within 7 days of discharge because this is not always possible. One commenter encouraged us to prioritize strategies designed to improve interoperability to better coordinate care transitions. Another commenter asked us to include pediatric-to-adult care transitions as part of this requirement and they suggested that this type of transition has a 6-month follow-up timeframe.

Response: We appreciate the perspective that interoperability improvements could assist practitioners with managing care transitions, and the feedback on pediatric-to-adult care transitions. We welcome additional information from interested parties on these topics. We emphasize that our intent with this proposal was to ensure that practitioners furnishing APCM services have flexibility within their practices as to how they satisfy the requirement, including how they ensure timely follow-up after their patient's care transition. While we understand that some patients and their caregivers may be difficult to reach, we expect that practices make an active effort to timely follow up with patients post-discharge. We would like to reiterate that we are finalizing that a practice should meet this 7-day follow-up requirement whenever possible.

After consideration of public comments, we are finalizing the management of care transitions service element as proposed, but with clarification that practitioners should make reasonable efforts to provide timely follow-up communication after an ED visit or hospital discharge within 7 days when possible. Consistent with other APCM service elements, we will require that the efforts to reach the patient/caregiver and any interaction must be documented in the patient's medical record. Timely follow-up with patients after care transitions is a key component of advanced primary care which we believe will help achieve timely, seamless care across settings, and we may consider revisions to this policy in future rulemaking.

(7) Practitioner, Home-, and Community-Based Care Coordination

We proposed in the CY 2025 PFS proposed rule to adopt for APCM services the ''Home- and Community-Based Care Coordination'' service element we established for CCM and PCM services with some modifications. As included in the APCM code descriptors, we proposed to specify that the ''ongoing communication and coordinating receipt of needed services'' is not only with home- and community-based service providers, but also with ''practitioners,'' ''community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), as applicable.'' We also proposed to add more detail about the communication documented in the patient's medical record in that it would include ''the patient's psychosocial strengths and needs, and functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors.''

Coordinated referral management with specialty groups and other community or healthcare organizations ensures referrals are properly managed, coordinated, and communicated. These efforts help practices achieve goals of enhancing the quality of patient care, improving the patient's care experience, and lowering cost, particularly for practices serving high-risk patient populations. Evidence suggests that the development of formal relationships (for example, collaborative care agreements) between the primary care practice and referred groups/organizations that define shared goals and responsibilities, facilitate the coordinated referral management process.[75] The foundation of successful coordinated referral management with specialty groups and other community or healthcare organizations is the development of processes and procedures to ensure high-value referrals, such as collaborative care agreements and electronic consultations (e-Consults). Establishing clear and agreed-upon expectations regarding communication and clinical responsibilities with

improving-health/ed-coordination/; Ventura, T., Brown, D., Archibald, T., et al. (2010, January–February). Improving care transitions and reducing hospital readmissions: establishing the evidence for community-based implementation strategies through the care transitions theme. *http://www.communitysolutions.com/assets/2012_Institute_Presentations/caretransitioninterventions051812.pdf.*

[74] Hempel, S., Stockdale, S., Danz, M., Rose, D. E., Kirsh, S., Curtis, I., & Rubenstein, L. V. (2018). Access management in primary care: Perspectives from an expert panel (Research Report No. RR–2536–DVA). Rand Corporation. *https://www.rand.org/content/dam/rand/pubs/research_reports/RR2500/RR2536/RAND_RR2536.pdf.*; O'Brien, L. K., Drobnick, P., Gehman, M., Hollenbeak, C., Iantosca, M. R., Luchs, S., Manning, M., Palm, S. K., Potochny, J., Ritzman, A., Tetro-Viozzi, J., Trauger, M., & Armstrong, A. D. (2017). Improving responsiveness to patient phone calls: A pilot study. Journal of Patient Experience, 4(3), 101–107. *doi:10.1177/2374373517706611.*

[75] Medicare Payment Advisory Commission (MedPAC). (2012, June). Report to the Congress: Medicare and the Health Care Delivery System. *http://medpac.gov/docs/default-source/reports/jun18_medpacreporttocongress_sec.pdf?sfvrsn=0.*

specialty practices and other care organizations, through a collaborative care agreement, improves the process. Collaborative care agreements often include the following elements: defining the types of referrals, consultation, and co-management arrangements available; specifying who is accountable for which processes and outcomes for care within the referral, consultation, or co-management arrangement; and specifying what clinical and other information should be provided, how the information is transferred, and timeliness expectations. The electronic e-Consults process is typically conducted through a system-wide EHR or a secure, web-based system by which a practice receives guidance from a specialty provider or other care organization.[76] In this process, a practitioner sends a clinical question and relevant clinical information to the specialist (or other care organization), who responds by providing a clinical opinion and guidance and/or confirms the need for a face-to-face appointment with the patient. This tool and process has the potential to streamline consultations, reduce cost and burden for patients, and improve access to specialty care for high-value referrals. As part of the CY 2019 PFS final rule, we finalized interprofessional consultation services codes, which support payment both to the treating, requesting (primary care) practitioner (CPT code 99452) and the receiving, consultative specialist (CPT codes 99446–99449 and 99451) who engage in e-Consults, and so some practitioners have already become accustomed to providing and billing for these services (83 FR 59687).

Strategies for addressing common health-related social needs (HRSNs) for a practice's high-risk patients include conducting needs assessments at regular intervals, creating a resource inventory for the most pressing needs of the patient population, and establishing relationships with key community organizations. Practices can focus on developing relationships with community-based organizations that support patients' most significant HRSNs. Practices can also seek to find common ground with community and social service organizations, focus on the structure and process of referrals, and develop a bidirectional flow of information. Successful practices work with their patients to ensure there is a shared understanding of the purpose of the referral and aim to understand bottlenecks and barriers to meeting their needs through the process. Many practices identify a care team member to be a community referral resource for their patients. Successful referrals can help practices determine the most useful and available resources in their community. We sought feedback on these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters were generally supportive of our proposal. Several commenters expressed appreciation for the inclusion of cultural and linguistic factors in the documentation requirements when coordinating with and referring to services outside the primary care clinic. One commenter was concerned that our proposals do not incentivize specialists and other clinicians to coordinate with primary care practitioners, recommending that we consider ways to encourage clinicians to communicate and collaborate with each other. One commenter was concerned that community-based aspect of care coordination may pose challenges for certain primary care practices if it extends beyond the routinely used home health services. For example, lower income and QMB patients may receive their primary care in practices that may not be able to meet these standards, such as low resource safety net practices. The commenters stated that this could potentially exacerbate disparities in care and payment for patients at the highest risk.

Response: We thank the commenters for their support, and we agree with commenters that specialists furnishing consultations in conjunction with primary care practitioners are an essential element of advanced primary care services. We are therefore clarifying in this final rule that the interprofessional consultation codes (CPT codes 99446–99449 and 99451) can be billed concurrently with APCM services. We note again that only one practitioner may furnish APCM services in a month, so the consulting practitioner must not also furnish APCM services to the same beneficiary. See Table 26. We believe that our policy to allow concurrent billing of interprofessional consultation codes and APCM services is responsive to commenters' concerns that our proposals may not incentivize specialists and other clinicians to coordinate with primary care practitioners. We appreciate the comments about safety net practices and their ability to furnish APCM services. As discussed previously in this final rule, we also encourage practitioners in practices that may not meet all of the requirements to bill the APCM codes to consider whether care management codes other than the APCM codes might describe the services they are delivering (for example, CCM, PCM, or certain other CTBS). Also as discussed previously in this final rule, we will continue to identify and evaluate ways to encourage practices and practitioners to make APCM services available to all their patients in order to support care improvement for underserved, high-risk beneficiaries.

After consideration of public comments, we are finalizing the practitioner, home- and community-based care coordination service element as proposed.

(8) Enhanced Communications Opportunities

We proposed in the CY 2025 PFS proposed rule to include for APCM services the element of ''Enhanced Communications Opportunities'' we established for CCM and PCM services with some modifications. Specifically, we proposed to add ''internet and patient portal'' as examples of asynchronous non-face-to-face consultation methods and specify that the practitioner will provide ''other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate'' as well as specify ''access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).'' Providing asynchronous non-face-to-face consultation methods and other CTBS services is an essential element of the delivery of care under an advanced primary care model of care, and this will allow patients to access their usual source of care more conveniently (see section II.G.2.c.(3) of this final rule). There is growing consensus that incorporating telehealth into primary care will allow patients to access their usual source of care more conveniently.[77] Patients using

[76] Vimalananda, V., Gupte, G., Seraj, S., Orlander, J., Berlowitz, D., Fincke, B., & Simon, S. (2015, September). Electronic consultations (e-consults) to improve access to specialty care: A systematic review and narrative synthesis. Journal of Telemedicine and Telecare 21(6), 323–330. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4561452/.*

[77] Levine DM, Linder JA. Retail Clinics Shine a Harsh Light on the Failure of Primary Care Access. J Gen Intern Med. 2016;31(3):260–262.; Dorsey ER, Topol EJ. State of Telehealth. N Engl J Med. 2016;375(2): 154–161.; Powell, Rhea E., et al.

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telehealth visits have reported high satisfaction, identifying convenience and perceived high quality of care as contributors,[78] such that these may be a good alternative and, in some cases, preferable to in-person communication.[79] Expansion of telehealth to address episodic and chronic conditions has been a significant trend in the evolution of telehealth applications, and there is some evidence that video visits may enable more timely communication of test results than in-person appointments.

As noted in section II.G.2.b. of the CY 2025 PFS proposed rule, we did not propose timeframe restrictions for this proposed element, which includes access to certain CTBS (for example, the restriction for virtual check-in services that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment). We sought feedback on these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the emphasis in our proposal on technology integration and agreed that the bundling of CTBS with APCM services demonstrates our overall commitment to adapting to the evolving healthcare landscape, where virtual and asynchronous interactions are becoming more prevalent. Several commenters agreed with us that the integration of digital health technology into chronic care management would enhance patient engagement, facilitate the delivery of continuous, patient-centered care, and drive efficiencies across the healthcare system. Some commenters asserted that this approach would be particularly beneficial in enhancing care delivery in rural and underserved areas, where access to specialized services may be limited.

Another commenter recommended that we eliminate the requirement to offer digital E/M services and virtual check-ins, since these may not be appropriate for certain specialized populations—for example, some home-bound patients may benefit from consistent face-to-face interventions in the home.

Response: We take this opportunity to clarify that virtual check-ins and digital online assessment and management and E/M visits (or e-visits) are not specific requirements of this service element, but rather, are listed as examples. We agree with commenters that practitioners are in the best position to determine how their patients interact with the practice and therefore are not requiring specific types of encounters, but rather encouraging practices to consider ways to ensure enhanced access to patient-initiated digital communications, including but not limited to virtual check-ins and digital online assessment and management and E/M visits (or e-visits).

Comment: Several commenters requested clarification on the documentation required for this proposed service element and the degree to which the primary care practitioner needs to be personally involved in furnishing CTBS.

Response: With respect to whether the primary care practitioner must be the individual in contact with the patient via any enhanced communication methods, as described earlier in this discussion, many APCM services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26, and as designated care management services could be provided by auxiliary personnel under the general supervision of the billing practitioner. However, some services, such as virtual check-ins or e-visits, necessarily involve the direct delivery of care by the primary care practitioner. Furthermore, we would not expect that the presence of enhanced communications opportunities and capabilities would be documented in each patient's medical record except to the extent that they are used to furnish APCM services. Rather, if the patient has an interaction with a care team member via an enhanced communication tool or service, we would expect that interaction to be documented in the patient's medical record. By billing for APCM services, the practitioner is attesting that the APCM service meets the requirements specified in the code descriptor.

After consideration of public comments, we are finalizing the enhanced communications opportunities service element as proposed.

(9) Patient Population-Level Management

We proposed in the CY 2025 PFS proposed rule to establish an APCM service element for Patient Population-Level Management that will include practice capabilities for population-based, data-driven approaches to manage preventive and chronic care for their patient population and to plan and implement strategies to improve care and outcomes. We proposed that all practices will use data to develop clear improvement strategies and analytic processes to proactively manage population health, including analyzing patient population data to identify gaps in care and risk-stratifying the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients (such as those at risk for poor health outcomes), and then will offer additional interventions, as appropriate.

These Patient Population-Level Management Standards are similar to several requirements tested in CMS Innovation Center models, including CPC+, which found that model participants used data to identify and resolve gaps in care. We have modeled the Patient Population-Level Management standards on the CPC+ care delivery requirements. In the CPC+ Model, participating practices were required, for example, to ''use a two-step risk stratification process for all empaneled patients, addressing medical need, behavioral diagnoses, and health-related social needs'' and ''define at least one subpopulation of patients with specific complex needs, develop capabilities necessary to better address those needs, and measure and improve the quality of care and utilization of this subpopulation.'' [80] Central to the delivery of advanced primary care is the organization of the practice into care teams that have the data they need to manage their patient populations and that have time allocated to plan and implement practice improvement strategies.[81] Using evidence-based protocols, registries, and the registry functionality of the EHR, reminders and outreach help practices deliver appropriate preventive care and consistent evidence-based management of chronic conditions for the entire patient population.[82] Measurement of clinically relevant data at the practice-

''Patient perceptions of telehealth primary care video visits.'' The Annals of Family Medicine 15.3 (2017): 225–229.

[78] Polinski JM, Barker T, Gagliano N, Sussman A, Brennan TA, Shrank WH. Patients' Satisfaction with and Preference for Telehealth Visits. J Gen Intern Med. 2016;31(3):269–275.

[79] Krishnan N, Fagerlin A, Skolarus TA. Rethinking Patient-Physician Communication of Biopsy Results—The Waiting Game. JAMA Oncol. 2015;1(8):1025–1026.; Cusack CM, Pan E, Hook JM, Vincent A, Kaelber DC, Middleton B. The value proposition in the widespread use of telehealth. J Telemed Telecare. 2008;14(4):167–168.

[80] *CPC+ Care Delivery Resource. January 2019.*

[81] *CPC+ Care Delivery Resource. January 2019.*

[82] *O'Malley AS, Draper K, Gourevitch R, Cross DA, Scholle SH. Electronic health records and support for primary care teamwork. J Am Med Inform Assoc. 2015 Mar;22(2):426–34. doi: 10.1093/jamia/ocu029. Epub 2015 Jan 27. PMID: 25627278; PMCID: PMC4394968.*

level guides testing and implementing strategies to improve care and outcomes. Patient Population-Level Management capabilities are essential to the delivery of care under an advanced primary care model of care and enable practices to meet the preventive and chronic care needs of their entire patient population. Regular use of data to identify populations or groups of patients with similar needs allows practices and care teams to use streamlined strategies, including setting goals with measurable outcomes, to positively impact their patient populations. Evidence shows that primary care teams supported with real-time, Population-Level clinical outcomes data effectively manage population health and address care gaps which eliminates external costs to close gaps in care.[83] More specifically, risk stratification allows practitioners to identify beneficiaries for longitudinal care management, track beneficiaries with higher levels of need and manage their conditions, and prevent beneficiaries from falling through the cracks, while developing strategies to address those patients who are at increased and rising risk and most likely to benefit from targeted, proactive, relationship-based care management and other strategies essential to APCM.[84] Empanelment, which assigns each active patient to a practitioner and/or care team with consideration of patient and caregiver preferences, allows practices to build responsive care teams to optimize patient care and to address the preventive, chronic, and acute needs of all patients, and provides a way for practices to identify care gaps and proactively reach out to patients who have not been seen or contacted in a while.[85] For example, these elements of advanced primary care management could increase screening rates and ultimately improve care of chronic conditions, such as hypertension and diabetes.

We noted as part of the CY 2025 PFS that this Patient Population-Level Management requirement of the APCM services would be met for practitioners billing for APCM services through a TIN that is participating in an ACO in the Shared Savings Program by virtue of the practitioner's participation in the ACO which must meet eligibility requirements for population management, care coordination and quality improvement, including required processes and patient-centeredness criteria in § 425.112. We note that ACOs in the Shared Savings Program and their practitioners are already engaged in analyzing the patient population for care gaps, risk-stratifying patients to further identify those at risk for poor health outcomes, and identifying patients for whom additional interventions are appropriate. Similarly, the ACO REACH, Making Care Primary, and Primary Care First CMS Innovation Center Models all require their participants to deploy population health strategies to identify and offer interventions to mitigate health risks.[86] Participants in these models and their practitioners are already engaged in population health management as described in Table 25. We sought feedback on these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that risk stratification and population management will increase a practice's ability to deliver care in the most efficient way possible. Another commenter stated that population management could help practitioners reach underserved populations. A few commenters indicated that the Patient Population-Level Management and any associated data analysis could be completed by the practice and did not necessarily need to be completed by the practitioner. One commenter suggested that because practices have different infrastructures, they should be allowed flexibility in how to implement this requirement. A few commenters stated that they did not believe patient Population-Level Management should be required to bill APCM, and another commenter indicated it may be resource intensive for small practices. One commenter requested that we develop an attribution method by which we would help practitioners identify patients for which they should conduct population management. Finally, one commenter requested that we require practices to conduct Population-Level management for the pediatric-to-adult referral population.

Response: As we indicated earlier, we agree that Population-Level management can be beneficial for practices, assisting them with addressing gaps in care. While Population-Level management requires the development of a process to analyze data and assess gaps in care, we believe that the standard we have proposed is broad enough to allow practices the flexibility to develop and implement processes in a way that best suits the needs of their practice and their patient population, and in a manner that does not require significant start-up costs. Furthermore, at this time, we do not believe it is necessary to dictate for which patients a practice should conduct specific types of Population-Level management. We did not propose that the Population-Level management needed to be completed by the practitioner billing APCM, and we agree with commenters that it is not necessary to require the practitioner to conduct this work. Finally, we appreciate the feedback that an attribution method may be useful for Population-Level management and we may consider that topic for future rulemaking.

Comment: Several commenters requested clarification on how to document that a practice meets the Patient Population-Level Management requirement.

Response: As previously explained, we would not expect that the practice-level requirements would be documented in each patient's medical record except to the extent they are used in furnishing APCM services to a specific patient, in which case we would expect the service to be documented in the patient's medical record. For example, if a practitioner calls a patient after a hospitalization and reviews medication changes, a record of what transpired during that conversation should be included in that patient's medical record. By billing for APCM services, the practitioner is attesting that the requirements included in the code descriptor have been met.

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[83] *https://www.cms.gov/priorities/innovation/files/x/cpcplus-practicecaredlvreqs.pdf.*

[84] *Hayes, S. L., & McCarthy, D. (2016, December 7). Care Management Plus: Strengthening Primary Care for Patients with Multiple Chronic Conditions. The Commonwealth Fund. http://www.commonwealthfund.org/publications/case-studies/2016/dec/care-management-plus*; Hong, C.S., Siegel, A.L., & Ferris, T.G. (2014, August). Caring for High-Need, High-Cost Patients: What Makes for a Successful Care Management Program? The Commonwealth Fund. *http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2014/aug/1764_hong_caring_for_high_need_high_cost_patients_ccm_ib.pdf Lakin, J.R., Robinson, M.G., Obermeyer, Z., Powers, B.W., Block, S.D., Cunningham, R., Tumblin, J.M.m Vogeli, c., & Bernacki, R.E. (2019). Prioritizing primary care patients for a communication intervention using the* ''*Surprise Question*''*: A prospective cohort study. Journal of General Internal Medicine, 8.*

[85] Grumbach, K., & Olayiwola, N.J. (2015). Patient empanelment: The importance of understanding who is at home in the medical home. Journal of the American Board of Family Medicine, 28(2), 170–272.; Altschuler, J., Margolius, D., Bodenheimer, T., & Grumbach, K. (2012). Estimating a reasonable patient panel size for primary care physicians with team-based task delegation. Annals of Family Medicine, 10(5), 396–400. *doi:10.1370/afm.1400.*

[86] ACO Realizing Equity, Access, and Community Health (REACH) Model Request for Applications. Available a: *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa*, Making Care Primary Request for Applications. Available at *https://www.cms.gov/files/document/mcp-rfa.pdf,* Primary Care First Request for Applications Cohort 2. Available at *https://www.cms.gov/priorities/innovation/media/document/pcf-cohort2-rfa.*

After consideration of public comments, we are finalizing the ''Patient Population-Level Management'' service element as proposed.

(10) Performance Measurement

We proposed, as part of the CY 2025 PFS, for the APCM services a practice-level requirement for ''Performance Measurement'' of primary care quality, total cost of care, and meaningful use of CEHRT. Performance measurement is a critical element of care management services delivered in the context of advanced primary care, and it forms the basis for practice improvement efforts by enabling practices to identify key measures for improvement activities (for example, cost and utilization data, clinical quality measures, patient experience of care data). Quality measurement improves care delivery, including prevention of heart attacks, increasing vaccination rates, and improving patient safety,[87] and quality measures are also effective tools to ensure that high-quality advanced primary care, including care management, is being delivered. Several performance measurement requirements were tested in CMS Innovation Center models (such as the CPC+ model's requirement that participating practices use data at both the practice- and panel-level to set goals to improve population health management and to continuously improve patients' health, experience, and quality of care, and decrease cost). Using data resources and developing workflows and analytics to guide practice changes can help practices achieve reductions in total utilization and cost of care, and improvements in patient experience and quality of care. Improving upon key outcome measures requires engaged clinical and administrative leadership and a commitment to continuous, data-driven improvement.[88] In the context of the PFS, performance management through quality measurement as a practice-level requirement also ensures integrity to the provision of advanced primary care because it holds billing practitioners accountable to factors that are affected by several service elements of APCM coding. For example, effective patient population-level management can mean the practices close care gaps in diabetes management, and the billing practitioner would perform better on diabetes quality measures that assess for a patient's control of hemoglobin A1c.

We proposed that this practice-level Performance Measurement standard could be met in several ways. For MIPS eligible clinicians, the requirement would be met by registering for and reporting the ''Value in Primary Care'' MVP. A practitioner who is part of a TIN that is participating in a Shared Savings Program ACO or a REACH ACO, or a Primary Care First or Making Care Primary practice would meet these requirements by virtue of meeting requirements under the Shared Savings Program or CMS Innovation Center ACO REACH, Making Primary Care Primary, or Primary Care First models. Because these models require their participating practitioners to report on quality and cost performance metrics that are aligned or overlap with the Value in Primary Care MVP, we proposed that requiring these practitioners to report the Value in Primary Care MVP for purposes of billing for APCM services would be substantially duplicative.

In the CY 2024 PFS final rule (88 FR 80042 through 80047), we finalized ''The Value in Primary Care'' MVP, which focuses on the clinical theme of promoting quality care for patients in order to reduce the risk of diseases, disabilities, and death. This MVP includes certain cost measures, improvement activities, and quality measures for common chronic conditions (for example, hypertension, diabetes, depression).[89] As with all MVPs, the Value in Primary Care MVP also requires meaningfully using CEHRT and reporting the objectives, measures, and attestations specified for the Promoting Interoperability performance category.

The Value in Primary Care MVP contains the Adult Universal Foundation quality measure set, which is consistent with the National Quality Strategy goal of using the Universal Foundation measures across as many programs as is feasible.[90] We proposed in the CY 2025 PFS proposed rule that this MVP is especially well-suited to reflect the delivery of care using the advanced primary care model as it was developed to include quality metrics that reflect clinical actions that are indicative of high-quality primary care. The quality measures include key elements such as cancer screening, immunization, blood pressure management, behavioral health, care coordination, person-centered care, and screening for social drivers of health.

The improvement activities include engaging community resources to address drivers of health, implementing changes in the practice's patient portal to improve communication and patient engagement, reviewing practices in place on targeted patient population needs, and chronic care and preventive care management for empaneled patients, aspects of advanced primary care already discussed in this proposal.

The cost measures include costs for common chronic conditions, such as asthma/chronic obstructive pulmonary disease (COPD), diabetes, depression, and heart failure, as well as the Total Per Capita Cost (TPCC) measure. The TPCC measure is a population-based cost measure which assesses the overall cost of care delivered to a patient with a focus on the primary care they receive from their provider(s) and captures the broader healthcare costs influenced by primary care.[91]

We proposed in the CY 2025 PFS proposed rule that the Value in Primary Care MVP serves to demonstrate performance measurement that is reflective of the care furnished using advanced primary care delivery. To ensure performance measurement consistent with the delivery of advanced primary care services, we proposed as an element of the APCM services that a practitioner who is a MIPS eligible clinician as defined in § 414.1305 can satisfy the performance measurement requirement by registering for and reporting the Value in Primary Care MVP for the performance year in which they bill for APCM services. A MIPS eligible clinician can report to MIPS as an individual, subgroup, group, APM Entity, or in any combination of these four participation options, and can participate in multiple ways to report MVPs.[92]

We discussed in the CY 2025 PFS proposed rule that MIPS eligible clinicians who report the MVP are also required to report the Promoting Interoperability performance category objectives, measures, and required attestations throughout the performance period in which they bill for APCM services,[93] as required under § 414.1375(b) (§ 414.1365(c)(4)(i)) (see section IV. of the CY 2025 PFS proposed

[87] *https://www.ahrq.gov/patient-safety/quality-measures/21st-century/challenges.html.*

[88] *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-primary-care-plus.*

[89] *Value in Primary Care.* Quality Payment Program. *https://qpp.cms.gov/mips/explore-mips-value-pathways/2024/M0005.*

[90] *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

[91] *https://qpp.cms.gov/docs/cost_specifications/2023-12-13-mif-tpcc.pdf.*

[92] *https://qpp.cms.gov/mips/mvps/learn-about-mvp-reporting-option?option=Group.*

[93] *The MIPS Promoting Interoperability performance period is a minimum of 180 consecutive days in the calendar year that occurs 2 years prior to the MIPS payment year (see 42 CFR 414.1320(i)).*

rule for details on reporting the objectives, measures, and required attestations for the MIPS Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and see section II.G.c.(10) in this final rule for a summary). The MIPS Promoting Interoperability performance category includes measures such as supporting electronic referral loops by sending health information, supporting electronic referral loops by receiving and reconciling health information, and providing patients with electronic access to their health information, all of which are reflective of important communication and coordination channels between primary care, other specialist practitioners caring for the patient, and the patient themselves. In addition, as set forth in § 414.1375(b)(3), the MIPS Promoting Interoperability performance category requires submission of affirmative attestations: (1) regarding their cooperation in good faith with ONC direct review of their CEHRT; and (2) that they did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT.[94]

We noted as part of the CY 2025 PFS that, for CCM services (CPT codes 99437, 99439, 99487, and 99489—99491) and PCM services (CPT codes 99424—99427), we established a practice-level service element requiring the meaningful use of CEHRT to record certain patient health information in a structured format, provide patients with access to their health information, and exchange all relevant patient health information, including in providing the ''Management of Care Transitions'' element of CCM services. For the APCM services, which are furnished as part of a practitioner's care delivery using the advanced primary care model, we proposed in the CY 2025 PFS proposed rule for practitioners who are MIPS eligible clinicians a practice level requirement to register for and report the MVP, including but not limited to reporting the Promoting Interoperability performance category objectives, measures, and required attestations which focus on meaningful use of CEHRT, for the performance year in which they furnish and bill for APCM services. This would ensure that patients/caregivers and physicians or other qualified practitioners or clinical staff have real-time access to patient's medical information. Meaningful use of CEHRT is a critical element of care management services delivered in the context of advanced primary care.

As we stated in adopting the CEHRT use element for CCM and PCM services, the meaningful use of CEHRT is vital to ensure that practitioners are capable of providing the full scope of services, such as timely care coordination and continuity of care (see our prior discussion of this issue at 79 FR 67723 and 84 FR 62696), and flexibility in how practices can provide the requisite 24/7 access to care, continuity of care, and management of care transitions, can facilitate appropriate access to these services for Medicare beneficiaries. The meaningful use of CEHRT helps ensure that members of the care team have timely access to the patient's most updated health information and offer an integrated view of a patient's clinical history from different points of care, supporting continuing, quality, and integrated healthcare while avoiding duplication of efforts and costs, such as repeated exams.[95] For example, practices can use EHRs to identify high-risk patients with chronic conditions to better coordinate care and can supplement the practice's EHR data with data from external sources (for example, State-level quality organizations) to obtain a more comprehensive view of patients. Practices can also integrate clinical data from EHRs, health plan claims data, and county-level social services data to evaluate population needs, stratify by risk, and assess what programs would be most effective for supporting at-risk patients.[96] Standardized communication methods, enabled by the meaningful use of CEHRT, are a significant part of the advanced primary care delivery model. Health IT systems that include remote access to the care plan or the full EHR after hours, or enable a feedback loop that communicates back to the primary care physician and others involved in the beneficiary's care regarding after-hours care or advice provided, are extremely helpful.[97] They help ensure that the beneficiary receives necessary follow up, particularly if the patient is referred to the ED, and follow up after an ED visit is required under the element of ''Management of Care Transitions.'' Accordingly, the meaningful use of CEHRT or remote access to the care plan is fundamental to providing the APCM service elements of 24/7 Access to Care, Continuity of Care, and Management of Care Transitions under an advanced primary care delivery model. Requiring performance of the MIPS Promoting Interoperability performance category requirements demonstrating the meaningful use of CEHRT is similar to several requirements tested in CMS Innovation Center models (such as the PCF model's requirement that participating practices adopt and maintain CEHRT for electronic clinical quality measure reporting, support data exchange with other providers and health systems, and connect to their regional health information exchange (HIE),[98] and the MCP model's requirement that participating practices use EHR technology that has been certified under the ONC Health IT Certification Program [99]). Furthermore, the Shared Savings Program generally requires ACO participants, providers/suppliers, and professionals (including MIPS eligible clinicians, QPs and Partial QPs participating in the ACO) to demonstrate meaningful use of CEHRT through the reporting of the MIPS Promoting Interoperability performance category measures and requirements annually beginning in Performance Year 2025 (§ 425.507).

We noted as part of the CY 2025 PFS that there are many practitioners who would not be MIPS eligible clinicians for a year because they would have earned Qualifying APM Participant (QP) status based on meeting threshold levels of participation in an Advanced APM. Based on the characteristics of Advanced APMs described in § 414.1415, including the requirement that payment is based on MIPS or MIPS-comparable quality measures, practitioners who have earned QP status are necessarily engaging in performance measurement through the Advanced APMs in which they participate in a way that is consistent with advanced primary care. We also recognize there are other practitioners who are not MIPS eligible clinicians for other reasons,

[94] Note that, under the Quality Payment Program, CMS may reweight the MIPS Promoting Interoperability performance category to zero percent of the MIPS final score, and not require an individual, group, or virtual group to use CEHRT and demonstrate whether they are a meaningful user of CEHRT, by granting a significant hardship exception or other type of exception based on certain circumstances as set forth in 42 CFR 414.1380(c)(2)(i)(C).

[95] McDonald, C.J., Tang, P.C., Hripcsak, G. and In: (eds) Biomedical Informatics. Springer, L. (2014), ''Electronic Health Record Systems,'' in Biomedical Informatics, Shortliffe, E.H. and Cimino, J.J., eds. London: Springer, pp. 391–421.

[96] Harvey, Jillian B., et al. ''Understanding how health systems facilitate primary care redesign.'' Health Services Research 55 (2020): 1144–1154.

[97] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3475839/#CR25.*

[98] *https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options.*

[99] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

such as practitioners who are newly enrolled in Medicare or bill a low volume of Medicare services. We proposed in the CY 2025 PFS proposed rule that these practitioners technically could bill for APCM services if they meet the service and practice level requirements to do so. We note that newly enrolled practitioners are only excluded from MIPS for one year, after which the practitioner would either be a MIPS eligible clinician who would need to report the MVP in order to bill for APCM services or excluded from MIPS on another basis such as QP status. status. In the case of practitioners with low Medicare volume, we anticipate that they would be unlikely to bill for APCM services since the delivery of advanced primary care generally involves time and resources to establish practice-level infrastructure, and the economies of scale usually make this a more likely investment if the infrastructure can be utilized across a larger patient panel.

We also proposed as described in section II.G.c. of this final rule, that the performance measurement element of the APCM services will be satisfied for practitioners billing for APCM services through a TIN that is participating in a Shared Savings Program ACO for a performance year in which they furnish APCM services. ACOs are currently required to report the APP quality measure set on behalf of their practitioners and will be required to report the APP Plus quality measure set in section III.G. of this final rule. Practitioners in ACOs are also already being held accountable for reporting and performance and outcomes on many of the Universal Foundation measures already, which are used in the Value in Primary Care MVP, and the APP Plus quality measure set would fully align the Shared Savings Program's quality performance standard with the Universal Foundation measures upon the complete implementation of the APP Plus measure set.

We proposed in the CY 2025 PFS proposed rule to include the performance measurement requirement as an element of APCM services furnished by practitioners, see section II.G.2.c. of this final rule. MIPS eligible clinicians who intend to report on the Value in Primary Care MVP for the CY 2025 performance period/2027 MIPS payment year must register to report the Value in Primary Care MVP as described under § 414.1365(b). Generally, a MIPS eligible clinician must register for an MVP during between April 1 and November 30 of the applicable CY performance period to report the MVP. MIPS eligible clinicians submit data on measures and activities in the first quarter of the year following (CY 2026) the MIPS performance period. Under this proposal, a MIPS eligible clinician billing for APCM services furnished in 2025 and who satisfies the performance measurement requirement through reporting the Value in Primary Care MVP, would need to register for the MVP between April and November of 2025 and report data between January and March 2026 on measures and activities in the Value in Primary Care MVP relating to services furnished in 2025. A MIPS eligible clinician billing for APCM services furnished in 2026 and who satisfies the performance measurement requirement through reporting the Value in Primary Care MVP, would need to register for the Value in Primary Care MVP between April and November of 2026, and report data between January and March of 2027 on measures and activities in the Value in Primary Care MVP relating to services furnished in 2026, and so on in subsequent years.

As described in section II.G.2.c(9) of this final rule, we sought feedback on ways to align the APCM services with other Medicare programs and initiatives, such as the Shared Savings Program and the Quality Payment Program, including MIPS and Advanced APMs. We sought to create a low burden way for practitioners to furnish APCM services by appropriately recognizing ways in which they may meet APCM billing requirements as part of these programs and initiatives, including other ways that practitioners may be fulfilling these performance measurement requirements.

We sought feedback on whether there are areas of duplication within the APCM service elements and practice capabilities that we should consider addressing.

We also sought comment on how to appropriately align the time period for which the practitioner bills the monthly APCM code with the calendar year reporting period covered by the MVP, and how we would verify and enforce the performance measurement requirement of the APCM service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments supporting the practice-level performance measurement requirement, and a few commenters appreciated that we were using an existing reporting pathway via the Value in Primary Care MVP for practices to meet the performance measurement requirement. A few commenters requested that we phase the performance measurement requirement over time, while others requested we remove it entirely, indicating it may be a barrier for some entities to utilize the APCM codes. Several commenters suggested that we require the reporting of specific quality or patient experience measures, while several other commenters offered that we should allow the reporting of other, specialty-specific MVPs to fulfill the performance measurement requirement, as specialists may bill for APCM if they are directing the beneficiary's primary care and continue to be the focal point of a beneficiary's primary care.

Response: We chose to propose the Value in Primary Care MVP as the mechanism for meeting the performance measurement requirement both because of the flexibility it offers practitioners in reporting on quality metrics that align with their patient populations and because the measures included in the Value in Primary Care MVP focus on the clinical theme of promoting quality care for patients in order to reduce the risk of diseases, disabilities, and death. While we understand that a specialist may intend to take responsibility for all of a patient's primary care and serve as the continuing focal point for all needed health care services, and meet other requirement to bill for APCM services, as discussed earlier, the specific measures within the Value in Primary Care MVP are best suited to measure the performance in the context of advanced primary care services; and that performance measurement is a key characteristic of advanced primary care that is critical for the improvement of primary care delivery over time. We appreciate the commenters' feedback and may take these points into consideration for possible future rulemaking. At this time, we continue to believe the Value in Primary Care MVP is the best fit for purposes of performance measurement for MIPS eligible clinicians furnishing APCM services. Therefore, it would not be appropriate to specify that the performance measurement requirement could be met by reporting a different MVP.

Comment: A few commenters indicated that it may be difficult or expensive for some practitioners to meet the MIPS Promoting Interoperability performance category requirements, so the electronic data sharing and integration requirements of the Value in Primary Care MVP should be removed or delayed.

Response: Health IT and interoperability, through electronic exchange of health information and having up-to-date information from

multiple clinicians, can have a positive impact on patient care and enhance efficiency and productivity. The same MIPS Promoting Interoperability performance category requirements we are adopting generally apply to those MIPS eligible clinicians who report MVPs as those reporting traditional MIPS. Therefore, MIPS eligible clinicians who want to furnish and bill for APCM services may demonstrate their meaningful use of CEHRT through the MIPS Promoting Interoperability performance category requirements.

We acknowledge that there are several cases in which a MIPS eligible clinician may be excepted from reporting for one or more MIPS performance categories and, thus, not all practitioners billing for APCM services will have to meaningfully use CEHRT and meet requirements for reporting the MIPS Promoting Interoperability performance category. A MIPS eligible clinician may request, that they be excepted from reporting MIPS Promoting Interoperability under the MIPS reweighting policies at § 414.1380(c)(2)(i). If we approve the reweighting/exception, then the MIPS eligible clinician does not need to adopt or meaningfully use CEHRT or report MIPS Promoting Interoperability objectives, measures, or attestations. Similarly, these same exceptions to reporting MIPS Promoting Interoperability have also been made available to ACO participants under 42 CFR 425.507(b).[100]

We also reiterate that there are practitioners who would not be MIPS eligible clinicians for various reasons—for example, they would have earned QP status based on meeting threshold levels of participation in an Advanced APM, they are newly enrolled in Medicare, or they bill a low volume of Medicare services. These practitioners could bill for APCM services if they meet the service elements and practice-level requirements to do so, but we believe it is appropriate for several reasons not to require these practitioners to meet the performance measurement requirement for APCM services through reporting the Value in Primary Care MVP to MIPS. Eligible clinicians excluded from MIPS based on their QP status earned through sufficient participation in an Advanced APM are necessarily engaging in performance measurement through the Advanced APMs in which they participate in a way that is consistent with advanced primary care. As noted previously, Advanced APMs must meet several criteria including payment based on MIPS or MIPS-comparable quality measures, CEHRT use, and assumption of more than a nominal amount of financial risk. Newly enrolled practitioners are excluded from MIPS for only one year, after which the practitioner would need to meet the performance measurement requirement to bill for APCM services. While some newly enrolled practitioners would not report at all during this initial year, we note that many others would furnish APCM services as part of a group practice with other practitioners who deliver advanced primary care. Such a practice would be likely to meet the practice-level requirements with respect to other practitioners in the group who may bill for APCM services. As for eligible clinicians excluded from MIPS based on low Medicare volume, these practitioners are unlikely to furnish advanced primary care or bill the Medicare program for APCM services since the delivery of advanced primary care generally involves routine and ongoing care delivery, and a significant investment of time and resources to establish practice-level infrastructure. Such a practice would be more likely to make the investments necessary to provide advanced primary care if the infrastructure can be utilized across a larger patient panel. We may consider whether to address performance measurement requirements for these practitioners in future rulemaking.

Comment: A few commenters suggested that we should not require practitioners participating in an APM to report the Value in Primary Care MVP. Several commenters requested that participants in other CMS Innovation Center models be able to meet the performance measurement requirement by meeting requirements of their model participation, and not have to report the Value in Primary Care MVP.

Response: While we understand that practitioners participating in many APMs, including other Advanced APMs, are subject to performance measurement requirements under the APM, the measures within the Value in Primary Care MVP are best suited to performance evaluation in the delivery of advanced primary care services. We specifically identified the Shared Savings Program, the ACO REACH model, the Primary Care First model, and the Making Care Primary model, as APMs in which the performance measurement requirements significantly overlap with or are aligned with the Value in Primary Care MVP. We proposed that for practitioners participating in these APMs, the practice-level performance measurement requirement for APCM services can be met by meeting requirements under these APMs. At this time, the performance measurement requirements of other APMs are not sufficiently aligned with the Value in Primary Care MVP.

Comment: Several commenters requested we clarify how APCM services and the performance measurement requirements could be implemented by Medicare Advantage or other payers, and expressed concern that other payers would not use the APCM coding and payment.

Response: We designed the APCM code set, including the practice-level performance measurement requirement, for purposes of payment under FFS Medicare. We recognize that the practitioners and practices that provide care using an advanced primary care delivery model would be likely to care for patients with a broad range of health care coverage. We also recognize that other health care payers sometimes pick up coding adopted for the FFS Medicare program to use for their own purposes. We note that the CPT Editorial Panel often considers establishing CPT codes that either replace or considerably overlap with HCPCS G-codes that CMS establishes. Other payers may consider working with the AMA in this regard. Additionally, we note that the code descriptors for the APCM services do not reflect all of the detailed, Medicare-specific characteristics of the billing and payment policies we are finalizing for APCM services. As such, we anticipate that other payers could adopt and use the APCM HCPCS codes by adapting their own billing and payment policies as needed. We note that the quality measures utilized in the Value in Primary Care MVP can also be utilized by other payers. To the extent that other payers, including Medicare Advantage organizations, Medicaid State plans, or commercial payers, decide to use the APCM codes, we encourage them to adopt requirements that align with ours in the interest of efficiency and burden reduction for practitioners. We also note that multi-payer alignment around performance measurement for APCM services would help focus attention on the Universal Foundation measures that are included in the Primary Care MVP.

After consideration of public comments, we are finalizing the ''Performance Measurement'' requirement as proposed. To satisfy this practice-level requirement, practitioners who are MIPS eligible clinicians must register for and report the Value in Primary Care MVP for the performance

[100] Link to recent guidance is at *https://www.cms.gov/files/document/frequently-asked-questions-shared-savings-program-requirement-report-objectives-and-measures-mips.pdf.*

year in which they bill for APCM services. A practitioner who is part of a TIN that is participating in a Shared Savings Program ACO or a REACH ACO, or in a Primary Care First or Making Care Primary practice would meet these requirements by virtue of meeting requirements under the Shared Savings Program or CMS Innovation Center ACO REACH, Making Primary Care Primary, or Primary Care First models.

We acknowledge that there are many practitioners who are not MIPS eligible clinicians for a year because they earned QP status through sufficient participation in an Advanced APM. These practitioners will meet the performance measurement requirement for APCM services through their involvement in an Advanced APM. We also recognize there are other practitioners who are not MIPS eligible clinicians for other reasons, such as practitioners who are newly enrolled in Medicare or bill a low volume of Medicare services.

We also acknowledge that there are several circumstances under which a MIPS eligible clinician may be excepted from reporting in one or more MIPS performance categories. Thus, some MIPS eligible clinicians could meet the performance measurement requirement for APCM services without demonstrating meaningful use of CEHRT by reporting the MIPS Promoting Interoperability performance category. A MIPS eligible clinician may request (and CMS may approve) that they be excepted from reporting MIPS Promoting Interoperability under the MIPS reweighting policies at 42 CFR 414.1380(c)(2)(i). If we approve the reweighting/exception, then the MIPS eligible clinician does not need to adopt or meaningfully use CEHRT or report MIPS Promoting Interoperability objectives, measures, or attestations. Similarly, these same exclusions/exceptions to reporting MIPS Promoting Interoperability have also been made available to ACO participants under 42 CFR 425.507(b). We note that these exceptions are generally temporary due to extraordinary circumstances, and in general, over the long term, practitioners and practices are expected to report in all MIPS performance categories.

We are clarifying that the practice-level performance measurement element of APCM services does not apply for practitioners who are not MIPS eligible clinicians, for example, because they are newly enrolled or bill a low volume of services under the Medicare. As explained previously, we recognize that these practitioners technically could bill for APCM services if they meet the other service elements and practice-level requirements to do so. We may consider whether to address performance measurement requirements for them in future rulemaking.

We summarize the final service elements and practice-level requirements for the APCM services in Table 25.

d. Duplicative Services and Concurrent Billing Restrictions

We proposed in the CY 2025 PFS proposed rule to identify the services that will overlap substantially with APCM services based on the elements of the scope of service for APCM which we have built into the service descriptors for G0556, G0557, and G0558 (see sections II.G.2.b. and II.G.2.c. of the CY 2025 PFS proposed rule). As such, we proposed that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with these other services: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits. Given that we have intentionally designed the elements of APCM services to track closely with the elements of several other care management service and CTBS codes, these services are substantially duplicative of APCM services. Further, these specific services (shown in Table 26) are duplicative with APCM services because there is significant overlap in the patient populations included in the code descriptors for these services and APCM services, such as patients who have chronic conditions, high-risk conditions, or both complex and chronic conditions.

TABLE 26: Care Management and CTBS which are Substantially Duplicative of APCM Services

Service	Description
Care Management Services (12 CPT Codes)	
Chronic Care Management (CCM) (CPT Codes 99487, 99489, 99490, 99491, 99439, 99437)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Principal Care Management (PCM) (CPT Codes 99424, 99425, 99426, 99427)	Management of all care for patients with one serious chronic condition, timed, per month
Transitional Care Management (TCM) (CPT Codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit (bundled into payment for the code), once per patient within 30 days post-discharge
Communication Technology-Based Services (15 CPT Codes)	
Interprofessional Internet Consultation (IPC) (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452)	Consultations between or among certain kinds of medical practitioners.
Remote Evaluation of Patient Videos/Images (HCPCS code G2250)	Remote evaluation of recorded video and/or images submitted by patient
Virtual Check-In (HCPCS codes G2251, G2252)	Virtual check-in service to decide whether an office visit or other service is needed
Online Digital E/M (e-Visit) (CPT codes 98970, 98971, 98972, 99421, 99422, 99423)	Communication between patient and their provider through an online patient portal

As we have described in the sections earlier, comprehensive care management services are essential to providing advanced primary care in the context of this proposal, and many of the service elements for CCM/PCM/TCM shown in Table 23 are substantially the same as the elements we proposed for APCM services.

Also described earlier, providing CTBS is an essential element of the delivery of care under an advanced primary care model of care. Recognizing this, we designed the APCM service elements to substantially overlap with the elements of the CTBS (for example, interprofessional consultation and e-Visits) shown in Table 26. CTBS are used in delivery of advanced primary care to maintain ongoing communication with patients and enable interprofessional care teams to provide comprehensive support to manage chronic conditions over time, which will allow patients to access their usual source of care more conveniently.[101] Furthermore,

[101] Levine DM, Linder JA. Retail Clinics Shine a Harsh Light on the Failure of Primary Care Access. J Gen Intern Med. 2016;31(3):260–262.; Dorsey ER, Topol EJ. State of Telehealth. N Engl J Med. 2016;375(2): 154–161.; Powell, Rhea E., et al.

Continued

interprofessional consultation can help promote integration of behavioral health and primary care.[102]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were mixed on many of our proposals. Many commenters did not agree with our proposed concurrent billing restrictions for the codes shown in Table 26 by a practitioner in the same practice as a practitioner who is furnishing APCM services for the patient. Some commenters pointed out that specialists within large hospital systems or multispecialty clinics may fall under the ''same practice'' restriction; these commenters also suggested that beneficiaries receiving APCM services from their primary care practitioner should still be eligible to receive PCM and many of the interprofessional consultation services furnished by specialists if needed to augment a beneficiary's care. One commenter stated that a patient may be receiving APCM services from their primary care practitioner but receiving PCM from their cardiologist who works for the same practice and was concerned the proposed concurrent billing restriction would impede the beneficiary's care. Other commenters expressed similar concerns regarding our inclusion of all of the interprofessional consultation codes, again stating that these codes are most often used by consulting specialists, and expressing concern that limiting these concurrent billing for these codes may have a cooling effect on specialists willing to provide consultations.

Most commenters agreed that CCM and TCM were duplicative with APCM if performed by the same practitioner. A few commenters stated that TCM may be duplicative, but that it depends on the reason for the hospitalization. For example, if a patient is hospitalized for cancer treatment or a surgery, it may be an oncologist or surgeon performing TCM, rather than the primary care practitioner performing APCM.

Response: Our intention in proposing the concurrent billing restrictions for APCM services and the identified codes was to prevent duplicative payment for advanced primary care services by multiple practitioners in the same practice. However, we agree with commenters who recommended that specialists should still be able to furnish the services listed in Table 26 concurrently to patients receiving APCM from another practitioner, when medically reasonable and necessary. We recognize that there are clinical circumstances where a specialist would be the practitioner who furnishes and primarily oversees the care of a beneficiary during one or more months. For example, an oncologist could primarily manage care, including providing TCM services, for a patient who is recently discharged after an admission related to chemotherapy side effects while another practitioner in the same practice could appropriately continue to furnish APCM services for the same patient during the same month. We agree with commenters that the services listed in Table 26 are not necessarily duplicative when billed by another practitioner in the same practice as the practitioner who is billing for APCM services, and accordingly, are finalizing a modified policy. After consideration of public comments, we are not finalizing the concurrent billing restrictions, except with respect to the one practitioner who is furnishing APCM services. The services listed in Table 26 may not be billed for a patient in the same month with APCM services by the same practitioner but may be billed when medically necessary for a patient in the same month by a practitioner other than the practitioner furnishing APCM services (HCPCS G0556, G0557, and G0558). We remain committed to engaging with interested parties on these policies, and we may examine these requirements further in future rulemaking.

We also considered whether other care management services (such as Behavioral Health Integration (BHI)), services addressing HRSNs (Community Health Integration (CHI), Social Determinants of Health Risk Assessment, and Principal Illness Navigation (PIN)), and/or other CTBS (Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM)) would be duplicative of the APCM services. These services, when appropriate, may complement APCM services rather than substantially overlap or duplicate services, and that these other services are sufficiently different from the APCM services in the nature and extent of the interventions and the qualifications of individuals providing the services, to allow concurrent billing for services when appropriate. While these may be services that a practitioner using the advanced primary care model will be likely to furnish, when appropriate, they are not part of the core, routinely and universally essential elements of the advanced primary care model. Several of these other services (such as BHI, CHI, SDOH Risk Assessment, and PIN) could be supplemental to APCM for patients that have specific identified health care needs.

We sought more information from interested parties through our Advanced Primary Care RFI about whether to consider incorporating additional service elements into the ACPM service elements and valuation for APCM codes; and whether and, if so, how to best incorporate E/M services into future coding (see section II.G.3. of this proposed rule). We note that, for BHI services, there is an established evidence base for approaches to caring for beneficiaries with behavioral health conditions which involve integration in the primary care setting, are typically provided by a primary care team, and include structured care management with regular assessments of clinical status and modification of treatment. BHI is a term that refers broadly to collaborative care that integrates behavioral health services with primary care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. For BHI in particular, including CPT codes 99492, 99493, 99494, and 99484 and HCPCS code G0323, we also sought information regarding how evolving changes in practice may warrant reconsideration of payment and coding policies.

We proposed that the care management and CTBS codes that are identified in Table 23 could not be separately billed with the APCM codes for the same beneficiary by the same practitioner, or a different one within the same practice, for the same service period. As explained previously, we are modifying this proposal to apply the concurrent billing restrictions for these codes only to the practitioner who bills for APCM services. We stated that we believed this would prevent duplicative payments for substantially similar services and would also be consistent with how we have paid for potentially overlapping care management services in the past.

As we refine our APCM policies, we note that we did not propose to make changes to the coding and payment policies for the existing care management and CTBS services, other than to prohibit concurrent billing for the same patient during the same month. For CY 2025, those codes will

''Patient perceptions of telehealth primary care video visits.'' The Annals of Family Medicine 15.3 (2017): 225–229.

[102] We are planning a separate proposal on expanding who can bill for IPC, including clinical psychologists, LCSWs, marriage and family therapists (MFTs), and MHCs; see further discussion in section II.I. of this final rule.

still be available for practitioners who do not furnish care using the advanced primary care model or who may find that the existing care management and CTBS codes best describe the services they furnish.

We also sought comment on potential overlap between APCM services and other services, including but not limited to care management and care coordination and other CTBS. If interested parties identify overlaps between APCM and other services, we sought comment on whether the degree of overlap will warrant a policy to restrict the services from being billed concurrently with APCM. We also sought comment on whether any overlap will depend upon whether the same or a different practitioner reports the services.

As we test new CMS Innovation Center models that include payments for the services defined earlier, including CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient videos/images, virtual check-in, and e-visits, or as changes in the advanced primary care model of care or more general changes to Medicare payment policy take place that affect existing CMS Innovation Center models, consistent with existing policy, we will address potential overlaps between payments made to model participants with our payment for APCM, elements of the proposed APCM service, and these duplicative services, and seek to implement appropriate payment policies.

We received public comments on these considerations. The following is a summary of the comments we received and our responses.

Comment: Nearly all commenters were supportive of our proposal to allow concurrent billing of BHI, CHI, PIN, PIN–PS, and the SDOH Risk Assessment with APCM services. Commenters agreed that these services are unique and serve specific needs not otherwise met by the proposed APCM coding. Many commenters discussed the importance of behavioral health (including mental health and substance use disorders) on overall health and urged us to consider including behavioral health in future rulemaking as it relates to advanced primary care citing the growing need for fully integrated physical and behavioral health. These commenters also urged us to examine utilization of APCM services in conjunction with BHI, PIN, and PIN–PS, to inform future work. One commenter requested clarification on whether the Psychiatric Collaborative Care Model (CoCM) codes could be billed in conjunction with APCM.

Response: We agree with commenters that these services are complementary to APCM services, and do not represent duplication of services as long as time and effort involved in furnishing these services are not counted more than once, requirements to bill the other services are met, and the services are medically reasonable and necessary. We also agree with commenters that behavioral health is important in the context of overall health, and we will take comments recommending strategies for further integration into consideration for future rulemaking. We are also clarifying that the BHI codes paid under the PFS (CPT codes 99492, 99493, 99494, and 99484 and HCPCS code G0323), including CoCM, can be billed concurrently with the APCM codes when all applicable requirements for billing both codes are met. As we stated in the CY 2025 proposed rule, for BHI services, there is an established evidence base for approaches to caring for beneficiaries with behavioral health conditions which involve integration in the primary care setting, are typically provided by a primary care team, and include structured care management with regular assessments of clinical status and modification of treatment. BHI is a term that refers broadly to collaborative care that integrates behavioral health services with primary care. BHI is a team-based approach to care that focuses on integrative treatment of patients with medical and mental or behavioral health conditions. We continue to be interested in the use of BHI services as they relate to advanced primary care and welcome input from interested parties, including how evolving changes in practice may warrant reconsideration of payment and coding policies.

Comment: Some commenters expressed that RTM and RPM should not be included within the APCM codes, but rather billed separately as complementary, non-duplicative services. A few commenters stated that RTM and RPM services are not core services that are routinely and universally essential elements of advanced primary care models and should therefore not be included in the definition of APCM. One commenter asserted that these services are not likely to be furnished by the types of practitioners who would also furnish advanced primary care services.

Response: We agree with commenters that RTM and RPM services are complementary to APCM services, and do not represent duplication of services, as long as time and effort involved in furnishing these services are not counted more than once, requirements to bill the other services are met, and the services are medically reasonable and necessary. While we agree with the commenter that these services may not be part of the core, routinely and universally essential elements of the advanced primary care model, we disagree that these services are unlikely to be furnished by a practitioner also furnishing advanced primary care services. We are finalizing our policy that RTM and RPM services can be billed concurrently with APCM services when all applicable requirements for billing both services are met. We continue to be interested in the use of RPM and RTM services as they relate to advanced primary care and welcome input from interested parties.

After consideration of public comments, we are finalizing our proposal to allow concurrent billing for BHI, CHI, PIN, PIN–PS, the SDOH Risk Assessment, RPM, and RTM services in the same month as APCM services. We remain committed to engaging with interested parties on these policies, including whether there is overlap between APCM services and other services and whether to consider incorporating additional service elements into the APCM service elements and valuation for APCM codes, and we may examine these policies further in future rulemaking.

e. Valuation of APCM Services—HCPCS Codes G0556, G0557, and G0558

To improve the accuracy of payment for the kinds of services furnished as part of advanced primary care and reduce the administrative burden associated with current coding and billing rules, we proposed to create three HCPCS codes to use for reporting the APCM service (HCPCS codes G0556, G0557, and G0558) (sections II.G.2.b. and II.G.2.c. of the CY 2025 PFS proposed rule). Although these codes are unique in that they would be created to differentially pay for advanced primary care management, the APCM services incorporate elements of existing services with the understanding that some patients will require more resources and some fewer based on variability in patient complexity and needs (see section II.G.2.b. of the CY 2025 PFS proposed rule). As we ordinarily do, we proposed to base the PFS valuation for APCM codes on the resources involved in furnishing the typical case of the service which may not necessarily reflect the actual resources involved in furnishing every individual service.

We detailed our methods to identify a typical case and set of resources involved in furnishing APCM, and the

valuation of these codes. To value APCM, we compared the service elements described by the APCM codes to the values we have established for the specific care management and CTBS codes on which we modeled the service elements of the APCM codes and which we built into the service descriptors for HCPCS codes G0556, G0557, and G0558 (see Table 23 and sections II.G.2.b. through II.G.2.d. of the CY 2025 PFS proposed rule). As stated above, the elements of APCM services reflect the comprehensive approach to care management involved in care delivery using the advanced primary care model. This is a model of primary care that is being integrated into current medical practice. As such, we stated that it would be appropriate to use the current valuation and uptake of the codes on which we modeled the APCM codes to inform our valuation of APCM services. Using Medicare FFS claims data and evidence from our primary care models, we sought to understand how these different services have been used historically and relate that information to the way we think about the service elements for APCM and the valuation of the three APCM code levels. We know that for Medicare beneficiaries who receive care management services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those five months. We also know that initial information from practitioner interviews conducted as part of our CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold time for billing the non-complex CCM base code; typically, these practitioners reported spending between 45 minutes and an hour per month on CCM services for each patient, with times ranging between 20 minutes and several hours per month (81 FR 80244). However, this does not account for the care management services that are provided beyond one time-based billing interval and without reaching the next; nor does it account for the resources involved in maintaining certain advanced primary care practice capabilities and continuous readiness and monitoring activities, including patient population monitoring and care needs assessment, to fully furnish and bill APCM services as is medically reasonable and necessary for any individual patient during any calendar month. Finally, this does not account for changes to utilization of APCM that may occur as a result of the billing and documentation requirements for APCM services when compared to the current coding and payment for care management and CTBS services. While our aim is to value APCM services based on refined assumptions that better recognize likely utilization of the new codes and the work required to furnish APCM services, this is challenging without more information. We welcomed comments on ideas for other sources of data that would help us to assess APCM services valuation.

We considered various alternatives for valuing the APCM services and how these may impact the broader health care landscape given that primary care is of such import across the country. We proposed to set baseline APCM code values for this first year based on historical utilization of the care management services we have drawn upon in designing the APCM codes. We noted that utilization of the care management services has been significantly higher than CTBS, and we found that CTBS are not typically billed for a patient in the same month as care management services. It is unclear whether the kinds of services described by the CTBS are not typically provided during these months or whether they are being provided but not separately reported. We will continue to seek information, including from public comments on the proposed rule, to help us identify the best approach to reflecting the proposed CTBS elements incorporated into the APCM monthly bundle, and we remain interested in data that could illuminate differences between what services are furnished and what is being reported separately.

We will continue to consider refinements to the valuation of APCM codes to reflect available information about changes in the volume and mix of care management and communication activities being furnished as part of APCM services in the delivery of advanced primary care.

We received many public comments on our proposed valuation. Following is a summary of comments received and our responses.

Comment: We received many comments in response to our request for other sources of data that would help us assess the valuation for APCM. Commenters expressed concerns with using the RUC as the basis for this information, citing underrepresentation on the RUC for primary care and historical underpayment of primary care services. Many commenters stated the need for empirical data for physician work, time and practice expense requirements for APCM services, with a few commenters discussing the challenge of adequately accounting for the resource costs associated with care management services and the use of team-based care. Many commenters discussed the need for time studies to validate valuation, and others stated there is a need for more research into primary care services that are not currently recognized for payment. One commenter suggested that physician time studies be conducted utilizing time stamp data from EHRs to accurately log how long practitioners spend on documentation. A few of the commenters asked us to conduct these studies, with another commenter asking us and Congress to undertake this work.

Response: We value the work and effort the RUC undertakes to provide us with data and recommendations for valuing services under the PFS, and we also remind commenters that we do not exclusively rely on RUC recommendations and can receive data and recommendations from other outside sources as well. We also agree with commenters that empirical information about how primary care services are provided would be invaluable to assist us in making refinements to payment for APCM services to improve accuracy. We are especially interested in practice-level data that are empirical, routinely updated, able to be audited, and comprehensive. We are also open to receiving partial information, and we note that interested parties can submit information to us through the potentially misvalued codes process that is described in Section II.C. of this final rule. We note that submissions for consideration in our next annual rule cycle should be received by our February 10th deadline. For example, this could include information related to the practice expense involved in furnishing these services, such as the types of clinical staff, disposable supplies, and equipment, as well as the physician or practitioner work involved in furnishing these services. We note that the CY 2025 PFS public use files, which are available on the CMS website under downloads for the CY 2025 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*, include a sample PE spreadsheet and a sample work spreadsheet.

Additionally, we are open to alternative recommendations for how to price these and other services, and we will consider all options presented to us, with a preference for information with empirical evidence behind it. We welcome interested parties to engage with us on how external data sources could be developed and leveraged.

Comment: Commenters generally suggested that the proposed valuation for APCM services underestimated the time and resources involved in providing the activities required under APCM such as 24/7 access to care, patient population-level management, and performance management. Commenters also stated concern with the increased costs of staff and infrastructure potentially associated with performing APCM. Commenters stated that with the low valuation proposed, practitioners would continue to choose existing care management codes or other PFS services, resulting in low uptake for APCM. Still others were concerned that inadequate payment could discourage provider participation, particularly in underserved areas where the need for comprehensive, team-based care is greatest. These commenters stated that smaller practices in rural areas may lack the potential to benefit from economies of scale to support the infrastructure necessary to meet APCM requirements.

Response: We generally agree with commenters that these services may be undervalued, given the time and resources that are necessary for the provision of advanced primary care, but we also recognize there could be a wide range of potential resource costs, especially during the initial use of the codes. Consequently, we may revisit valuation of these APCM services in future rulemaking. As previously described, if interested parties submit additional data and information upon which to base revised valuation assumptions, that information could form a basis upon which we could refine values for the APCM codes through future rulemaking. We appreciate that the scope and service elements for APCM are more expansive than existing CCM and PCM coding; however, we recognize that some beneficiaries will need more services and some less, and thus, as we ordinarily do, we proposed to value these services based upon the typical service. We agree with commenters that ensuring that these services are available to rural and underserved populations is an important priority. We may consider making refinements to the valuation, billing rules, and documentation requirements through future rulemaking, as necessary.

Comment: Commenters discussed our valuation methodology, urging us to avoid continuing what they view as underinvestment in primary care by valuing APCM services with reference to CCM services. Commenters also stated that CCM is not a correct reference for valuation of APCM services as CCM does not include all the service elements required for APCM. Other commenters recommended we use CMS Innovation Center model per beneficiary per month (PBPM) payments and conduct greater research to determine more appropriate payment rates. Commenters also discussed valuation in the context of concurrent billing restrictions, with some commenters citing the inclusion of CTBS and interprofessional consultation services for which payment rates are in some cases higher than the monthly rate for APCM.

Response: We continue to believe that the most accurate mechanism for determining the appropriate work RVU for this service is to refer to values established for existing CPT codes. We note further that using CCM codes as a reference to value the APCM codes would have the benefit of assuring appropriate relativity with similar services.

Comment: We also received comments that were in favor of our proposed valuations. A few commenters recommended that we finalize as proposed and monitor utilization as the codes are implemented. Another commenter recommended that we finalize as proposed, even if the code descriptors and associated payment rates need to be refined in the future as interested parties gain experience with the new codes and provide feedback.

Response: We agree with commenters that the valuation of these services is likely to be an iterative process, and we may revisit our valuation of these codes in future rulemaking.

(1) APCM Level 1 (HCPCS Code G0556)

For APCM Level 1, we assume the typical case will involve fewer resources than the current care management services based upon the G0556 code descriptor and a broad eligible population that will require limited monthly APCM services; however, it will also involve certain resources inherent to maintaining advanced primary care practice capabilities and continuous readiness and monitoring activities, including patient population monitoring and care needs assessment, to fully furnish and bill APCM. As described in sections II.G.2.b. and II.G.2.c. of the CY 2025 PFS proposed rule, certain elements of the APCM service require resources to maintain continuous readiness and monitoring activities to furnish covered services consistent with the advanced primary care model of care. We concluded that the APCM Level 1 services will be similar in work to that of two billing units of the non-complex code for CCM services (CPT code 99490 (*CCM services provided by clinical staff per calendar month*)) over the course of a year, and therefore based the inputs on CPT code 99490 multiplied by ⅙ (or 2 units over 12 months). Specifically, we propose a work RVU for G0556 of 0.17, which is the work RVU for CPT code 99490 multiplied by ⅙. The resulting PE and MP RVUs are proportionately similar to those for CPT code 99490 and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[103] Table 27 displays payment amount estimates using the 2024 PFS Conversion Factor.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed concerns that the proposed valuation of G0556 would be inadequate to support the work and necessary infrastructure of this care delivery model. Several commenters pointed out that the proposed work RVU of 0.17 for G0556 is significantly lower than or similar to the work RVUs for the following duplicative component services that cannot be billed during the same period with APCM: CPT code 99426 (*PCM, first 30 minutes*) which has a work RVU of 1.00 and CPT code 99427 (*PCM, each additional 30 minutes*) which has a work RVU of 0.71, and these codes would be appropriate for managing similar patients as G0556. Another commenter stated that HCPCS code G2012 (*Virtual check-in*), which is a type of CTBS that cannot be billed concurrently with APCM is reimbursed at a national rate of $13.81, which is less than the proposed rate for one month of care as described by HCPCS code G0556. Several commenters also asserted that HCPCS code G0556 would result in more billing and administrative costs than would be covered by the proposed $10 payment, leading to decreased uptake. A few commenters also discussed a ''payment gap'' between G0556 and G0557, stating that the difference in both work and practice expense (PE) between the two codes is not as disparate as a $40 change in payment suggests.

Response: We are sensitive to the administrative burden of new coding and payment and sought to reduce administrative burden through the use of bundling elements of existing codes

[103] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

for APCM. We appreciate the commenters' thoughts on the investments required to perform APCM in general, and we understand the commenters' perspectives about the ''payment gap'' between two codes that require the same level of practice capabilities. We look forward to continuing to engage with interested parties as these codes are billed, and we remain open to feedback on how to best value these codes in future rulemaking.

Comment: Commenters had several proposed solutions to increase the valuation of HCPCS code G0556. Several commenters suggested that we increase the work RVU for G0556 to 0.77, equal to that of G0557, to reflect the equivalent physician time required when managing any number of chronic conditions and to better align with existing work RVUs for CCM and PCM. Another commenter suggested we align the valuation of HCPCS code G0556 to the population-based payments made under the Primary Care First (PCF) model. Another commenter agreed that we should use PCM and the PCF model's payments as benchmarks but instead suggested that we increase the work RVU for G0556 to 0.25, equal to three billing units of CPT code 99490 over an annual period, or 60 minutes of physician work in CCM equivalents. This commenter also suggested that the proposed work RVU of 0.17 underestimates the physician work required to establish and maintain these plans of care, even if many service elements are not performed every month. This commenter estimated that the creation of a care plan as described in the service elements would take between 20 and 40 minutes, which they viewed as incompatible with our proposal of estimating 2 units of 99490 or 40 minutes of work time spread over 12 months.

Another commenter argued that the assumption that Level 1 APCM services would be similar in work to that of two billing units of CPT code 99490 over the course of a year is flawed, as it assumes a ''sick care'' model of care delivery rather than one focused on prevention. Several commenters also pointed out that the infrastructure required to furnish all of the practice elements must be in place even if that beneficiary does not need those services that month and that this was especially true for beneficiaries receiving G0556.

Response: We appreciate the alternate methods suggested by commenters, and we are persuaded that the proposed rate for G0556 would not fully capture the relative resource costs involved in providing continuous, ongoing care management through an advanced primary care model of care delivery. We agree with commenters that the methodology suggested of increasing HCPCS code G0556 to the equivalent of three units of 99490 divided over 12 months would better account for the work and PE involved in furnishing APCM services.

After consideration of public comments, we are increasing the valuation of HCPCS code G0556 to reflect the equivalent of three units of 99490 or 60 minutes of work time in CCM equivalents divided over 12 months, or approximately $15 per month. This represents a work RVU of 0.25. We recognize this is a relatively modest increase in valuation for G0556, and we may revisit the valuation of this and other APCM codes in future rulemaking.

(2) APCM Level 2 (HCPCS Code G0557)

For APCM Level 2, which describes APCM services to patients with two or more chronic conditions we assumed the typical, higher intensity work associated with managing a patient with multiple chronic conditions will involve significantly more resources and require more, and more frequent, APCM service elements. We concluded that the APCM Level 2 services will be similar to current utilization assumptions of five billing units of the non-complex CCM code (CPT codes 99490) (*CCM services provided by clinical staff per calendar month*) and three billing units of add-on codes annually, given that, for Medicare beneficiaries who receive these CCM services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those 5 months. Additionally, we proposed to account for continued underutilization of CCM services in this patient population by adding one billing unit of the complex CCM code (CPT code 99490 (*CCM services provided by clinical staff per calendar month*) annually. As we noted in the CY 2020 PFS final rule, ''utilization [of CCM services] has reached approximately 75 percent of the level we initially assumed under the PFS when we began paying for CCM services separately under the PFS; while these are positive results, this evidences that CCM services (especially complex CCM services) continue to be underutilized,'' as discussed in the CY 2020 PFS final rule (81 FR 80244 and 84 FR 62688), considering the number of eligible Medicare beneficiaries. In 2019, approximately 22.6 million FFS beneficiaries were identified as being potentially eligible for CCM (or 63.4 percent of the 35.6 million Medicare FFS beneficiaries); however, the use of CCM services was low among potentially eligible beneficiaries, such that just 4.0 percent of beneficiaries potentially eligible for CCM received any CCM services.[104] Therefore, we based the proposed inputs on CPT code 99490 multiplied by 5/12 (or, five units over 12 months), plus CPT add-on code 99439 (*CCM services each additional 30 minutes by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by 1/6 (or two units), plus CPT add-on code 99489 (*Complex CCM services each additional 30 minutes by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by 1/12 (one unit), plus CPT code 99487 (*Complex CCM services provided by clinical staff directed by a physician or other qualified health care professional, per calendar month*) multiplied by 1/12 (one unit). Specifically, we proposed a work RVU for G0557 of 0.77, which is the sum of the work RVU for CPT codes 99490, 99439, 99489, and 99487 multiplied by their respective proportions above. The resulting PE and MP RVUs are proportionately similar and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[105] Table 27 displays payment amount estimates using the 2024 PFS Conversion Factor.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters appreciated our attempt to account for the underutilization of CCM services in the proposed valuation, but one commenter asserted that those adjustments still only account for the resources associated with CCM and not the increased work or practice expenses incurred with maintaining practice-level advanced primary care capabilities or providing APCM services to more beneficiaries.

[104] *The determination of potential eligibility for CCM was based on presence of two or more Chronic Condition Warehouse (CCW) chronic condition flags, one of which was hypertension, hyperlipidemia, or diabetes. Beneficiaries on Medicare Advantage, with end stage renal disease (ESRD) or using the hospice benefit were excluded. ASPE. Analysis of 2019 Medicare Fee-for-Service (FFS) Claims for Chronic Care Management (CCM) and Transitional Care Management (TCM) Services. March 2022. https://aspe.hhs.gov/sites/default/files/documents/31b7d0eeb7decf52f95d569ada0733b4/CCM-TCM-Descriptive-Analysis.pdf.*

[105] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

Like HCPCS code G0556, several commenters pointed out that the proposed work RVU of 0.77 for HCPCS code G0557 is lower than for the following duplicative component services that cannot be billed during the same period with APCM: CPT code 99426 (*PCM, first 30 minutes*) which has a work RVU of 1.00; CPT code 99427 (*PCM, each additional 30 minutes*) which has a work RVU of 0.71; CPT code 99490 (*CCM, clinical staff first 20 minutes*) which has a work RVU of 1.00; and CPT code 99439 (*CCM, clinical staff each additional 20 minutes*) which has a work RVU of 0.70. Commenters assert that the proposed HCPCS code G0557 closely resembles CPT codes 99490 and 99439 for CCM, as all three codes would apply to care management for patients with two or more chronic conditions. One commenter recommended that payment of G0557 be equal to or greater than CPT code 99490. Another commenter asserted that the proposed valuation for G0557 does not account for the extensive work in creating a comprehensive care plan, citing that this was an initial barrier when the care management codes were first introduced and improved somewhat once the guidelines became less prescriptive.

Another commenter was concerned about an inconsistency between the assumptions underlying valuation and those underlying our utilization estimates for the services. The commenter explained that for purposes of estimating utilization, we assumed that beneficiaries who receive APCM services will do so for 12 months each year; however, the valuation methodology assumed beneficiaries receive only a fraction of that—for example, the proposed inputs for G0557 were based on CPT code 99490 multiplied by 5/12, CPT add-on code 99439 multiplied by 1/6, CPT add-on code 99489 multiplied by 1/12, and CPT code 99487 multiplied by 1/12. From their perspective, it seems unreasonable to expect practices to maintain APCM capabilities and provide APCM services for 12 months while setting the value of those capabilities and services at a fraction of that time.

Response: We thank commenters for their feedback. We continue to reiterate that because the APCM codes are a bundle of existing care management and other services, not all of which would be furnished in each month in which the APCM services are billed, and the estimates of utilization of services are divided across the span of 12 months, we believe that our proposed valuation reference is an appropriate approach to estimate the work, time, and intensity of HCPCS code G0557. We also reiterate our assumption that beneficiaries receiving APCM services may not require any services one month and may have increased utilization the next month. We are attempting to reflect the varying care needs of the beneficiary, with an understanding that needs often ebb and flow over a period of months for which APCM services are furnished. As discussed previously, we appreciate that APCM services require different practice capabilities as compared to other care management services and may revisit valuation of all APCM services in future rulemaking.

After consideration of public comments, we are finalizing the valuation of G0557 as proposed. We are finalizing the proposed work RVU of 0.77.

(3) APCM Level 3 (HCPCS Code G0558)

For APCM Level 3 (HCPCS code G0558), which describes APCM services to patients with QMB status and two or more chronic conditions, we proposed to value the service as a relative increase to the valuation of APCM Level 2 based on recent Medicare expenditure data for dually eligible Medicare beneficiaries. In CY 2021, per person per year spending on dually eligible beneficiaries was $24,370 and for non-dually eligible beneficiaries was $11,172. The difference between these two amounts is 218 percent. We have considered the likely resource demands and intensity of the practitioner-patient interaction for this patient population, consistent with our coding and valuation policies that reflect variations in resource cost and patient-centered care delivery policies.[106] By taking into consideration the difference in Medicare spending on a per person per year basis between dually eligible and non-dually eligible Medicare beneficiaries, we can capture the increased resources involved in furnishing APCM services to patients with QMB status and multiple chronic conditions. Therefore, we based the inputs for the APCM Level 3 code on the APCM Level 2 inputs multiplied by 218 percent. Specifically, we proposed a work RVU for G0558 of 1.67, which is the work RVU for G0557 multiplied by 218 percent. The resulting proposed PE and MP RVUs are proportionately similar to those and are available in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).[107] Table 27 displays payment amount estimates using the 2024 PFS Conversion Factor.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most of the comments we received about the valuation of HCPCS code G0558 were in conjunction with comments about expanding or changing our proposed population for HCPCS code G0558 and did not provide specific valuation recommendations. A few commenters thanked us for this proposal and hoped that including QMBs specifically would incentivize practitioners to care for this population. Other commenters stated that CMS Innovation Center models like Primary Care First (PCF) and Comprehensive Primary Care Plus (CPC+) make high complexity payment rates of $200-$250, and these commenters recommended we align G0558 with these values.

Response: We appreciate the reference to various CMS Innovation Center models. We note that each of the models targeted specific patient populations with different approaches and payment methodologies, serving a different but complementary purpose than the coding and payment policies for APCM services. We share the hope of commenters that HCPCS code G0558 will encourage practitioners to furnish APCM services to this population. As discussed previously, we may revisit APCM service valuations in future rulemaking.

After consideration of public comments, we are finalizing the valuation of G0558 as proposed. We are finalizing the proposed work RVU of 1.67.

Table 27 includes the finalized codes, short descriptors, reference codes, work RVUs, and approximate payment rate. For illustration purposes, we multiplied the APCM relative values for work, practice expense (PE), and malpractice (MP), without geographic adjustment, by the CY 2024 conversion factor (CF) ($32.7442) to convert the relative value units (RVUs) into approximate national payment rates.

[106] *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsData Book-508.pdf.*

[107] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

TABLE 27: Final APCM Bundled Codes and Valuation

Code	Short Descriptor	Reference Codes	CMS Work RVU	Approximate National Non-Facility Rate
G0556	APCM for patients with up to one chronic condition	99490	0.25	$15
G0557	APCM for patients with multiple (two or more) chronic conditions	99490, 99439, 99487, 99489	0.77	$50
G0558	APCM for QMBs enrollees with multiple chronic conditions	Calculated as a relative increase from G0557	1.67	$110

We sought feedback on whether these values appropriately reflect the resource costs involved in furnishing these services, or whether adjustments to the values or additional coding may be needed. We are broadly interested in public comments and input from interested parties on potential refinements in code and service definitions, including how we might refine our utilization assumptions for these codes, and other important information involving coding and payment for APCM services to better reflect the current practice of advanced primary care, including elements of CTBS and care management services. We are interested in developing a better understanding of the resource costs involved in furnishing comprehensive care management as part of advanced primary care to various patient populations, including specifically QMBs.

We intend to engage in further discussions with the public over the next several years to potentially refine our policies for future years, and we expect that having APCM utilization data, once the codes are established, will inform future refinement of the valuations for these codes.

Finally, as described in the Advanced Primary Care RFI that follows, we note that there is potential for the valuation of these codes and future related codes to change and/or scale into larger units if we expand them to incorporate more service elements (see section II.G.3. of the CY 2025 PFS proposed rule). As we receive more information about how these codes are being used and implemented in medical practice, we anticipate that these codes and future related codes will be refined over time. We note that the development of payment and coding policies for these and other kinds of services under the PFS is typically an iterative process that responds to changes in medical practice and may be best refined over several years through annual rulemaking for the PFS, and through the development of CPT codes by the AMA's CPT Editorial Committee.

As described in the next section (see also section XXX of the CY 2025 PFS proposed rule), this new APCM code set can serve as a chassis to incorporate primary care model learnings over time under the PFS and an additional pathway to accountable care for primary care practitioners.

3. Request for Information: Advanced Primary Care Hybrid Payment

a. Background

Recent evidence reviews show that while primary care is the only part of the health system in which investments routinely result in not only improved outcomes but also increased equity,[108] the practice and sustainability of the primary care sector is under significant strain.[109] The NASEM found that many of these challenges relate to a primary care payment system that principally rewards visit volume versus creation and maintenance of longitudinal [110] care relationships over time.[111] We have set a goal of having 100 percent of traditional Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030. Accountable care occurs when a person-centered care team takes responsibility for improving quality of care, care coordination and health outcomes for a defined group of individuals, to reduce care fragmentation and avoid unnecessary costs for individuals and the health system.[112] Advanced primary care is a core mechanism for achieving this goal. With this goal, we acknowledge the need to increase the capability of primary care clinicians to engage, maintain, and promote longitudinal and accountable relationships with beneficiaries through incentives and flexibilities to manage quality and total cost of care.

Over the past 11 years, the CMS Innovation Center has tested a number of primary care models: CPC, CPC+, Maryland Primary Care Program, PCF, as well as the upcoming MCP and ACO Primary Care Flex. Each of these primary care models has focused on testing what happens when we pay for primary care services with hybrid payments (a mix of fee-for-service and population-based payments), as described earlier. While these models have not met the criteria for expansion to date, the findings suggest advanced primary care may reduce unnecessary utilization and improve diabetes care and cancer screening rates.

In addition to testing new approaches to improve care for beneficiaries by supporting primary care, we have focused on approaches to incorporating these innovations into Medicare programs. For example, lessons learned from the CMS Innovation Center's ACO models may be incorporated into the Shared Savings Program. As such, part of the intent of our proposal to create new APCM payment and coding was that we would have a similar foundation to scale advanced primary care model learnings over time.

Previous Innovation Center primary care model tests have helped us learn lessons to inform our current and future work. For example, participants in primary care models have indicated difficulty investing in and maintaining primary care redesign activities due to a range of challenges. First, additional non-visit-based primary care payments have been generally layered upon base

[108] National Academies of Sciences, Engineering, and Medicine (NASEM); Implementing High-Quality Primary Care (*https://nap.nationalacademies.org/read/25983*).

[109] Milbank Memorial Fund, The Health of US Primary Care: 2024 Scorecard (*https://www.milbank.org/wp-content/uploads/2024/02/Milbank-Scorecard-2024-ACCESS_v06.pdf*).

[110] Longitudinal care management is long-term, proactive, relationship-based care management that augments routine and acute visits with intentional, proactive outreach, especially during times of illness and transitions of care.

[111] NASEM, Implementing High-Quality Primary Care (*https://nap.nationalacademies.org/read/25983*).

[112] *https://www.cms.gov/priorities/innovation/key-concepts/accountable-care-and-accountable-care-organizations.*

payments still predominantly FFS in structure. As such, the incentives and abilities of practices to focus on proactive, population-based non-visit activities may be limited if the funding stream for these activities is limited in scope and duration.[113] [114] (Examples of non-visit-based activities include, but are not limited to: activities to improve care coordination, implement data-driven quality improvement, or enhance targeted care management for beneficiaries identified as high-risk.) Further, model funding for the clinical and administrative staff needed to accomplish advanced primary care coordination and population health functions is contingent on continued participation in these models.[115] Once the models end, practices are left without the funding that they received under the models for the clinical and administrative staff that had supported population health functions under the model. Moreover, because these models involve additional payments tied to performance rather than changes to base primary care payment, practices report that the funding they use to support non-visit activities is sometimes received well after the non-visit services have occurred, leading to further challenges sustaining these efforts fiscally. Solving these challenges is a key goal of future Innovation Center model work.[116]

To strengthen the primary care infrastructure within FFS Medicare, we explored opportunities to create new sustainable pathways to support advanced primary care, equitable access to high-quality primary care, and continued transformation among a wide variety of practices. One potential strategy to increase access to advanced primary care and prepare practitioners in traditional Medicare to engage in more accountable care is through the creation and ongoing refinement of specific billing and coding under the PFS that better recognizes advanced primary care and incorporates the resources involved in furnishing longitudinal care and maintaining relationships with patients over time. In section II.G.2. of the CY 2025 PFS proposed rule, we proposed a set of APCM services that make use of lessons learned from the CMS Innovation Center's primary care models, grouping existing care management and CTBS service elements into a bundle for use starting in CY 2025.

We sought feedback regarding potential further evolution in coding and payment policies to better recognize advanced primary care. Through this Advanced Primary Care RFI, we are committed to collaborating with interested parties to lay the path for a more transparent movement to value-based care. Specifically, we requested input on a broader set of questions related to care delivery and incentive structure alignment and five foundational components:

- Streamlined Value-Based Care Opportunities
- Billing Requirements
- Person-Centered Care
- Health Equity, Clinical, and Social Risk
- Quality Improvement and Accountability

We encouraged input on the questions in this section from diverse voices, including beneficiaries and advocates, community-based organizations, providers, clinicians, researchers, unions, and all other interested parties. We plan to summarize comments received in response to our Advanced Primary Care RFI in a separate publication, which we intend to make available via the Medicare Physician Fee Schedule website (*https://www.cms.gov/medicare/payment/fee-schedules/physician*). Below is a description of the solicitation and questions posed in the RFI.

b. Solicitation of Public Comments

We sought feedback regarding potential changes to coding and payment policies for advanced primary care services to be incorporated in traditional Medicare. For example, in the future, coding for APCM services (in section II.G.2. of the CY 2025 PFS proposed rule) could be revised to include additional service elements, including traditional E/M services. This Advanced Primary Care RFI is designed to solicit feedback on how we can further the goals of reducing administrative burden to refocus time on patient care; better recognizing the relative resources involved in furnishing care; recognizing interdisciplinary, team-based primary care; and supporting primary care sustainability and stability (especially for underserved communities). Whenever possible, respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses. We anticipate potential changes to primary care coding and payment policies, such as use of coding that recognizes groups of services furnished over a fixed time period, that will offer a new opportunity within the PFS for primary care clinicians to move to payment structures that are not fully dependent on billing for each discrete component of overall care and act as a step toward accountability for the cost and quality of patient care. Therefore, we sought feedback on building advanced primary care payment mechanisms that create pathways to recognize how primary care practice has moved away from an encounter-based orientation toward population-based care. This Advanced Primary Care RFI is the first step in ensuring ample opportunity for public input, followed by notice and comment rulemaking in subsequent years.

(1) Streamlined Value-Based Care Opportunities

We sought to create a stepping stone for primary care clinicians, including those new to value-based care, to move away from either encounters or other discrete components of overall care as the dominant method of primary care payment and toward payments in larger units that are better tied to the relative resource costs involved in population-based, longitudinal care. Feedback from interested parties has been helpful when considering how to scale the availability of payments into larger units, and incorporate population-based variability in resources, all while driving toward accountability, and person-centered care. Ultimately, to create more opportunities for beneficiaries to receive high-quality, accountable primary care, we are focused on creating multiple pathways to recognize delivery of integrated care across settings, and engagement in comprehensive, team-based, longitudinal care.

When considering the evolution of a hybrid payment system within the PFS, we sought input on the following questions:

- How can CMS better support primary care clinicians and practices who may be new to population-based and longitudinal care management?
- What are the primary barriers to providing particular strategies or supports needed for pediatric clinicians and practices?
- How can CMS ensure that potential future advanced primary care payment will not induce clinicians to leave

[113] Independent Evaluation of Comprehensive Primary Care Plus (CPC+): Final Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[114] Schurrer J, Timmins L, Gruszczynski M, et al. Evaluation of the Primary Care First Model: Second Annual Report. Mathematica. February 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[115] CMS defines population health as health behaviors and outcomes of a broad group of individuals, including the distribution of such outcomes affected by the contextual factors within the group.

[116] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

effective accountable care relationships and clinician networks that already produce positive results? Additionally, how can CMS support growth over time in existing effective accountable care relationships and clinician networks?

- Should CMS evolve the proposed APCM services into an advanced primary care payment that includes E/M and other relevant services, or maintain a separate code set for APCM?
- If E/M services are bundled together for advanced primary care payments, how can CMS ensure that there is not a disincentive for primary care clinicians to continue to provide E/M visits, or increase accountability to E/M visits as warranted?
- As many codes depend on E/M visits (for example, as the base code for an add-on code, or to initiate specific care management activities), how should CMS consider the downstream impacts of incorporating E/M visits into advanced primary care payments?
- Should CMS consider incorporating other CTBS services into advanced primary care hybrid payments, such as Remote Physiologic Monitoring and/or Remote Therapeutic Monitoring?
- Should CMS consider incorporating other services that involve comprehensive care management and care coordination, such as Behavioral Health Integration, End-Stage Renal Disease Monthly Capitation Payment (ESRD MCP), Assessment/Care Planning for Cognitive Impairment, and/or Advance Care Planning?
- Should CMS consider incorporating other services while the patient is under care of home health agencies or hospices, such as Care Plan Oversight?
- Newly finalized HCPCS codes are eligible for use by other payers, including commercial insurers, State Medicaid agencies, and others. We note that value-based alignment is a key goal of CMS. If the APCM codes are finalized, they would be eligible for use by these other payers as well. To what extent are other payers interested in adopting the APCM codes? Are there any other changes that would be necessary for other payers to adopt the codes?
- CMS has historically used information presented by the Relative Value Scale Update Committee to determine PFS payment rates. Are there other sources of data on the relative value of primary care services that CMS should consider when setting hybrid payment rates?

(2) Billing Requirements

Previous CMS Innovation Center primary care models have provided key lessons learned about how to increase comfort with population-based payments, the importance of reducing the administrative burden of billing, and how to begin addressing gaps in equitable access to population-based payments.[117] Specifically, we have learned through Innovation Center initiatives that retrospective reconciliation or adjustment of payments for services rendered can be especially frustrating for practitioners, as it reduces the predictability and stability of payments.[118]

For these reasons, we sought to understand how advanced primary care hybrid payments can balance program integrity, high-quality care, payment stability, and clinician burden.

We sought input on the following questions:

- How can CMS reduce the potential burden of billing for population-based and longitudinal care services?
- Are there particular types of items or services that should be excluded from the advanced primary care bundle?
- Are there particular services paid under the PFS today that should be included in the advanced primary care bundle?
- Care management activities are currently billed monthly. What episode lengths should CMS consider when thinking about an advanced primary care bundle of services for hybrid payment? Include evidence to support the proposed episode length.
- Should CMS attribute the advanced primary care clinical episode to a single clinician, or consider weighted attribution and payment for multiple entities or clinicians? How could weighted attribution and payment work? What rules or processes should CMS consider to attribute the episode?
- Care management coding and payment have historically required an initiating visit prior to starting monthly billing, to ensure that the services are medically reasonable and necessary and consistent with the plan of care. Are there other ways that CMS could ensure the clinician billing APCM is responsible for the primary care of the Medicare beneficiary?
- Care management coding and payment require beneficiary cost sharing. Has beneficiary cost sharing been a barrier to practitioners providing such services?
- Consistent with the initiating visit requirement in the APCM proposal, should CMS require the billing of specific qualifying services for billing of an advanced primary care bundle that is larger in scale and scope than APCM?
- Are there Health IT functions beyond what is proposed for APCM services that clinicians should be required to have to bill for an advanced primary care bundle? What should CMS consider in the design of the advanced primary care bundle to effectively incorporate Health IT standards and functionality, to support interoperability and the aims of advanced primary care?
- Should CMS limit the types of non-physician clinicians that can bill for an advanced primary care bundle that is larger in scale and scope than APCM? If so, include evidence to support the restriction.
- How should CMS reconcile instances where an advanced primary care bundle is billed, but primary care services are then billed for and provided by separate entities?

(3) Person-Centered Care

Person-centered care integrates individuals' clinical needs across providers and settings, while addressing their social needs.[119] We strive for better, more affordable care and improved health outcomes. Key to this mission are care innovations that empower beneficiaries and clinicians, while reducing the administrative burden of providing episode-based and longitudinal care management. We sought comment on how an advanced primary care code(s) could be structured to both increase efficiency and promote the use of high-value services.

We sought input on the following questions:

- What activities that support the delivery of care that is coordinated across clinicians, support systems, and time should be considered for payment in an advanced primary care bundle that are not currently captured in the PFS?
- How can CMS structure advanced primary care hybrid payments to improve patient experience and outcomes?
- How can CMS structure advanced primary care hybrid payments to ensure appropriate access to telephonic and messaging primary care services?
- What is the best reporting structure to ensure that targeted services are

[117] Independent Evaluation of Comprehensive Primary Care Plus (CPC+): Final Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report*; Independent Evaluation of Primary Care First: Second Annual Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[118] Independent Evaluation of Primary Care First: Second Annual Report. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/pcf-second-eval-rpt.*

[119] CMS White Paper on CMS Innovation Center's Strategy: Driving Health System Transformation—A Strategy for the CMS Innovation Center's Second Decade (*https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper*).

delivered without causing undue or excessive documentation?

• How can CMS facilitate coordination between primary care clinicians that bill for advanced primary care bundles and specialists to reduce costs and improve patient outcomes?

(4) Health Equity, Social and Clinical Risk

We define health equity as, ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [120] The CMS Framework for Health Equity lays out how we are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[121] For advanced primary care hybrid payments, this may mean incorporating different types of social and clinical risk into the payment than have typically been considered in traditional E/M or care management codes.

Recent models such as ACO REACH [122] and Making Care Primary [123] have incorporated risk adjustment for social risk factors, such as Part D Low Income Subsidy enrollment status and Area Deprivation Index, to better capture factors relevant to care of the patient. We sought input on how advanced primary care billing and payment policy could be used to reduce health disparities and social risk. Furthermore, we sought to balance a simple payment structure that encourages the uptake of advanced primary care services, while ensuring that the risk adjustment method used to develop the payment rates incentivizes the appropriate coding of patient conditions and needs, including those that have previously been under-documented, such as dementia and patient frailty.[124]

We sought input on the following questions:

• What non-claims-based indicators could be used to improve payment accuracy and reduce health disparities, and how can CMS ensure that they are collected uniformly and documented consistently without unduly increasing administrative burden?

• What risk factors, including clinical or social, should be considered in developing payment for advanced primary care services?

• How can CMS account for apparent changes in risk that are due to changes in coding patterns rather than changes in health status?

• What risk adjustments should be made to proposed payments to account for higher costs of traditionally underserved populations?

• What indicators are used to capture added social risk in commercial insurance? Should CMS consider using these?

• What metrics should be used or monitored to adjust payment to ensure that health disparities are not worsened as an unintended consequence?

• How can CMS ensure that advanced primary care hybrid payment increases access to health care services for patients without a usual source of primary care?

• Are there steps CMS can take to ensure advanced primary care billing and coding is utilized for dually eligible beneficiaries, and by safety net providers?

• Should CMS incorporate Community Health Integration and/or Principal Illness Navigation services and payment into an advanced primary care bundle?

(5) Quality Improvement and Accountability

We are committed to affordable quality health care for all people with Medicare. We seek feedback regarding how we can continue to strengthen beneficiary access to high-quality health services within FFS Medicare. One goal of the CMS Innovation Center Strategy Refresh is to increase the capability of practitioners furnishing advanced primary care to engage in accountable care relationships with beneficiaries through incentives and flexibilities to manage clinical quality, outcomes, patient experience, and total cost of care. As such, part of the intent of evolving and creating over time advanced primary care hybrid payments is that the practitioners who bill for these services are engaged in a relationship where they are responsible for the quality and cost of care for the beneficiary, counting toward the overall 2030 goal of every person with Traditional Medicare being in an accountable care relationship. This Advanced Primary Care RFI seeks input from beneficiaries and their caregivers, primary care and other clinicians, and health plans on how advanced primary care bundles could support that goal.

We sought input on the following questions:

• How can CMS ensure clinicians will remain engaged and accountable for their contributions to managing the beneficiary's care?

• What are key patient-centered measures of quality, outcomes and experience that would help ensure that hybrid payment enhances outcome and experience for patients?

• How could measures of quality, outcomes, and experience guard against and decrement in access or quality?

• As described in the APCM proposal, registration for and reporting of the ''Value in Primary Care'' MVP would be an APCM service element for MIPS eligible clinicians. Since this MVP contains measures focused on both the total cost and quality of care, would its inclusion as an APCM service element be sufficient to count as ''accountable care?'' If not, what other service delivery or quality reporting would be expected in ''accountable care?''

• What should CMS consider so that advanced primary care bundles could be used to promote accountable care across payers, both commercial and Medicaid?

• What quality measures are other payers using to drive improvements in primary care?

• What utilization measures are other payers using to drive improvements in primary care?

• What patient experience measures are other payers using to drive improvements in primary care?

• Should CMS consider flexibilities for smaller practices to bill the advanced primary care bundle? Should CMS consider flexibilities for entities exempt from MIPS to bill the advanced primary care bundle?

• Would clinicians be willing to take on more accountability to further reduce the frequency and/or administrative burden of billing?

• For APCM services, are there other key practice-level elements of the service that should be considered for

[120] *https://www.cms.gov/pillar/health-equity.*

[121] Centers for Medicare & Medicaid Services, The CMS Framework for Health Equity (2022–2032). April 2022. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[122] *https://www.cms.gov/priorities/innovation/innovation-models/aco-reach.*

[123] *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary.*

[124] National Academies of Sciences, Engineering, and Medicine (NASEM); Committee on the Decadal Survey of Behavioral and Social Science Research on Alzheimer's Disease and Alzheimer's Disease-Related Dementias. Reducing the Impact of Dementia in America: A Decadal Survey of the Behavioral and Social Sciences. National Academies Press. July 26, 2021. *https://nap.nationalacademies.org/catalog/26175/reducing-the-impact-of-dementia-in-america-a-decadal-survey.*

advanced primary care practices to bill for advanced primary care?

Most commenters responding to the Advanced Primary Care RFI were generally optimistic about the future of advanced primary care but cautioned that fee-for-service payments are still necessary for certain services. While several commenters expressed concern about administrative burden, many commenters also noted that capacity building investments could provide significant support to providers new to longitudinal care. Furthermore, a few commenters expressed the need for increased payment for primary care and provided recommendations of alternative sources of data for determining hybrid payment rates. Some commenters preferred to restrict APCM billing to ACOs or total cost of care models. Lastly, many commenters supported waiving cost sharing, incorporating patient-reported outcome measures, including health equity factors (social risk adjustments, stratifying quality data) and increasing integration of behavioral health.

We appreciate the support for our efforts to understand how we might build and evolve over time advanced primary care hybrid payments. We will continue to review feedback in response to the Advanced Primary Care Hybrid Payment RFI as it pertains to future rulemaking.

4. Cardiovascular Risk Assessment and Risk Management

a. Background

Cardiovascular disease (CVD) is a leading cause of death, disability, and health care expenditures in the U.S.[125] The burden of CVD is unequal, with black Americans experiencing higher rates of CVD-related morbidity than white Americans.[126] Atherosclerotic CVD [127] is also distinct among leading causes of death for Americans in the proportion of CVD attributable to behavioral causes,[128] making improvement in modifiable CVD risk factors (for example, diet, exercise, smoking cessation) is a key treatment target to reduce the burden of CVD across populations.[129]

The CMS Innovation Center's Million Hearts® Cardiovascular Disease (CVD) Risk Reduction model [130] (hereafter referred to as Million Hearts® model) was launched in 2017 as part of the ongoing HHS Million Hearts® Initiative.[131] The model's goals were to decrease the incidence of first-time heart attacks and strokes among medium and high-risk Medicare beneficiaries over five years and reduce Medicare spending on cardiovascular events. The model was implemented as a randomized design where participant organizations in the intervention group agreed to (1) calculate traditional Medicare beneficiaries' risk of having a heart attack or stroke over 10 years, and (2) provide cardiovascular care management services to high-risk patients (defined as a risk of a cardiovascular event in the next decade of greater than thirty percent). The model also identified medium-risk patients (more than fifteen percent risk of an event in the next decade) in its evaluation. In exchange for doing so, CMS paid participant organizations $10 for each eligible traditional Medicare beneficiary for whom the organizations assessed risk, and in the first year of the model, $10 for each high-risk beneficiary during each month when cardiovascular care management services were provided.[132] In subsequent years of the model (2018 to 2022) participants were expected to reassess cardiovascular risk and were paid based on cardiovascular risk reduction ($0 to $10 per beneficiary per month) for high-risk beneficiaries.

All CMS Innovation Center models are independently evaluated [133] and the evaluation of the Million Hearts® model found the model reduced the rate of death from any cause for medium and high-risk beneficiaries by four percent, as well as reduced the risk of death from a cardiovascular event (that is, heart attack or stroke) by eleven percent.[134] We consider this to be due to increased rates of cardiovascular risk assessment, discussion of cardiovascular risk by participants' clinicians, and the use of appropriate medications to reduce cardiovascular risk (for example, aspirin and statins).[135]

During the Million Hearts® (MH) model (which was tested from 2017–2022), there was a recently-introduced ASCVD risk assessment tool to incorporate demographic (age, sex, race), clinical (blood pressure, cholesterol, history of diabetes), and risk behavior (smoking status, use of anti-hypertensives, use of statins, use of aspirin) established by the American College of Cardiology (ACC),[136] as well as a longitudinal re-assessment tool used within the model.[137] This tool calculated the 10-year risk of a cardiovascular event for beneficiaries ages 40–79. Subsequently, additional ASCVD risk assessment tools have been developed.[138]

Today in clinical practice, ASCVD risk is generally calculated using a tool combining demographic data, personal history (risk behaviors and medical history), and laboratory data (lipid

[125] *Heart Disease and Stroke Statistics—2023 Update: A Report from the American Heart Association* Connie W. Tsao, MD, MPH, FAHA et. al. Circulation. 2023;147:e93–e621.

[126] *Cardiovascular Health in African Americans: A Scientific Statement From the American Heart Association* Mercedes R. Carnethon, Ph.D., FAHA et al. Circulation. 2017;136:e393–e423.

[127] What is Atherosclerosis? NIH NHLBI. *https://www.nhlbi.nih.gov/health/atherosclerosis.*

[128] Libby, P., Buring, J.E., Badimon, L. *et al.* Atherosclerosis. *Nat Rev Dis Primers* 5, 56 (2019). *https://doi.org/10.1038/s41572-019-0106-z.*

[129] Ebrahim S, Taylor F, Ward K, Beswick A, Burke M, Davey Smith G. Multiple risk factor interventions for primary prevention of coronary heart disease. *Cochrane Database Syst Rev.* 2011;(1):CD001561 *https://pubmed.ncbi.nlm.nih.gov/21249647/.*

[130] Sanghavi DM, Conway PH. Paying for prevention: a novel test of Medicare value-based payment for cardiovascular risk reduction. *JAMA.* 2015;314(2):123–124. *https://jamanetwork.com/journals/jama/fullarticle/2300705.*

[131] Frieden TR, Berwick DM. The ''Million Hearts'' initiative: preventing heart attacks and strokes. *N Engl J Med.* 2011;365(13):e27. *https://pubmed.ncbi.nlm.nih.gov/21913835/.*

[132] Blue L, Kranker K, Markovitz AR, et al. Effects of the Million Hearts Model on Myocardial Infarctions, Strokes, and Medicare Spending: A Randomized Clinical Trial. *JAMA.* 2023;330(15): 1437–1447. *doi:10.1001/jama.2023.19597.*

[133] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[134] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model, p. 43. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[135] Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model, p. 26. Final Report. August 2023. Mathematica. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt.*

[136] Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC, Sperling L, Virani SS, Yeboah J. 2018 ACC guideline on the management of blood cholesterol: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2018. *https://tools.acc.org/ldl/ascvd_risk_estimator/index.html#!/calulate/estimator/.*

[137] Lloyd-Jones DM, Huffman MD, Karmali KN, Sanghavi DM, Wright JS, Pelser C, Gulati M, Masoudi FA, Goff DC Jr. Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report From the American Heart Association and American College of Cardiology. Circulation. 2017 Mar 28;135(13):e793–e813.

[138] Leading Cardiologists reveal new cardiovascular disease prevention risk calculator. *https://newsroom.heart.org/news/leading-cardiologists-reveal-new-heart-disease-risk-calculator#:~:text=The%20American%20Heart%20Association%20PREVENT,CKM%20syndrome%20into%20CVD%20prevention.*

panel).[139] This information is used to calculate into a 10-year estimate of a patient's ASCVD risk for use in determining treatment advice provided by the treating practitioner. This determination requires both data collection at a visit and laboratory data, which may not be available at an initial visit. This change in clinical practice occurred over time after a series of guidelines from the American Heart Association (AHA) recommended using ASCVD risk in determining treatment decisions for patients without a prior history of CVD.[140] This treatment guideline also includes recommendations for lifestyle modifications for all patients. The CMS Innovation Center Million Hearts® model contributed to this change in clinical practice by demonstrating through a rigorous randomized control trial that the quantitative assessment of 10-year cardiovascular risk improves quality of care, including mortality, compared to prior practice.[141]

In the Million Hearts® model, cardiovascular-focused care management services included an initiating visit where an ASCVD risk assessment is performed, structured recording of patient health information using CEHRT, and a comprehensive care plan focused on cardiovascular risk reduction (including the ABCS focused on in the Million Hearts® model), but did not require 24/7 access to care, management of care transitions, or home and community-based coordination because these services are necessary for the management of complex conditions placing a beneficiary at high risk of death, acute exacerbation/decompensation, or functional decline, and these services are provided to prevent the development of these complex chronic conditions. In the Million Hearts® model, cardiovascular-focused risk management services were provided to beneficiaries at high risk for CVD (more than a thirty percent risk of a cardiovascular event in the next 10 years).

We interpret the findings of the Million Hearts® model to be both reflective of and perhaps augmenting an evolution in clinical practice toward quantitative ASCVD risk assessment. We also do not believe the resources involved in these activities are appropriately reflected in current coding and payment policies. As such, we proposed to establish codes to describe a separately billable cardiovascular disease risk assessment that is furnished in conjunction with an E/M visit and cardiovascular-focused risk management, when reasonable and necessary due to the presence of increased cardiovascular risk factors identified for the individual patient.

b. ASCVD Risk Assessment

We proposed a new stand-alone G-code, HCPCS code G0537 (GCDRA), *Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors on the same date as an E/M visit, 5–15 minutes, not more often than every 12 months.* Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment refers to a review of the individual's demographic factors, modifiable risk factors for CVD, and risk enhancers for CVD. We proposed this new code to identify and value the work involved in administering an ASCVD risk assessment when medically reasonable and necessary in relation to an E/M visit.

We further proposed that the ASCVD risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the ASCVD risk assessment will be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition to cardiovascular disease that may put them at increased risk for future ASCVD diagnosis. These conditions could include but are not limited to, obesity, a family history of CVD, a history of high blood pressure, a history of high cholesterol, a history of smoking/alcohol/drug use, pre-diabetes, or diabetes. We further proposed that the ASCVD risk assessment will not be separately billable for patients with a cardiovascular disease diagnosis or those who have history of a heart attack or stroke.

We did not propose any specific tool that will have to be used for the ASCVD risk assessment, although the assessment tool must be standardized and evidence-based. Proposed elements of the ASCVD risk assessment service would include:

- Current (from the last 12 months) laboratory data (lipid panel) for inputs needed for the risk assessment tool.
- Administration of a standardized, evidence-based ASCVD risk assessment tool that has been tested and validated through research, and includes the following domains:

++ The output of the tool must include a 10-year estimate of the patient's ASCVD risk. This output must be documented in the patient's medical record.

++ Demographic factors (such as age, sex).

++ Modifiable risk factors for CVD (such as blood pressure & cholesterol control, smoking status/history, alcohol and other drug use, physical activity and nutrition, obesity).

++ Possible risk enhancers (such as pre-eclampsia, pre-diabetes, family history of CVD).

++ Billing practitioners may choose to assess for additional domains beyond those listed above if the tool used requires additional domains. Examples of tools include but are not limited to, the ACC ASCVD Risk Estimator [142] and the AHA PREVENT tool.[143] CMS expects that the tool that is used would not introduce discriminatory bias, consistent with Section 1557 final rule.

We proposed for HCPCS code G0537 to have a duration of 5–15 minutes for the administration of an ASCVD risk assessment tool, billed no more often than once every 12 months.

We requested comments on these proposals, as well as information pertaining to potential clinician education for these proposed codes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were supportive of establishing a payment mechanism for cardiovascular risk assessment and the proposed coding to improve cardiovascular health for beneficiaries. Commenters were generally in support of our proposed required domains of the ASCVD risk assessment tool. We received a few

[139] 2019 ACC/AHA Primary Prevention of Cardiovascular Disease. *https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000678.*

[140] Arnett DK et. al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019 Sep 10;140(11):e596–e646. *doi: 10.1161/CIR.0000000000000678.*

[141] Blue L, Kranker K, Markovitz AR, et al. Effects of the Million Hearts Model on Myocardial Infarctions, Strokes, and Medicare Spending: A Randomized Clinical Trial. *JAMA.* 2023;330(15):1437–1447. *doi:10.1001/jama.2023.19597.*

[142] Lloyd-Jones DM, Huffman MD, Karmali KN, Sanghavi DM, Wright JS, Pelser C, Gulati M, Masoudi FA, Goff DC Jr. Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report From the American Heart Association and American College of Cardiology. Circulation. 2017 Mar 28;135(13):e793–e813.

[143] Leading Cardiologists reveal new cardiovascular disease prevention risk calculator. *https://newsroom.heart.org/news/leading-cardiologists-reveal-new-heart-disease-risk-calculator#:~:text=The%20American%20Heart%20Association%20PREVENT,CKM%20syndrome%20into%20CVD%20prevention.*

requests to require other domains, such as coronary calcium score.

Response: We remind commenters that, as stated in the code descriptor for ASCVD risk assessment, ''billing practitioners may choose to assess for additional domains beyond those listed above if the tool used requires additional domains.'' We are also not requiring the use of any specific ASCVD risk assessment tool. After consideration of public comments, we are finalizing the required elements of the ASCVD risk assessment as proposed.

Comment: Commenters pointed out that the PREVENT tool is an AHA tool, not an ACC tool as we stated in the proposed rule.

Response: We thank commenters for pointing out the error, and have accordingly revised the discussion in this final rule.

Comment: Many commenters requested that the ASCVD risk assessment not be required to be furnished on the same date as the associated E/M visit since practitioners may not have the necessary laboratory data on the same date as the E/M visit.

Response: We agree with commenters that there are circumstances where test results may identify the need for an ASCVD risk assessment on a day other than the date of an E/M service, so are not finalizing the requirement that the ASCVD risk assessment must be performed on the same date as the associated E/M visit. We continue to believe that in most cases, HCPCS code G0537 would not be performed in advance of the associated E/M visit. We reiterate that the ASCVD risk assessment code, HCPCS code G0537, when performed in conjunction with an E/M visit is not designed to be a general screening, but rather tied to at least one predisposing condition to cardiovascular disease that may put the patient at increased risk for future ASCVD diagnosis. We are finalizing the code descriptor to align with this change, which will now read: ''*Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors, 5–15 minutes, not more often than every 12 months.*''

Comment: Commenters requested that we provide an exclusionary list of predisposing conditions to cardiovascular disease or a list of compounding risk factors that may put patients at increased risk for future ASCVD diagnosis since there may be a wide range of severity and complexity of the beneficiaries' risk factors.

Response: We do not generally provide exclusionary lists of risk factors and/or diagnoses so as not to interfere with the practice of medicine. It is up to the practitioner to determine if the patient's risk factors, such as obesity, a family history of CVD, a history of high blood pressure, a history of high cholesterol, a history of smoking/alcohol/drug use, pre-diabetes, or diabetes, may put the patient at increased risk for future ASCVD diagnosis.

Comment: We received comments requesting clarification on the types of practitioners who can administer the ASCVD risk assessment.

Response: We believe these services would typically involve direct contact between the patient and the billing practitioner or billing practitioner's auxiliary personnel who administers the assessment. Typically, CMS does not specify specific specialty codes for billing services, and in this case, CMS expects this code to be frequently billed both by primary care providers and specialists (that is, cardiologists), but other specialists can furnish these services if all other requirements are met. Because the ASCVD risk assessment must be associated with an E/M visit, the practitioners who can bill for ASCVD risk assessment services are limited to those who can furnish E/M services.

Comment: We received comments requesting changes in the requirement that the ASCVD risk assessment can only be furnished ''not more often than every 12 months'' per beneficiary in cases where a different practitioner may need to furnish the risk assessment to furnish appropriate ASCVD risk management services. For example, if a beneficiary's primary care practitioner conducted the ASCVD risk assessment and they were determined to be at high risk for a future ASCVD diagnosis, the primary care practitioner may feel the need to refer the beneficiary to a cardiologist to finish ASCVD risk management services. If needed, the cardiologist could furnish another ASCVD risk assessment and ASCVD risk management services if they also determined the beneficiary to be at increased risk.

Response: We agree with commenters about this concern. We are finalizing that the ASCVD risk management service can be furnished not more often than once every 12 months per practitioner per beneficiary. We expect that this service is only furnished by practitioners who furnish the bulk of the beneficiary's care, and as this service is for Medicare beneficiaries without a previous diagnosis of coronary artery disease, it may be most frequently billed by primary care, but some beneficiaries may also have a cardiologist for other cardiovascular conditions predisposing to ASCVD. We would like to reemphasize that the ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition to cardiovascular disease that may put them at increased risk for future ASCVD diagnosis and is not separately billable for patients with a cardiovascular disease diagnosis or those who have history of a heart attack or stroke.

After consideration of public comments, we are finalizing the code descriptor for G0537 ''*Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors, 5–15 minutes, not more often than every 12 months per practitioner.*'' We are finalizing all other aspects of G0537 as proposed.

(1) Valuation for ASCVD Risk Assessment G0537

We proposed a direct crosswalk to HCPCS Code G0136 (*Administration of a standardized, evidence-based SDOH assessment, 5–15 minutes, not more often than every 6 months*), with a work RVU of 0.18 as we believe this service reflects the resource costs associated when the billing practitioner performs the service described. HCPCS code G0136 has an intra-service time of 15 minutes, and the physician work is of similar intensity to the proposed HCPCS code G0537. Therefore, we proposed a work time of 15 minutes for HCPCS code G0537 based on this same crosswalk to G0136. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0537.

We sought comments on these proposals. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally in support of our proposed valuation of ASCVD risk assessment services (G0537). Some commenters suggested that the valuation should be increased, as they stated that the proposed crosswalk HCPCS code G0136 is undervalued.

Response: We believe the crosswalk to G0136 is an appropriate crosswalk because these services are clinically similar standardized risk assessments that take 5–15 minutes. If commenters believe that HCPCS code G0136 is undervalued, we welcome information from interested parties on a more accurate valuation that we may consider for future rulemaking. Individuals and groups may submit codes for review under the potentially misvalued codes

initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox at *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes.'' Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline.

After consideration of public comments, we are finalizing the valuation of G0537 as proposed.

c. Atherosclerotic Cardiovascular Disease Risk Management Services (G0538)

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other healthcare professionals, especially in the context of evolving changes in medical practice using evidence-based models of care, such as the Million Hearts® model. We proposed to establish a G-code to describe ASCVD risk management services that incorporate the ''ABCS'' of CVD risk reduction (aspirin, blood pressure management, cholesterol management, and smoking cessation) for beneficiaries at medium or high risk for ASCVD (≤15 percent in the next 10 years) as previously identified through an ASCVD risk assessment. We believe that ASCVD risk management services include continuous care and coordination to reduce or eliminate further elevation of ASCVD risk over time, and potentially prevent the development of future cardiovascular disease diagnoses or first-time heart attacks or strokes.

We proposed new G-code, G0538 (GCDRM), *Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month.* Atherosclerotic Cardiovascular Disease (ASCVD) risk management services refer to the development, implementation, and monitoring of individualized care plans for reducing cardiovascular risk, including shared decision-making and the use of the ABCS of cardiovascular risk reduction, as well as counseling and monitoring to improve diet and exercise. We proposed that the elements of the Atherosclerotic Cardiovascular Disease (ASCVD) risk management service will include:

- ASCVD Specific Risk Management, which may include:

++ Promoting receipt of preventive services (including tobacco cessation counseling, diabetes screening, diabetes self-management training)
++ Medication management (including aspirin or statins to maintain or decrease risk of CVD)
++ Ongoing communication and care coordination via certified electronic health record (EHR) technology
—Synchronous, non-face-to-face communication methods must be offered

- ASCVD-Specific, Individualized, Electronic Care Plan

++ Must address modifiable risk factors and risk enhancers specific to CVD, as applicable, such as:
—blood pressure and cholesterol control
—smoking, alcohol, and other drug use status, history, and cessation
—physical activity and nutrition
—obesity
++ Plan must be established, implemented, and monitored and must incorporate shared decision-making between the practitioner and the patient

Although there is no minimum service time requirement for ASCVD risk management services in a month, each of the elements must be addressed to bill for the service, unless a particular element is not medically indicated or necessary at that time for that specific patient. For example, the element of smoking cessation will not be addressed for a patient who does not use tobacco. Documentation of each service element in the patient's medical record is required.

Comment: Commenters were generally supportive of the proposed elements of the ASCVD risk management service. We received requests to include the use of blood pressure medications in the medication management service element.

Response: We clarify that medication management is not limited to the examples of aspirin and statins that were listed in the proposed rule but could include other medications needed to maintain or decrease risk of CVD.

After consideration of public comments, we are finalizing the service elements for G0538 as proposed.

Physicians and non-physician practitioners (NPPs) who can furnish E/M services could bill for ASCVD risk management services. We anticipate that ASCVD risk management services will ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with our regulation at § 410.26. We proposed that ASCVD risk management services will be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

We proposed that patient consent must be obtained before starting ASCVD risk management services. Like other care management services, ASCVD risk management services will typically be provided by clinical staff outside of face-to-face patient visits. Consent can be written or verbal and must be documented in the medical record. Consent should also include informing the patient about these services, as well as potentially applicable Medicare cost sharing.

We proposed that ASCVD risk management services can be billed no more often than once per calendar month, and that payment is limited to one practitioner per beneficiary per month. Patients must be determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment and must not have a current diagnosis of cardiovascular disease or have a history of heart attack or stroke.

We sought comments on each of these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments requesting clarification on whether concurrent billing of other services would be allowed with G0538. Some of the examples provided by commenters were care management services, Self-Measured Blood Pressure (SMBP) (99473–99474), G0446

(*Intensive Behavioral Therapy for Cardiovascular Disease*), and Smoking and tobacco use cessation counseling visits (99406–99407).

Response: Concurrent billing with G0538 would be allowed during the same month if time and effort are not counted more than once, requirements to bill both services are met, and the services are medically reasonable and necessary. We would like to remind practitioners that the patient consent requirement for this service includes informing the patient about potentially applicable Medicare cost sharing. When G0538 is billed concurrently with preventive services, like G0446 (Intensive Behavioral Therapy for Cardiovascular Disease), practitioners should be sure to inform the patient that G0538 is not a preventive service, and that cost sharing may apply.

Comment: We received many comments providing us with further information about the current clinical practice metrics for identifying patients at medium to high risk of CVD. Many standardized, evidence-based risk assessment tools use different percentage ranges that may fall outside of the proposed ''>15 percent in the next 10 years.'' Many current tools identify ''intermediate risk'' as 7.5%–19.9% and ''high risk'' as >20%. Commenters also believed that this specific designation may not align with changing clinical recommendations for cardiovascular risk intervention.

Response: The elements of G0538 were designed with the findings from the Million Hearts® model in mind, and so the specific risk percentiles used in the model were included in the proposed rule. We acknowledge that clinical practice evolves over time and the categorization of risk percentiles into categories of risk may also evolve as risk prediction tools and clinical guidelines are refined. We note the most recent 2019 AHA/ACC clinical guidelines for primary prevention of cardiovascular disease establish (distinct from the Million Hearts® model) categories of 'low risk,' 'borderline risk,' 'intermediate risk,' and 'high risk,' and these categories may evolve over time as well. For these reasons, we will remove the risk management threshold percentile from the code description for G0538 services, given that the intent of the Million Hearts® model was to identify patients commonly considered to be at intermediate (or medium) or high risk of ASCVD for G0538 services.

After consideration of public comments, we are finalizing G0538 with the following code descriptor, ''*Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at intermediate, medium, or high risk for CVD as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month.*'' We are finalizing all other policies for G0538 as proposed.

(1) Valuation for ASCVD Risk Management Services (G0538)

We proposed a direct crosswalk to CPT Code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*), with a work RVU of 0.18 as we believe this service reflects the resource costs associated when the billing practitioner performs HCPCS code G0538. CPT code 99211 has a physician intraservice time of 5 minutes, and the physician work is of similar intensity to our proposed HCPCS code G0538. Therefore, we proposed a work time of 5 minutes for HCPCS code G0538 based on this same crosswalk to CPT 99211. We also proposed to use this crosswalk to establish the direct PE inputs for HCPCS code G0538, with modifications to reflect non-face-to-face services. These modifications include eliminating PE inputs used in face-to-face services such as preparing and cleaning the room. We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally in support of our proposed valuation of ASCVD risk management services (G0538).

Response: After consideration of public comments, we are finalizing the work RVU of 0.18 and our proposed PE inputs for G0538.

H. Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care With a Physician or NPP Order, and KX Modifier Thresholds

1. Supervision of Outpatient Therapy Services in Private Practices

In the CY 2024 PFS final rule, we finalized our proposal to allow remote therapeutic monitoring (RTM) services to be furnished by occupational therapy assistants (OTAs) and physical therapy assistants (PTAs) under the general supervision of occupational therapists (OTs) and physical therapists (PTs) in private practice, in an effort to align with the general supervision policy for these services for physicians and other practitioners described in the CY 2023 final rule (88 FR 78990). We also noted that we would consider for possible future rulemaking the commenters' responses to our request for information (RFI) on changing the supervision of therapy assistants in the private practice setting to general supervision for all therapy services (88 FR 78990 through 78992).

In the CY 2024 PFS proposed rule, we reviewed the statutory provisions at sections 1861(p) and 1861(g) (by cross-reference to section 1861(p)) of the Act that describe outpatient physical therapy and occupational therapy services furnished to individuals by physical therapists (PTs) and occupational therapists (OTs) meeting licensing and other standards prescribed by the Secretary if the services meet the necessary conditions for health and safety. These statutory provisions refer separately to outpatient therapy services furnished by a provider of services (such as a rehabilitation agency) and those services furnished in the therapist's office or the individual's home, thus distinguishing therapists who work for an institutional provider of therapy services from therapists who furnish and bill independently for these outpatient therapy services (88 FR 52358 through 52359). In regulations, we have addressed these therapists as physical or occupational therapists in private practice (PTPPs and OTPPs) (63 FR 58868 through 58870). The regulations specific to services furnished by occupational or physical therapists in private practice are found at §§ 410.59(c) and 410.60(c), respectively.

We also summarized a history of related regulatory provisions in the CY 2024 PFS proposed rule. In the CY 2005 PFS final rule with comment period (69 FR 66236, 66351 through 66354), we explained that the personnel requirements that are applicable for Home Health Agencies (HHAs) at 42 CFR part 484 for therapists, therapy assistants and speech-language pathologists (SLPs) apply to all outpatient physical therapy, occupational therapy, and speech-language pathology services. In the CY 2005 PFS final rule, we also added a basic rule at §§ 410.59(a) and 410.60(a), respectively, by cross-referencing the

qualifications for OTs and their OTAs and PTs and their PTAs for all occupational therapy and physical therapy services, respectively, including those who work in private practices, to 42 CFR part 484. Later, in the CY 2008 PFS final rule (72 FR 66328 through 66332), we updated the qualification standards at 42 CFR part 484 for OTs, OTAs, PTs, PTAs, and SLPs.

In the CY 2024 PFS proposed rule, through our RFI on general supervision of OTAs and PTAs by OTPPs and PTPPs, respectively, we solicited public comment, along with supporting data, for our consideration for possible future rulemaking about the following: (a) the questions and concerns we highlighted related to access, patient safety, and utilization; (b) revising §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to permit general supervision of OTAs and PTAs by the OTPP and PTPP, respectively, when furnishing therapy services; and (c) any appropriate exceptions to allowing general supervision in the furnishing of therapy services (88 FR 52358 through 52359).

In the CY 2024 PFS final rule, we reviewed the comments we received in response to the proposed rule (please refer to (88 FR 78990 through 78992)). We noted that we would consider these comments for possible future rulemaking—see our review of comments on the RFI in the CY 2024 PFS final rule (88 FR 78992).

Over the past several years and again more recently, we have heard from interested parties that the direct supervision requirements in the private practice setting are problematic for OTPPs and PTPPs who must remain on-site and immediately available when Medicare patients are treated to bill for therapy services furnished by their supervised OTAs and PTAs. As a remedy to this situation, interested parties have requested that we revise our requirement for PTPPs and OTPPs to provide direct supervision of OTAs and PTAs to align with the general supervision policies for OTs and PTs that work in Medicare institutional settings that provide therapy services (for example, rehabilitation agencies, outpatient hospitals, SNFs and comprehensive outpatient rehabilitation facilities (CORFs), etc.), to allow for the general supervision of their therapy assistants. These interested parties tell us that their respective State laws and policies allow general supervision of therapy assistants (most often requiring the OT or PT to be in touch with their therapy assistants via telecommunication) in at least 44 States for PTAs,[144] and all but one State for OTAs.

Some interested parties have reported that allowing for general supervision of OTAs and PTAs by OTPPs and PTPPs, respectively, would allow for patients to have increased access to outpatient therapy services, even with ongoing healthcare workforce shortages. The shortages of OTs [145] and OTAs,[146] PTs,[147] and PTAs,[148] are noted by the United States Bureau of Labor Statistics, which shows thousands of open positions in all of these fields. Interested parties noted that over 22,000 PTs left the workforce in 2021.[149] Additionally, these interested parties noted that workforce shortages have greater impact on private practices in rural and underserved areas where hourly wages are lower, and the OTPPs and PTPPs in these areas tend to have small practices. The interested parties stated that Medicare's direct supervision policy, which requires the PTPP and the PTA to both be present when a Medicare patient is treated, does not allow small practices with one PT and one or two PTAs, for example, to work different or overlapping schedules in order to accommodate all patients' availability by allowing the OTA/PTA to work before or after the OTPP/PTPP normal hours. The interested parties also stated that the direct supervision requirement can unfairly delay care for Medicare patients when, for example, a PTPP or OTPP is out sick, the practice does not have alternative coverage, and appointments for Medicare patients must be canceled.

In light of this input, we believe that the direct supervision requirement for OTPPs and PTPPs of OTAs and PTAs, respectively, may have had an unintended consequence of limiting access to needed therapy services. As noted by interested parties, both the OTPP/PTPP and their respective OTA/PTA must be present in the office to bill and receive Medicare payment for therapy services furnished by OTAs and PTAs. This means, for example, that an OTPP/PTPP cannot bill and receive payment for therapy services furnished to a Medicare patient in their home when furnished by an OTA/PTA, without the presence of the OTPP/PTPP. The direct supervision requirement for OTAs and PTAs in the private practice setting is more stringent than the supervision requirements for OTAs and PTAs in institutional settings. For example, as we noted in the CY 2024 PFS proposed rule, 42 CFR 485.713 specifies that when an OTA or PTA provides services at a location that is off the premises of a clinic, rehabilitation agency, or public health agency, those services are supervised by a qualified occupational or physical therapist who makes an onsite supervisory visit at least once every 30 days. We also cited Table 4 in our Report to Congress, titled ''Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services,'' [150] in the CY 2024 PFS proposed rule to demonstrate that the minimum level of supervision by PTs and OTs for services performed by PTAs and OTAs working in institutional settings is a general level of supervision, in accordance with various regulations (88 FR 52359). Therefore, we believe that a change from direct to general supervision would allow OTPPs and PTPPs the flexibility to better accommodate patients' availability and act to ensure access to necessary therapy services. A change from direct to general supervision would also allow OTPPs and PTPPs to bill and receive Medicare payment for therapy services furnished by their OTAs and PTAs when they are not in the office or patient's home at the same time.

We also believe that it is important to better align our supervision policies for OTPPs and PTPPs with the majority of state-established supervision levels for therapy assistants providing occupational therapy and physical therapy services. We note that the majority of states allow OTs and PTs to provide general supervision of their

[144] Federation of State Boards of Physical Therapy Jurisdiction Licensure Reference Guide *https://www.fsbpt.net/lrg/Home/SupervisionRequirementLevelsBySetting.*

[145] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Occupational Therapists, at *https://www.bls.gov/ooh/healthcare/occupational-therapists.htm* (visited *April 17, 2024*).

[146] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Occupational Therapy Assistants and Aides, at *https://www.bls.gov/ooh/healthcare/occupational-therapy-assistants-and-aides.htm* (visited *April 17, 2024*).

[147] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Physical Therapists, at *https://www.bls.gov/ooh/healthcare/physical-therapists.htm* (visited *April 17, 2024*).

[148] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Physical Therapist Assistants and Aides, at *https://www.bls.gov/ooh/healthcare/physical-therapist-assistants-and-aides.htm* (visited *April 17, 2024*).

[149] See the report by Definitive Healthcare dated October 2022 at *https://www.definitivehc.com/sites/default/files/resources/pdfs/Addressing-the-healthcare-staffing-shortage.pdf.*

[150] See Table 4 of the Report to Congress titled Standards for Supervision of PTAs and the Effects of Eliminating the Personal PTA Supervision Requirement on the Financial Caps for Medicare Therapy Services at *https://www.cms.gov/Medicare/Billing/TherapyServices/Downloads/61004ptartc.pdf.*

respective OTAs and PTAs when furnishing occupational therapy and physical therapy services. We believe that States are well aware of the health and safety needs for their residents who receive therapy services from OTs and their supervised OTAs, and PTs and their supervised PTAs. Given these beliefs and the input from interested parties, we proposed to revise our regulations at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow for general supervision of OTAs and PTAs by OTPPs and PTPPs, when the OTAs and PTAs are furnishing outpatient occupational and physical therapy services, respectively. We expect that this proposal will both increase access to therapy services and more closely align Medicare policy with the majority of State practice acts for occupational therapy and physical therapy. This revised policy will parallel the 44 States that allow general supervision of PTAs and the 49 States that allow general supervision of OTAs (most often described by States as requiring the PT or OT to be in touch via telecommunication). For the States with more restrictive supervision levels, such as direct supervision, Medicare-covered therapy services provided in those States are required to be furnished in compliance with State law. We note that while we proposed to allow for general supervision by OTPPs and PTPPs of their OTAs/PTAs, an OTPP or PTPP will still be required to provide direct supervision to unenrolled OTs and PTs, respectively, in accordance with §§ 410.59(c)(2) and 410.60(c)(2).

We solicited comment on our proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to change the required level of supervision of PTAs and OTAs in PT and OT private practices from direct to general supervision. Many of these commenters cited potential benefits including increased patient access to therapy services, alignment with State laws and practice acts and reduced administrative burdens. Other commenters appreciated the proposal for general supervision because it would provide greater flexibility in scheduling and resource allocation—allowing PT and OT clinics to address staffing shortages, particularly in rural areas, since the therapists and therapy assistants no longer need to both be onsite to treat Medicare patients. Some commenters supported our proposal because consistent general supervision policies across all Medicare therapy settings will decrease administrative burden and confusion. Many commenters informed us that providers have demonstrated the ability to provide safe and effective care for many years with general supervision of PTAs and OTAs in other Medicare therapy settings and believe these safeguards will protect patients in the private practice setting. A few commenters thanked us for the general supervision proposal, since some of the institutional settings with general supervision, for example, home health agencies (HHAs) and SNFs, include patients with more complex conditions than those in private practice settings where direct supervision is required. One commenter supported our proposal for general supervision as they believe this change could increase employment opportunities for their graduates and allow them to better serve patients in their communities. We heard from several other commenters that suggested this change in supervision could result in Medicare savings—up to an estimated $271 million over 10 years—based on a 2022 report by Dobson DaVanzo & Associates commissioned by therapy organizations.[151] One of these commenters that believes the analysis presents convincing data that general supervision in private practices would create significant savings, even if the supervision change resulted in a modest increase in therapy service, is that some services of the PT would shift to the PTA—resulting in a greater percentage of claims for services furnished by PTAs being paid at 85 percent of what we otherwise make to the therapist under the PFS when those services are furnished in whole or in part by a PTA.

Response: We appreciate the support for our proposed policy from the many commenters.

Comment: One commenter expressed concerns over potential risks to patient safety, quality of care, lost professional development opportunities, lack of consistency in treatment, and legal and ethical issues, recommending the retention of the direct supervision policy.

Response: PTAs and OTAs, who are State-licensed or State-regulated professionals, will continue to be required to comply with their respective State laws, and work under the direction of the PT or OT in private practice, which sufficiently safeguards patients' safety and quality of care. We do not believe that a change to general supervision will affect the consistency in treatment delivery of therapy services under the physical therapy or occupational therapy plan of care; nor will it create gaps in training and development of PTAs and OTAs by their supervising PTs and OTs. Further, we do not agree with the commenter that the change to general supervision where it is permitted under State law will cause a change in the way therapists or therapy assistants fulfill their legal obligations or comply with ethical standards.

After consideration of public comments, we are finalizing as proposed the revisions to §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow for general supervision of OTAs and PTAs by OTPPs and PTPPs, when the OTAs and PTAs are furnishing outpatient occupational and physical therapy services, respectively.

We believe that this policy will increase access to therapy services and more closely align Medicare policy with the majority of State practice acts for occupational therapy and physical therapy. In States with more restrictive supervision levels, such as direct supervision, Medicare-covered therapy services provided in those States are required to be furnished in compliance with State law.

2. Certification of Therapy Plans of Care With a Physician or NPP Order

Sections 1861(p), (g), and (ll)(2) of the Act define outpatient physical therapy services, outpatient occupational therapy services, and outpatient speech-language pathology services as services provided to an individual outpatient who is under the care of a physician and for whom a plan for the physical therapy, occupational therapy, or speech-language pathology services that are to be furnished has been established by a physician or by a qualified PT, OT, or SLP and is periodically reviewed by a physician. Sections 1835(a)(2)(C) and 1835(a)(2)(D) of the Act require that payment for Medicare therapy services may be made for outpatient physical therapy, occupational therapy, and speech-language pathology services only if a physician certifies (and recertifies, where such services are furnished over a period of time) that: (a) the services are or were required because the patient needs or needed therapy services; (b) a plan for furnishing such services was established by a physician or therapist providing such services, and is periodically reviewed by the physician; and (c) the services are or were furnished while the individual is or was under the care of a physician.

[151] See report at: *https://www.dobsondavanzo.com/index.php?src=directory&view=Publications&submenu=_pubs&category=Cost%20Estimation&srctype=Publications_lister_redesign.*

In accordance with the statute and § 424.24(b), Medicare Part B pays for outpatient physical therapy and speech-language pathology services furnished by providers only if a physician certifies the content specified in § 424.24(c)(1) or (4). We recognize that it may not be clear that § 424.24(c) applies to the occupational therapy services furnished by providers, since occupational therapy services are currently only explicitly mentioned in the recertification requirements at § 424.24(c)(4). We note that there are multiple references to § 424.24(c) in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 15, sections 220.1—Conditions of Coverage and Payment for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services, 220.1.2—Plans of Care for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services, and 220.1.3—Certification and Recertification of Need for Treatment and Therapy Plans of Care, which convey our current policy that all outpatient physical therapy, occupational therapy, and speech-language pathology services are subject to requirements for certification and recertification at § 424.24, whether furnished by providers or by suppliers such as therapists in private practice (TPPs). We note that while section 1835 of the Act explicitly refers to services furnished by providers of services, which would include hospitals and other institutional providers as defined in section 1861(u) of the Act, and clinics, rehabilitation agencies, or public health agencies as further described in section 1835(a) of the Act, we have interpreted the requirements of section 1835(a)(2)(C) and 1835(a)(2)(D) as applying to therapy services furnished by both providers and suppliers, which would include a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.[152] See Medicare Benefit Policy Manual, Pub. 100–02, chapter 15, sections 220.1, 220.1.2, and 220.1.3 for references to § 424.24. We believe that this interpretation is based on the certification and recertification requirements under section 1835(a) of the Act as a way to effectuate the requirement in sections 1861(p), (g), and (ll)(2) of the Act that the patient is under the care of a physician, and that the plan of treatment/care for the physical therapy, occupational therapy, or speech-language pathology services has been established by a physician or by a qualified PT, OT, or SLP and is periodically reviewed by a physician. Additionally, we thought it was important to establish conforming policies for these therapy services in both the outpatient provider and private practice settings.

Due to the foregoing concerns, we proposed to revise the headings of paragraphs (c) introductory text and (c)(1)(i) to include the term ''occupational therapy'' after physical therapy. We proposed to replace the term speech pathology with the accepted term speech-language pathology in 42 CFR 424.24(c)(1)(i). We also proposed to add the term ''occupational therapist'' to 42 CFR 424.24(c)(3)(ii) between physical therapist and speech-language pathologist.

The regulations at 42 CFR 424.24(c) require that a physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) who has knowledge of the case sign the initial certification for the patient's plan of treatment. We reminded readers that plan of treatment is synonymous with the ''plan of care'' mentioned above. This terminology appears in several sections of Pub. 100–02, chapter 15, and both terms may be used interchangeably. In accordance with § 424.24(c)(2), the initial certification must be obtained as soon as possible after the plan is established by a PT, OT, or SLP. In Pub. 100–02, chapter 15, section 220.1.3 for Certification and Recertification of Need for Treatment and Therapy Plans of Care, we specified that the physician or nonphysician practitioner (NPP) must sign the initial plan of care (POC) with a dated signature or verbal order within 30 days from the first day of treatment, including evaluation (or 14 days if a verbal order), in order for the PT, OT, or SLP to be paid for the services. For this reason, the manual also states that the therapist should forward the treatment plan to the physician/NPP as soon as it is established rather than waiting to do so. The manual allows for a delayed certification when the physician or NPP completes certification and includes a reason for the delay, and delayed certifications are accepted without justification up to 30 days after the due date.

The regulations at § 424.24(c)(4) require recertification at least every 90 days, and the plan or other documentation in the patient's medical record must indicate the continuing need for physical therapy, occupational therapy, or speech-language pathology services. The physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan must recertify the plan by signing the medical record. Pub. 100–02, chapter 15, section 220.1.4.C clarifies that payment and coverage conditions require that the plan of care be reviewed as often as necessary but at least whenever it is certified or recertified, to meet the certification requirements. We explained in the CY 2008 PFS final rule, when changing the plan of care recertification interval from 30 to 90 days, this was done to allow more flexibility to the physician/NPP to order the appropriate amount of therapy for each patient's needs (72 FR 66333). Thus, a physician or non-physician practitioner (NPP) may certify or recertify a plan of care at an interval the physician or NPP determines is appropriate, as long as the amount of time between each recertification does not exceed 90 calendar days. As many episodes of therapy treatment are completed in less than 30 calendar days, we expect that physicians and NPPs will continue to certify plans of care that appropriately estimate the duration of needed therapy treatment for a patient, even if the duration is less than 90 days.

Over the past two years, representatives of several therapy-related organizations have requested that CMS reduce the administrative burden involved with attempting to obtain signed plans of treatment from the physician/NPP. They expressed concern that therapists are held accountable for the action or inaction of physicians/NPPs who may be overwhelmed with paperwork. These interested parties report that therapists make exhaustive efforts to obtain the physician/NPP's signature—some reporting that they contact physician offices (via phone, email, or fax, etc.) more than 30 times. Without the required signature, the therapist will not meet the conditions to be paid for the services they deliver. These interested parties recommend that payment for therapy services should be determined by the medical necessity of the service and whether the therapist has met their statutory and regulatory requirements. Some of these interested parties have noted that Pub. 100–02, chapter 15, section 220.1.1, states that the physician/NPP order provides evidence that the patient is under the care of a physician and that the services are medically necessary. Interested parties told us that while CMS allows treatment to begin before the physician's/NPP's signature is obtained, PTs, OTs, and SLPs in private practice do so at their own risk, knowing that they might not

[152] 42 CFR 400.202.

be paid for the services if the physician's office does not send back the signed plan of treatment. Accordingly, such interested parties have said that care is delayed while awaiting a physician's signature, which could place the beneficiary's health at risk due to the delay in obtaining outpatient therapy services.

While we do not require an order or referral for a Medicare patient to see a PT, OT, or SLP, we have explained that the presence of a signed order from the treating physician satisfies statutory requirements that therapy is/was medically necessary and the patient is/was under the care of a physician (Pub. 100–02, chapter 15, section 220.1.1). However, with this order documented in the medical record, after the therapist evaluates the patient and establishes the plan of treatment, based on the evaluation's findings, the therapist forwards the patient's plan of treatment back to the referring physician/NPP to obtain a dated signature for the same patient with the same diagnosis to meet coverage and payment conditions to satisfy the initial certification requirement—creating an administrative burden for both the physician/NPP and the therapist. Interested parties have reported to us that most patients seeking outpatient therapy services have written orders from their physician, not to be confused with a written plan of treatment. These interested parties have suggested that we amend the regulation at § 424.24(c) to permit the presumption of a physician/NPP signature for purposes of certification and recertification in cases where a signed written order or referral from the patient's physician/NPP is on file and there is written documentation in the patient's medical record to substantiate the method and date (such as a fax, email, etc.) that the therapist forwarded the plan of care to the physician/NPP.

Additionally, interested parties representing all therapy disciplines requested that CMS allot time for plan of treatment changes. Interested parties requested that when a physician/NPP orders the therapy services, the physician/NPP be allotted 10 business days to modify the plan of treatment by contacting the therapist directly after receiving it from the therapist. For patients without a physician/NPP order, interested parties requested that physician/NPPs be given 30 days after receipt of the plan of treatment to modify the treatment plan.

After reviewing our current regulatory requirements and considering the suggestions of interested parties, we believe it would be appropriate to propose to amend the regulation at § 424.24(c) for those cases when a patient has a signed and dated order/referral from a physician/NPP for outpatient therapy services. Since our policy has been to accept the physician or NPP's signature on the plan of treatment to be their certification of the treatment plan's conditions in the content requirements of § 424.24(c)(1)—that the patient needs or needed physical therapy, occupational therapy or speech-language pathology services, the services were furnished while the individual was under the care of a physician, NP, PA, or CNS, and the services were furnished under a plan of treatment that meets the requirements of § 410.61—we proposed that a signed and dated order/referral from a physician/NPP combined with documentation of such order/referral in the patient's medical record along with further evidence in the medical record that the therapy plan of treatment was transmitted/submitted to the ordering/referring physician or NPP is sufficient to demonstrate the physician or NPP's certification of these required conditions. Rather than characterizing this proposal as a ''presumption,'' we are taking the view that when the patient's medical record includes a signed and dated written order or referral indicating the type of therapy needed, CMS (and our contractors) would treat the signature on the order or referral as equivalent to a signature on the plan of treatment. We believe our proposal will be reflective of the intent of the ordering/referring physician/NPP when that order/referral is on file in the patient's medical record. We further believe that this will still be consistent with the initial certification required under section 1835(a) of the Act for providers of therapy services and our current policy for therapy in the private practice setting. When the ordering/referring physician writes the referral for the type of therapy services they determine their patient needs or needed, they also review the treatment plan the therapist established at the time it is forwarded to them, and they verify that the services are or were furnished while the patient is or was under their care. As such, we proposed to carve out an exception to the physician signature requirement at § 424.24(c) by adding a new paragraph (c)(5). The policy will be an exception to the physician signature requirement for purposes of an initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation. However, at this time, we did not propose and do not intend to establish an exception to the signature requirement for purposes of recertification of the therapy plan of treatment. We believe that physicians and NPPs should still be required to sign a patient's medical record to recertify their therapy treatment plans, in accordance with § 424.24(c)(4), to ensure that a patient does not receive unlimited therapy services without a treatment plan signed and dated by the patient's physician/NPP.

Under our proposal, CMS or its contractors will be able to treat the physician/NPP signature on the order or referral as equivalent to a signature on the plan of treatment for purposes of the initial certification if that physician/NPP has not signed and returned the patient's plan of treatment to the therapist within 30 days of the initial evaluation, but only in cases where the patient's physician/NPP has signed and dated the written order or referral and indicated the type of therapy needed, and that written order or referral is on file in the medical record. This policy will not affect a contractor's ability or authority to determine whether therapy services are reasonable and necessary for a given beneficiary. Lastly, because there is no requirement for a physician/NPP order or referral for patients to obtain outpatient therapy services, we proposed to make clear in § 424.24(c)(5) that the references to an order or referral in § 424.24(c)(5) shall not be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services. We welcomed comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our technical revisions to § 424.24(c) to specifically include occupational therapy services under the certification requirements and to add the services of an occupational therapist, in addition to physical therapists and speech-language pathologists, as these revisions more clearly identify that the certification requirements outlined in § 424.24(c) apply to the outpatient therapy services furnished by OTs.

Response: We thank the commenter for their support.

Comment: Several commenters expressed support for our proposal to accept a physician's or NPP's signed and dated order as equivalent to a signature on the initial certification of a therapist-established plan of treatment

in cases where the written order or referral from the patient's physician/NPP is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician/NPP within 30 days of the initial evaluation. They stated this change will reduce administrative burden for therapists and physicians/NPPs, as well as encourage more timely and efficient care delivery. Many of these commenters urged us to finalize the proposal so that they would no longer have to waste time and resources tracking down physicians who fail to return signed plans of care and added that the proposed exception to the signature requirement, if finalized, would greatly reduce uncertainty of payment, in addition to reducing administrative burden.

Response: We thank the commenters for their supportive comments.

Comment: A few commenters expressed concerns. One commenter stated that before we make any changes to the certification process, we should consider the roles and contributions of each health care provider involved in the patient's care plan and ensure that the physician is still the head of the care team, while not hindering access to needed therapy.

Response: PTs, OTs, and SLPs are all practitioners of outpatient therapy services and while coverage for outpatient therapy services relies on the patient being under the care of a physician, these practitioners do not require the supervision of physicians or NPPs to furnish Medicare-covered therapy services. However, the plans of care that therapists establish require the signature of the physician, NP, PA, or CNS who has knowledge of the case. As such, the care plan team consists of the physician or NPP and the therapist. This care plan team is the same as the one that currently exists for treatment plans requiring the physician/NPP signature for certification and will remain unchanged once our proposal to amend the certification regulations is finalized.

Comment: Some commenters agreed with our proposal to recognize the signed and dated order for only the initial certification and that the existing signature requirements should be kept for certifications when the patient does not have an order or referral and for all recertifications irrespective of a whether the patient has a referral. Several commenters suggested that the recertification should also be included as part of our proposal, while a few other commenters, perhaps misunderstanding our proposal, stated that they supported our proposal for both the certification and recertification of treatment plans. One commenter asked that we confirm our proposed policy.

Response: We are confirming that our proposed policy as noted in the CY 2025 PFS proposed rule (89 FR 61739) would only apply to the certification in those cases where the patient has an order or referral for physical therapy, occupational therapy, or speech-language pathology services; and, stress that we did not propose, nor did we intend to establish an exception to the signature requirement for purposes of recertification of therapy plans of treatment. In cases when the patient does not have a written order or referral from their physician/NPP, the POC signature requirement for certifications would still apply, as we proposed at § 424.24(c)(5).

Comment: Several commenters asked CMS to make the policy in this proposal clear to our contractors (MACs), that is, the specifics of what we included in the CY 2025 PFS proposed rule (89 FR 61739): ''When the patient's medical record includes a signed and dated written order or referral indicating the type of therapy needed, CMS (and our contractors) would treat the signature on the order or referral as equivalent to a signature on the plan of treatment.'' They additionally asked that we notify our MACs/contractors through a formal program memorandum prior to the policy becoming effective on January 1, 2025, stating that physician signature requirement for the POC certification has been a frequent targeted area for denials and oversight.

Response: The proposed exception to the signature requirement would take effect for dates of service on and after January 1, 2025, based on the date of the therapist's initial evaluation (which begins the episode of care); and we would plan to notify our contractors of the policy changes to the certification process through our usual change management process using the same or similar language suggested by the commenters.

Comment: Several commenters asked us to provide a comprehensive list of all the acceptable ways that the plan of care can be delivered/transmitted to the physician/NPP. Three of these commenters gave examples of the methods of delivery that their members and/or staff have utilized in the past. Their collective list includes the following: electronic health record (EHR) systems (with a time stamp) and electronic signatures, other electronic means, facsimile sheets/logs, paper records and paper logs (for example, physicians providing signatures at the nursing desk in a facility), electronic date stamps, call logs, tracking forms, and those POCs hand delivered to physicians (including to physicians in their offices or during weekly rounds in the facility). Two of these commenters stated that CMS must convey to the MACs that all of these methods of documentation are acceptable. One commenter asked CMS to confirm if facsimile logs or other electronic means could be accepted as evidence that the POC was submitted/transmitted to the referring physician/NPP.

Response: We have not established and are not aware of a comprehensive listing of ''acceptable'' delivery mechanisms. However, since policies relating to POC delivery/transmission to the physician/NPP have been in place for many years, we will direct our contractors to continue to accept the same methods of delivery as they have in the past.

Comment: Several commenters requested that we issue clarifying guidance materials to ensure the ordering/referring physicians and treating therapists are fully aware of the information that must be included in the order or referral.

Response: As we stated in the proposed rule, the order or referral must be written, dated and signed by the ordering or referring physician/NPP and include the type of therapy—physical therapy, occupational therapy, or speech-language pathology—the patient requires. We are clarifying here that we would also expect the order or referral to include information to identify the beneficiary and ordering/referring physician/NPP.

Comment: Two commenters informed us that they believe there is a difference between the terms order and referral—stating that a referral is broadly inclusive of the more specific term ''order'' that might contain specific treatment specifications (for example, duration, frequency) and would be treated functionally the same as a referral broadly specifying the need for therapy services. They pointed out that the Medicare Benefit Policy Manual (MBPM) contains the term ''order'', and it may be confusing if the regulation and MBPM terminology differ. These commenters stated that they would like us to use only one term, ''referral'', ''order'' or ''order/referral'', preferably ''referral'', for this policy and regulation and related MBPM sections for therapy services that they claim will be helpful to PTs who use the MBPM to learn about and understand our policies.

Response: We thank the commenters for their remarks. As we have used the ''order or referral'' and ''order/referral'' terminology throughout this rulemaking

for our proposed exception to the signature requirement policy, we will continue to use it here and in the regulation text at § 424.24(c)(5). We agree that our Medicare Benefit Policy Manual (MBPM), Pub. 100–02, chapter 15, should conform with the regulation and, as such, we will revise the manual in section 220, to reflect that the terms ''order or referral'' can be used interchangeably.

After consideration of public comments, we are finalizing our proposal to amend the certification regulations at 42 CFR 424.24(c) to provide an exception to the physician/NPP signature requirement on the therapist-established treatment plan for purposes of the initial certification in cases where a written order or referral from the patient's physician/NPP is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician/NPP within 30 days of the initial evaluation. We are also finalizing the regulation text at § 424.24(c), as proposed for paragraphs (c), (c)(1)(i), and (c)(3)(ii). We are finalizing the added paragraph (c)(5) with a modification to replace the term ''plan of care'' with ''plan of treatment.'' We recognize that we have used the term ''plan of care'' and ''POC'' in our preamble discussion in the CY 2025 PFS proposed rule and in this final rule, and consider ''plan of care'' and ''plan of treatment'' to have the same meaning. However, we are substituting the term ''plan of treatment'' for ''plan of care'' in the regulation to be consistent with the other uses of plan of treatment found at § 424.24(c). We will be implementing this exception to the signature requirement policy and the clarifications added above via our usual change management process to our contractors.

In addition, we solicited comments to gather more information about the need for a regulation that will address the amount of time for changes to plans of treatment. Our regulations at 42 CFR 410.61(d), which are further clarified in our manual provisions in Pub. 100–02, chapter 15, section 220.1.2.C, currently allow for changes to the treatment plan by the physician/NPP without time restrictions. Interested parties have suggested that we allow physicians/NPPs to have just 10 business days from the date of receipt of a plan of care to modify that plan of care (in the case of a patient with an order for the therapy services).

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported having a 10-business day window of opportunity for the physician or NPP to provide modification to the plan of care while some of these commenters stated that 10 business days was a reasonable timeline for the physician/NPP to make changes to the patient's POC. One commenter supporting the 10-business day timeline expressed concern that POC communications about his/her patients to and/or from the smaller therapy provider without a robust EHR system may prove challenging.

Response: We thank the commenters for their comments.

Comment: Several commenters did not support the 10-business day window. One commenter stated that the NPP may not be able to respond within 10 days, and could determine that a modification is necessary after a later review. Another commenter opposed any limitation on the physician's ability to modify the plan of care stating that his/her order/referral in these cases means that they are relinquishing their ability to direct the patient's care, including those occasions when during the episode of care a patient sees the physician with a change in their condition that necessitates a modification. Another commenter voiced concern about establishing restrictive time limits for physicians/NPPs to make POC modifications since none exist currently and they recommend we maintain standing policy until more input is gathered from stakeholders.

Response: We thank the commenters for their comments.

Comment: A few commenters stated that allowing 10 days for a physician to provide modification to the POC was too long. One commenter pointed out that this 10-day window is a disservice to patients since it could postpone healing, pain relief, or receipt of other needed care including increased mobility; and it could complicate scheduling appointments that will accommodate them and their caregivers.

Response: We thank the commenters for their comments.

Comment: Many commenters urged us to clarify that physician/NPP modifications to therapy POCs are only applied on a prospective basis and asked us to guarantee payment for those therapists' services provided prior to a physician/NPP modification to the POC as the patient was under the care of a physician/NPP. They believe that prior to the modification of the POC, the therapy services provided to the patient met Medicare requirements for reimbursement—being both medically necessary and under the care of a physician. The commenters further stated unless we ensured payment for the therapy services furnished prior to the POC being modified by the physician/NPP, therapists would continue to have to decide, just as they do now, whether to risk providing timely care or waiting 10 days before providing therapy services to avoid nonpayment for a modification. We also heard from many therapist commenters who told us they believe the 10-day window both guarantees payment for their services and allows physicians/NPPs the opportunity to provide input to the POC without impeding the provision of timely therapy services. One commenter stated that the time limit was not needed at all if we were to guarantee payment for services prior to physicians/NPPs modification of the POC during the episode of care.

Response: We thank the commenters for their comments.

Comment: One commenter stated their support for the 10-day review policy; however, they also stressed that it is important to preserve existing processes that allow therapists and physicians to work closely together to deliver medically necessary care. Currently, physicians may request changes to POCs at any point throughout the episode of care and the therapist will adjust the POC based on the physician's recommendation. If we finalize the 10-day window review policy, the commenter suggests we view the 10-day review period as an opportunity for establishing the physician's immediate feedback and that it does not preclude their ability to provide future input later in the episode.

Response: We appreciate the commenters' remarks as to the importance of maintaining the ability of the physician/NPP to make changes to a patient's POC outside of the 10-day window, as noted at § 410.61(d), if we were to adopt this 10-day window policy.

Comment: Two commenters requested that we clarify how the physician-modified POC is treated once the therapist has adjusted the POC and sent it back to the referring physician/NPP. They both question whether the modified POC ''presumptively'' meets the signature requirement because the physician input has been incorporated; while one of these commenters also asked if the amended POC requires a physician signature or whether the new POC is subject to the same exception requirement and if the 10-day review period restarts from the date the new

POC was transmitted back to the physician.

Response: The fact that a physician/NPP has modified the POC does not alter the fact that the POC was first established by the therapist at the beginning of the episode of care with an order/referral from that physician/NPP which is maintained in the patient's medical record. If we were to adopt the 10-business day window policy, we would continue to treat the modified plan of care as meeting the exception to the signature requirement, unless the physician/NPP returns the POC with the modifications to the therapist signed, at which point it meets the signature requirement and the exception would not be needed.

Comment: One commenter stated that we should educate the MACs well in advance of the effective date of these new policies and suggested we consider a formal program memorandum to do so. They stated that the MACs have singled out the signature requirement for the POC certification most frequently for denials and oversight, citing examples of the Targeted Probe and Educate program and claims audits. These commenters requested that we ensure that the new finalized policies are understood by our contractors in advance of claims processing for 2025.

Response: Currently, MACs primarily perform prepayment review after claims from therapists or providers are submitted and prior to claims processing. However, the physician/NPP signature itself does not represent medical necessity or ensure payment for the therapy service whether it's on the order/referral or on the POC without an order—in these prepayment review cases, the MACs would look at the therapy services provided to determine their medical necessity. The physician/NPP order/referral would demonstrate the intent for the skilled service, which should then be reflected in the therapist-established plan of care. We will implement these provisions using our usual change management process to provide instructions to contractors and make manual revisions to the applicable sections of the MBPM, chapter 5.

After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

We acknowledge the concerns raised by commenters about payment for any therapy services furnished prior to a physician/NPP modifying a plan of care. We agree with commenters that payment should be made for such therapy services if all applicable payment requirements, including medical necessity, are met. We are clarifying that whenever a physician/NPP amends the therapist-established POC at any point during the patient's episode of care, payment determinations for services provided by the therapist prior to the amendment should be based on the POC that had been timely submitted to the physician/NPP who had written the order/referral, or under a POC without an order/referral submitted to the physician/NPP with knowledge of the case, and considering all other applicable payment requirements, including medical necessity. That said, we remind readers that our final policy, as we noted in the CY 2025 PFS proposed rule (89 FR 61739), will not affect a contractor's ability or authority to determine whether therapy services are reasonable and necessary for a given beneficiary; and, as noted above, the same medical necessity requirements are applied for POCs established with and without orders, with the exception that for those POCs established with an order, the medical reviewers may additionally look for documentation in the patient's medical record of the written order/referral and evidence that the POC was submitted to the physician/NPP within 30 days of the therapist's evaluation. We believe that our finalized policy to permit the physician/NPP written order/referral for therapy services to substitute for the signature on the initial certification of the therapist-established treatment plan, will allow therapists to provide therapy services without any delay and at the same financial risk that he/she would have after receiving, after a period of waiting for, a signed POC from the physician/NPP without an order. This is because, as we noted above, the physician/NPP signature itself—whether on the order/referral or on the POC without an order—does not determine medical necessity or ensure payment for the therapy service. While the therapist has a 30-day timeline to send the POC to the physician/NPP writing the order/referral, sending the POC to the physician/NPP as soon as it is established would allow a MAC conducting medical review on a prepayment basis to be able to see the order on file and evidence that the POC had be sent to the physician/NPP in a timely manner while reviewing all documentation in order to determine the medical necessity of the POC and services provided. Additionally, we reiterate what we stated in the CY 2025 PFS proposed rule (89 FR 61739), and wish to clarify in this final rule, and at § 424.24(c)(5) with a minor amendment, that any reference to an order or referral at § 424.24(c)(5) cannot be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services. As we noted in the above section, we will implement these provisions using our usual change management process to provide instructions to contractors and make manual revisions to the applicable sections of in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 15, Sections 220 and 230. We are also considering providing education to therapy providers through a separate article should the usual education correlating to the program instruction with manual changes not be available until after the new policy takes effect on January 1, 2025.

Additionally, we solicited comment as to whether there should be a 90 calendar day time limit on the order/referral for outpatient therapy services in cases where the order/referral is intended to be used in relation to the proposed regulatory amendment for the initial certification of the treatment plan at § 424.24(c)(5) discussed previously—that 90-day limit would span from the order/referral date until the initial treatment of the patient, including the evaluation furnished by the PT, OT, or SLP. We also sought feedback about whether this limit, or one of a different duration, should be incorporated into the regulatory provision we proposed previously for § 424.24(c)(5).

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Some comments voiced opposition to the 90-day limitation we discussed in the comment solicitation. One commenter stated 90 days was too short and suggested a 6-month limit as more reasonable. Another commenter stated a 90-day limit to physician referrals would pose significant problems for certain patients whose physicians write referrals for therapy at the same time they order surgery, and by the time the patient is able to start therapy the referral could be older than 90 days—taking into consideration time for the surgery to be scheduled followed by a recovery period when needed. This commenter also said that having to implement different workflows for the referrals over 90 days would be difficult to manage. One commenter stated their concerns about the creation of a 90-day limit on orders/referrals that would be used specifically for purposes of the exception to the signature requirement on POC certification as it would create confusion and administrative burden

and may limit patients from receiving timely therapy services. Two commenters stated that workforce distribution has created variable staffing challenges across the country and believes that a backlog of referrals may exist in some states that typically results in therapy being scheduled months in advance—sometimes having to schedule new patients over 90 days after they received the referral. This commenter stated that they believe that a 90-day limit would overcomplicate the ability of these staffing-challenged therapy clinics because they would have the added burden of tracking down physician signatures and could have benefitted from the certification policy without the 90-day order limit. Both commenters suggested that we could reconsider this policy in the future should the agency determine that a significant amount of therapy is initiated beyond 90 days.

Response: We thank the commenters for their comments.

Comment: Several commenters supported the 90-day limit to the order/referral for these therapy services. Two of these commenters stated that a greater than 90-day period between the order/referral and the receipt of therapy might result in changes the patient's condition that could potentially require the referring physician/NPP to reevaluate or reassess the patient's condition in order to provide needed additional direction to the therapist. One of these commenters stated that their support for the exception to the signature requirement policy is contingent upon the adoption of the 90-day time limit on the physician order/referral.

Response: We thank the commenters for their comments.

After consideration of public comments, we appreciate the feedback from commenters and will take the comments into consideration for possible future rulemaking.

We clarify that we did not propose to amend § 424.27 for comprehensive outpatient rehabilitation facilities (CORFs) physical therapy, occupational therapy, and speech-language pathology treatment plans to align with our proposed amendments at § 424.24 because section 1861(cc) of the Act and regulation at 42 CFR 410.105(c) require these treatment plans to be established by a physician.

3. KX Modifier Thresholds

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA) and were formerly referred to as the therapy cap amounts. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2025, we proposed to increase the CY 2024 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2025, the proposed MEI increase was estimated to be 3.6 percent and was based on the expected historical percentage increase of the 2017-based MEI. Multiplying the CY 2024 KX modifier threshold amount of $2,330 by the proposed CY 2025 percentage increase in the MEI of 3.6 percent ($2,330 × 1.036) and rounding to the nearest $10.00 resulted in a proposed CY 2025 KX modifier threshold amount of $2,410 for physical therapy and speech-language pathology services combined and $2,410 for occupational therapy services. We also proposed to update the MEI increase for CY 2025 based on historical data through the second quarter of 2024, and we proposed to use such data, if appropriate, to determine the final MEI percentage increase and the CY 2025 KX modifier threshold amounts in the CY 2025 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels will be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2025, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

(1) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(2) The therapy provider has a billing pattern for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(3) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(4) The services are furnished to treat a type of medical condition.

(5) The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceed one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

Comment: Several commenters supported the change in the KX modifier threshold amounts for CY 2025 and urged us to finalize them.

Response: We appreciate the supportive remarks from the commenters.

Comment: One commenter asked us to provide a clarification as to why we grouped physical therapy and speech-language pathology together stating they should each have their own distinct threshold.

Response: Section 1833(g) of the Act defines dollar amounts for the KX modifier thresholds—there is one amount for physical therapy and speech language pathology services combined and a separate amount for occupational therapy services—just as with the incurred expenses for the prior therapy cap amounts. More information about

the KX modifier threshold amounts can be found on the therapy services web page in the article titled *The Implementation of the Bipartisan Budget Act of 2018* that is located at *https://www.cms.gov/medicare/coding-billing/therapy-services*.

We stated in the CY 2025 PFS proposed rule that we would use the MEI update based on historical data through the 2nd quarter of 2024 to determine the final MEI percentage increase and the CY 2025 KX modifier threshold amounts in the CY 2025 PFS final rule. The final CY 2025 MEI is 3.5 percent based on historical data through the second quarter of 2024. Using this percentage increase results in a KX modifier threshold amount of $2,410 for physical therapy and speech-language pathology services combined and $2,410 for occupational therapy services, which we are finalizing for CY 2025.

I. Advancing Access to Behavioral Health Services

1. Safety Planning Interventions and Post-Discharge Telephonic Follow-Up Contacts

a. Background

In the CY 2024 PFS proposed rule, we sought comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department (ED) or other crisis settings for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated. Several commenters encouraged CMS to enable wider implementation under Medicare of the Safety Planning Intervention (SPI) and the Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) and expressed that the current payment mechanisms are not sufficient, noting that the lack of adequate payment mechanisms and suitable billing codes for these interventions are barriers that are essential to address. The commenters noted that EDs are not the only care setting where there is need and opportunity to enhance suicide prevention, but that elevated suicide risk is particularly prevalent among ED patients. One commenter noted that a designated code for SPI would make it significantly easier to document that SPI was furnished, including in quality reporting and value-based payment programs.

More than 49,000 people died by suicide in 2022 [153] and death by suicide is growing significantly in older adults, who comprise most of the Medicare population. Among those age 65 and older, the suicide rate increased 4.5% from 2021 to 2022.[154] We recognize data showing that suicide by intentional overdose is a growing concern, particularly among young people, older people, and Black women, although researchers acknowledge the complexities of distinguishing intentional from unintentional death.[155]

b. Safety Planning Interventions (SPI)

Safety planning interventions involve a patient working with a clinician to develop a personalized list of coping and response strategies and sources of support that the person can use in the event of experiencing thoughts of harm to themselves or others. This is not a suicide risk assessment, but rather, an intervention provided to people determined to have elevated risk for suicide. Safety planning interventions have also been used to reduce the risk of overdose. The basic components of a safety plan include the following: (1) recognizing warning signs of an impending suicidal crisis or actions that increase the risk of suicide; (2) employing internal coping strategies; (3) utilizing social contacts and social settings as a means of distraction from suicidal thoughts and/or taking steps to reduce the risk of suicide; (4) utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; (5) contacting mental health professionals, crisis services, or agencies; and (6) making the environment safe, including restricting access to lethal means, as applicable.[156] One important aspect of making an environment safe could be, for example, addressing a person's access to lethal means, such as firearms, environmental means (including bridges and tall structures), and medications/drugs.

We understand that safety planning is consistent with current practice standards and that many hospitals and clinicians in other settings are already providing some or all of these services to the people who need them, including through the Department of Veterans Affairs (VA).[157] [158] However, in one survey of EDs, only 15.3 percent could confirm routinely implementing safety planning with all of the structured elements mentioned above. Provision of individual safety planning elements ranged from 24.8 percent (n = 492) to 79.2 percent (n = 1710), with 2 of 6 elements being routinely provided more than 50 percent of the time: lists of professionals or agencies to contact in a crisis (1710 [79.2 percent]) and helping patients to recognize warning signs of suicide (1075 [52.2 percent]).[159] Suicide risk among people with substance use disorders who also are at high risk for or may have experienced an intentional overdose is not well recognized.[160]

Therefore, we proposed in the CY 2025 PFS proposed rule to establish separate coding and payment under the PFS describing safety planning interventions. Specifically, we proposed to create an add-on G-code that would be billed along with an E/M visit or psychotherapy when safety planning interventions are personally performed by the billing practitioner in a variety of settings. We recognize that training and expertise are needed to perform these interventions safely and appropriately and sought comment regarding whether clinical staff who meet the definition of auxiliary personnel defined at 42 CFR 410.26(a)(1) or who are employed by a hospital could participate in furnishing this service under the supervision of the billing practitioner in certain settings with the relevant training needed to perform the service as well as what sort of training would be needed.

The proposed G-code is HCPCS code G0560: *Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis;*

[153] *https://www.cdc.gov/suicide/facts/data.html.*

[154] *https://wonder.cdc.gov/.*

[155] *https://www.nih.gov/news-events/news-releases/suicides-drug-overdose-increased-among-young-people-elderly-people-black-women-despite-overall-downward-tren.*

[156] Barbara Stanley, Gregory K. Brown, Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk, Cognitive and Behavioral Practice, Volume 19, Issue 2, 2012, Pages 256–264, ISSN 1077–7229, *https://doi.org/10.1016/j.cbpra.2011.01.001.*

[157] *https://www.mentalhealth.va.gov/docs/vasafetyplancolor.pdf.*

[158] *https://www.mirecc.va.gov/visn19/research/our-research/implementation.asp.*

[159] Bridge JA, Olfson M, Caterino JM, Cullen SW, Diana A, Frankel M, Marcus SC. Emergency Department Management of Deliberate Self-harm: A National Survey. JAMA Psychiatry. 2019 Jun 1;76(6):652–654. *doi: 10.1001/jamapsychiatry.2019.0063.* PMID: 30865243; PMCID: PMC6552299.

[160] Ries RK, Livengood AL, Huh D, et al. Effectiveness of a Suicide Prevention Module for Adults in Substance Use Disorder Treatment: A Stepped-Wedge Cluster-Randomized Clinical Trial. *JAMA Netw Open.* 2022;5(4):e222945. *doi:10.1001/jamanetworkopen.2022.2945.*

contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy). We welcomed comments on the proposed elements of the safety planning code.

We proposed to value HCPCS code G0560 based on the valuation for CPT code 90839 (*Psychotherapy for crisis*), which describes 60 minutes, and which we believe describes a similar level of intensity as HCPCS code G0560. For HCPCS code G0560, we assumed a typical time of 20 minutes, resulting in a work RVU of 1.09 (based on one third of the work value currently assigned to CPT code 90839, which is 3.28). We welcomed comments on whether 20 minutes accurately captures the typical amount of time spent with a patient on safety planning interventions, including all six elements enumerated in this section. Additionally, we welcomed comments on whether these interventions typically occur in the context of an encounter, such as an E/M visit or psychotherapy, or whether there may be times when they may be furnished as a standalone service and whether we should consider allowing this code to be billed on its own. We also welcomed comments regarding which clinician types might be most likely to bill such a code on its own.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters recommended that we finalize this code as a standalone code, rather than an add-on code, noting that practitioners need a way to capture time spent performing safety planning interventions beyond the initial 20 minutes. Commenters noted that in settings such as emergency departments, crisis centers, and primary care, SPI will be conducted on its own at times and at other times, SPI will be provided in addition to services such as psychotherapy or E/M services and stated it is essential to establish a billing mechanism that meets the requirements for each of these scenarios. They noted that as currently proposed, there is a risk that additional services that are not required will be conducted to justify billing this code. Other commenters emphasized that the flexibility to bill SPI as a standalone service is essential for providing timely interventions, especially in emergency settings or during critical periods when a full E/M visit or psychotherapy session may not be feasible. These commenters also believe that the proposed typical time of 20 minutes does not accurately capture the typical amount of time spent with a patient to provide evidence-based safety planning interventions, noting that 20 minutes would be the minimum and that 20–45 minutes is typical, while some commenters stated that 45–60 minutes is typical for adults and 90 minutes would be typical for minors or adults who require caregiver assistance. Many commenters recommended that we should allow this code to be billed in units of 20 minutes and allow up to 6 units per encounter. The commenters state that this would accommodate the varying needs of patients, ensuring that those requiring more intensive intervention receive the appropriate level of care.

Response: We thank the commenters for their feedback. We are persuaded by the commenters that there may be times when SPI may need to be furnished as a standalone service, that more time may be needed to complete safety planning interventions and that one 20-minute code may not accurately reflect the resource costs involved in furnishing these services. Therefore, we are finalizing HCPCS code G0560 as a standalone code that can be billed in 20-minute increments.

Comment: Several commenters stated they believe that there is sufficient evidence to support trained clinical staff providing this service under the supervision of the billing practitioner and stated that restricting the service to only allowing the billing practitioner to personally provide the service will severely limit uptake and access for beneficiaries. Several commenters noted that allowing a broader spectrum of staff to provide SPI mirrors the approach used in clinical studies and is consistent with how many existing programs operate. Some commenters stated they agreed that training and practicing within scope is crucial, and also noted that continued training and education is also important and cited that most providers who furnished suicide safety planning desired further training. Other commenters recommended that we require the same staff qualifications that are required for mental health community case management and/or mental health community support under the Medicaid Rehabilitation Option as these positions are frequently used to provide the same services under Medicaid.

Response: We appreciate the feedback from the commenters on this issue. While some commenters emphasized the importance of training, we did not receive specific feedback regarding the nature of the training that would be needed. We also note that for services furnished in hospital settings, services provided by clinical staff would not be separately payable. We are finalizing as proposed that HCPCS code G0560 would need to be personally performed by the billing practitioner for CY 2025, but we will continue to consider this issue for future rulemaking. We also note that the billing practitioner could be any practitioner who is authorized to furnish services for the diagnosis and treatment of mental illness, including Clinical Social Workers, Mental Health Counselors, Marriage and Family Therapists, Clinical Psychologists, as well as physicians and NPPs.

Comment: Some commenters requested that this code be allowed to be billed when furnished via telehealth.

Response: We thank the commenters for this response. Since HCPCS code G0560 is similar to other services already on the Medicare Telehealth list, such as psychotherapy for crisis, we are finalizing adding HCPCS code G0560 to the Medicare Telehealth list. The full list of services being added to the Medicare Telehealth list for CY 2025 can be found Section II.D. of this final rule, Payment for Medicare Telehealth Services Under Section 1834(m) of the Act.

Comment: A few commenters noted that we acknowledged the increasing usage of safety plans related to overdose prevention, but pointed out that the proposed code descriptor reads as if the code is specific to safety planning to prevent an impending suicidal crisis. The commenters suggested that we update the code descriptor to reflect ''recognizing warning signs of an impending suicidal or substance use-related crisis'' and to update the language regarding contacting professionals to read, ''contacting mental health or substance use disorder professionals or agencies.'' Similarly, another commenter also requested that we update the language regarding utilizing social contacts and social settings as a means of distraction from suicidal thoughts to also add the language, ''or risky substance use.'' Other commenters requested that we add an additional step in the language in the code descriptor to include reference to a ''crisis narrative'' in which the patient is asked to describe how they found themselves at a point where they were thinking of suicide and also, for clarity, to add the words ''that are documented in a form.''

Response: We thank the commenters for their feedback and note that we are updating the code descriptor to include ''recognizing warning signs of an impending substance-use related crisis,'' ''contacting mental health or substance use disorder professionals or agencies,''

and adding ''or risky substance use,'' as suggested. In response to the comments requesting that we revise the code descriptor to refer to a crisis narrative and add the words ''that are documented in a form,'' we agree that a crisis narrative would be a typical component of these services and that the safety plan would be documented in a form, however, we do not believe that these items need to be listed in the code descriptor. Additionally, we note that GSPI1 was a placeholder code and the final code number is HCPCS code G0560 (*Safety planning interventions, each 20 minutes personally performed by the billing practitioner, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal or substance use-related crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts or risky substance use; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health or substance use disorder professionals or agencies; and making the environment safe.*

In summary, after consideration of public comments, we are finalizing our proposal to create separate coding and payment for safety planning interventions, with modifications. Specifically, we are finalizing HCPCS code G0560 as a standalone code, rather than an add-on code as proposed. We are also finalizing that HCPCS code G0560 can be billed in units of 20 minutes. We are finalizing as proposed that HCPCS code G0560 would need to be personally performed by the billing practitioner for CY 2025, but we will continue to consider this issue for future rulemaking.

c. Post-Discharge Telephonic Follow-Up Contacts Intervention (FCI)

Some research suggests that patients seen in the ED with deliberate self-harm, intentional overdose, and/or suicidal ideation have been associated with substantially increased risk of suicide and other mortality during the year following their visit to the ED.[161] FCI is a specific protocol of services for individuals with suicide risk involving a series of telephone contacts between a provider and patient in the weeks and sometimes months following discharge from the emergency department and other relevant care settings, that occurs when the person is in the community and is designed to reduce the risk for subsequent adverse outcomes. FCI calls are typically 10–20 minutes in duration and aim to encourage use of the Safety Plan (as needed in a crisis) and updating it to optimize effectiveness, expressing psychosocial support, and helping to facilitate engagement in any indicated follow-up care and services. We note that this service would not be within the scope of Medicare telehealth services and not subject to the restrictions described in Section 1834(m) because these services are specifically structured to be delivered via audio-only phone calls and are not a substitute for an in-person service.

In a recent study led by the Joint Commission, which surveyed a national sample of hospitals to assess the prevalence of SPI and several other recommended suicide prevention services, fewer than half of responding hospitals reported furnishing any post-discharge follow-up contacts. Of these, only 33 percent (16 percent of responding hospitals overall) reported reaching discharged patients ''most of the time.'' Further, among hospitals that furnish follow-up contacts, fewer than half reported covering any of the main aims of FCI, for example, 41 percent review the Safety Plan, 49 percent provide psychosocial support, and 38 percent facilitate outpatient care.[162]

However, some studies have demonstrated that SPI and other services may be able to reduce suicidal behaviors. For example, in the ED–SAFE trial for emergency department (ED) patients identified with elevated suicide risk, the intervention included SPI and up to seven post-discharge follow-up calls with the patient ''focused on identifying suicide risk factors, clarifying values and goals, safety and future planning, facilitating treatment engagement/adherence, and facilitating patient-significant other problem-solving.'' [163] In the SAFE VET study [164] of ED patients identified with elevated suicide risk, the intervention included SPI and at least two follow-up calls with patients ''to monitor suicide risk, review and revise the SPI, and support treatment engagement.'' [165] Each of these studies reported significantly lower suicide behaviors—attempts and/or deaths—among intervention patients compared to the respective control conditions.

In light of this, we proposed in the CY 2025 PFS proposed rule to create a monthly billing code to describe the specific protocols involved in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month, each lasting between 10–20 minutes. The G-code is HCPCS code G0544: *Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.* We sought comment on whether we should consider finalizing a specified duration that HCPCS code G0544 could be billed) following discharge, for example, allowing this code to be billed for up to two months following discharge or whether a longer duration would be appropriate, the number of calls per month, the billing structure (for example, four calls for each discharged patient), and any other relevant feedback.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

We proposed to price this service based on a direct crosswalk to CPT code 99426 (*Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional*), which is assigned a work value of 1.00 work RVUs. Since CPT code 99426 describes care management for a single condition, we believe the work will be similar in nature and intensity. We noted that under this proposal, HCPCS code G0544 could be billed regardless of whether HCPCS code G0560 was also furnished and billed for the same patient. We proposed that the billing practitioner will need to meet a threshold of at least one real-time telephone interaction with the patient in order to bill HCPCS code G0544, and that unsuccessful attempts to reach the patient will not qualify as

[161] Goldman-Mellor S, Olfson M, Lidon-Moyano C, Schoenbaum M. Association of Suicide and Other Mortality With Emergency Department Presentation. JAMA Netw Open. 2019 Dec 2;2(12):e1917571. *doi: 10.1001/jamanetworkopen.2019.17571.* PMID: 31834399; PMCID: PMC 6991205.

[162] *https://www.sciencedirect.com/science/article/pii/S1553725024000679?via%3Dihub.*

[163] Miller IW, Camargo CA Jr, Arias SA, Sullivan AF, Allen MH, Goldstein AB, Manton AP, Espinola JA, Jones R, Hasegawa K, Boudreaux ED; ED–SAFE Investigators. Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. JAMA Psychiatry. 2017 Jun 1;74(6):563–570. doi: 10.1001/jamapsychiatry.2017.0678. PMID: 28456130; PMCID: PMC5539839.

[164] *https://pubmed.ncbi.nlm.nih.gov/29998307/.*

[165] Stanley B, Brown GK, Brenner LA, Galfalvy HC, Currier GW, Knox KL, Chaudhury SR, Bush AL, Green KL. Comparison of the Safety Planning Intervention With Follow-up vs Usual Care of Suicidal Patients Treated in the Emergency Department. JAMA Psychiatry. 2018 Sep 1;75(9):894–900. doi: 10.1001/jamapsychiatry.2018.1776. PMID: 29998307; PMCID: PMC6142908.

a real-time telephone interaction. We welcomed comments on this threshold to bill HCPCS code G0544, recognizing that while practitioners may attempt to reach the patient, there may be times when the patient cannot be reached. We also proposed that the billing practitioner could not count time or effort more than once for the purposes of billing this code and another service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that we unbundle these calls, stating they should be billable per call, allowing up to four calls per month. Commenters stated that unbundling would discourage delaying initiation of these services due to concerns about having enough time in a calendar month to complete a call, especially given the challenges of reaching patients; would incentivize placing multiple calls per month; provide flexibility; and generate data on the number of calls completed, which could be used for future refinement of the code. Commenters also noted that qualifying index visits for billing FCI should include discharge from psychiatric inpatient units/facilities. Several commenters also cited that evidence from the Emergency Department Safety Assessment and Follow-Up Evaluation (ED–SAFE) trial indicates that a longer follow-up period (6 months to a year) significantly enhances the effectiveness of suicide prevention efforts.

Response: We thank the commenters for their feedback. However, we continue to believe that a monthly billing structure would be the most efficient manner in which to bill these services and therefore, we are finalizing HCPCS code G0544 as a monthly bundle, as proposed. Regarding the comments about a longer follow-up period, we acknowledge the evidence cited and are not finalizing a set duration that this could be billed for; rather, we are finalizing that we will allow for this code to be billed and paid for as long as the service is medically reasonable and necessary.

Comment: A commenter suggested that instead of establishing G-codes, CMS could propose extending the use of or revising the existing CPT codes for transitional care management and/or discharge day management services to help patients safely return to their home or community from the ED or other settings.

Response: We appreciate these comments and may consider them for future rulemaking. We are finalizing HCPCS code G0544 as proposed. We also recognize that the CPT Editorial Panel has frequently created CPT codes describing services for which we originally established G-codes and adopted them through the CPT Editorial Panel process. We would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

Comment: A few commenters recommended that payment or partial payment be made for earnest attempts to contact the individual, even if the contact is unsuccessful, in order to recognize the effort and time it takes for the provider to attempt to furnish critical follow up.

Response: We thank the commenters for this feedback. However, we are finalizing as proposed that the billing practitioner will need to meet a threshold of at least one real-time telephone interaction with the patient in order to bill HCPCS code G0544, and that unsuccessful attempts to reach the patient will not qualify as a real-time telephone interaction.

Comment: A few commenters suggested that CMS should value HCPCS code G0544 based on a crosswalk to CPT code 99490, Chronic Care Management, first 20 minutes, which is assigned a work RVU of 1.00.

Response: The proposed work RVU for HCPCS code G0544 is 1.00, based on a crosswalk to CPT code 99426 (Principal Care Management). Since CPT code 99426 and 99490 are currently both assigned the same work RVU of 1.00, we are finalizing this valuation as proposed.

Comment: Several commenters suggested that HCPCS code G0544 should be applicable to other settings where an individual is discharged for a crisis encounter and some commenters suggested that CMS should allow this service to be provided in conjunction with a discharge from a hospital, inpatient behavioral health facility, and other inpatient settings.

Response: We thank the commenters for this feedback. We wish to clarify that HCPCS code G0544 can be billed by practitioners in any instance in which the beneficiary has been discharged following a crisis encounter, including discharge from psychiatric inpatient care, or crisis stabilization.

Comment: Some commenters requested clarification regarding whether auxiliary personnel could participate in furnishing the services described by HCPCS code G0544 incident to the services of the billing practitioner.

Response: We thank the commenters for this request. We wish to clarify that the services described by HCPCS code G0544 can be provided by auxiliary personnel incident to the services of the billing practitioner in accordance with the requirements of § 410.26.

Additionally, as we recognized that behavioral health practitioners, training programs, and institutions have worked conscientiously to have risk assessment and safety planning for high-risk patients integrated into their workflows for many years and that discharge instructions and after visit planning may represent one of many final products from the synthesis of all the steps involved in these encounters, we noted that we do not intend to unnecessarily disaggregate aspects of streamlined clinical workflows that providers are successfully using to treat high risk patients. Moreover, we recognized that practitioners may currently be billing for safety planning activities using existing coding, such as E/M visits, psychotherapy, and crisis management codes or potentially for follow-up calls using existing care management services. However, to the extent that this intervention is part of the standard of care, we believe that Medicare payment should accurately reflect the additional resource costs involved in furnishing this service.

Lastly, as applicable Part B cost sharing would apply for HCPCS code G0544, we proposed to require the treating practitioner to obtain verbal (or written) beneficiary consent in advance of furnishing the services described by G0544, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with care management and other non-face-to-face services paid under the PFS. We noted that under this proposal, obtaining advance consent would include: (1) ensuring that the patient is aware that Medicare cost sharing applies to these services; (2) furnishing and receiving the necessary information to enable the patient to receive these services (for example, obtaining the patient's telephone number(s)); and (3) confirming that the patient consents to the contacts.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that while they agree that consent would be necessary for these services given the financial liability the patient will incur, it may not be possible to obtain consent before performing the services and therefore urged CMS to allow consent to be obtained during the initial phone call. Some commenters suggested

eliminating cost sharing for this service, noting that who require these services are already in an emotionally and mentally vulnerable place and may be reluctant to interact with healthcare providers.

Response: We thank the commenters for this feedback. In response to the comments, we agree that it may not be possible to obtain consent prior to the first phone call, and therefore, we are finalizing to allow consent to be obtained either prior to, or during the initial phone call. Regarding the suggestion to eliminate cost sharing for this service, we note that we do not have statutory authority to waive cost sharing for these services.

Lastly, we note that GFCI1 was a placeholder code. The final code number describing this service is HCPCS code G0544.

2. Digital Mental Health Treatment (DMHT)

We proposed Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. We refined the digital cognitive behavioral therapy ''digital CBT'' terminology that we have used previously (88 FR 52262, 52370 through 52371, 88 FR 78818, 79012 and 79013). In this final rule we use the term ''digital mental health treatment (DMHT) device'' to include the term ''digital CBT'' we used in prior rulemaking and in general to refer to software devices cleared, approved, or granted De Novo authorization by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health. We noted first that the *Diagnostic and Statistical Manual of Mental Disorders–5 (DSM–5)* does not refer to psychiatric disorders but to mental disorders. In this section, following the DSM–5, we used the term behavioral health conditions and mental disorders interchangeably and to mean psychiatric disorders as referenced in FDA regulation, 21 CFR 882.5801. This includes substance use disorders. Second, we noted that FDA guidance refers to computerized behavioral therapy by the acronym CBT. We stated in the proposed rule that we aimed to both provide access to vital behavioral health services and gather further information about the delivery of digital behavioral health therapies, their effectiveness, their adoption by practitioners as complements in the care they furnish, and their use by patients for the treatment of behavioral health conditions. We also noted that we recognized that there are certain statutory limitations on payment for products under the broader category of ''digital health interventions.'' We acknowledged that the field of digital therapeutics is evolving and are open to feedback from the public on this topic, including the CPT Editorial Panel. Additionally, we recognized that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G codes and adopted them through the CPT Editorial Panel process. We noted that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

a. Background

Over the last 5 years the AMA CPT Editorial Panel and CMS have developed coding and separate payment for monitoring physiologic status using software enabled devices that capture and record or transmit data that may be reported to and interpreted by practitioners to manage a patient under a specific treatment plan (83 FR 59452, 59574). Medicare payment has long been available for practitioner provision of monitoring equipment and other kinds of devices provided incident to or integral to the practitioner's professional services. Most recently we have finalized payment for devices which record data related to signs, symptoms, and functions of a therapeutic response (typically for use in association with physical or occupational therapy care) (86 FR 64996, 65114–65116).

However, technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical and are not well accounted for in our practice expense (PE) methodology. PE resources involved in furnishing services are characterized as either direct or indirect costs. Direct costs of the PE resources involved in furnishing a service are estimated for each HCPCS code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage is the Physician Practice Information Survey (PPIS), last administered in 2007 and 2008, prior to the adoption of digital therapy technologies (86 FR 65037). Nevertheless, in past rulemaking, we have recognized that in some cases practitioners do incur resource costs for the purchase and ongoing use of software (86 FR 65038).

In the CY 2023 PFS final rule, we finalized our proposal to accept the RUC recommendation to contractor price CPT code 98978 (*Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavior therapy, each 30 days*), a PE-only device code (86 FR 69523, 69646). At the time, specialty societies indicated that the technologies for this service are still evolving, and that as a result, there were no invoices for devices specific to the cognitive behavioral therapy monitoring services described by the code that could be shared. Further, there was no professional work associated with the code.

In the CY 2024 PFS proposed rule, we requested information on digital therapeutics for behavioral health. Among many questions, we asked how practitioners determine which patients might be best served by digital therapeutics and how practitioners monitor the effectiveness of prescribed interventions on an ongoing basis once the intervention has begun. We also asked how the treating clinician was involved in the services received. We asked what scientific and clinical evidence of effectiveness CMS should consider when determining whether digital therapeutics for behavioral health, including care for substance use disorders, depression, sleep disorders and other conditions are reasonable and necessary. We asked whether DMHT devices were used as incident to supplies or independent of a patient visit with a practitioner and if practitioners in such cases issued an order for such devices (88 FR 52262, 52370 through 52371). These factors related to the nature of this treatment compared to other PFS services pose challenges for fitting DMHT services into the existing benefit structure under the PFS.

Setting appropriate pricing under the PFS has also presented challenges. As noted previously, technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware are not well accounted for in our practice expense

(PE) methodology, even though these items may be appropriately considered practice expenses. Consequently, over the past several years, we have relied on a crosswalk methodology to approximate relative resource costs for these kinds of services relative to other PFS services, or contractor pricing.

Interested parties requested that we adopt coding specifically for DMHT devices, where the digital software device is the actual therapy/intervention (the algorithm software is the DMHT) as opposed to a therapeutic monitoring device that transmits patient data as described by CPT code 98978 for which we finalized contractor pricing in CY 2023. Interested parties have also asked us to set national pricing for the service to supply the DMHT device and education/onboarding that reflects the direct practice expense incurred by practitioners when furnishing DMHT. One of the interested parties submitted invoices to provide data we could use as the basis to set payments for DMHT coding. The interested party submitted four invoices reflecting considerable variation in the cost of the DMHT treatment over 30-day and 90-day periods.

As the field of innovative products including digital therapeutics and computerized behavioral therapy devices for psychiatric or mental disorders develops and expands, the FDA and Substance Abuse and Mental Health Services Administration (SAMHSA) among other agencies such as the Veterans Health Administration (VHA) are also monitoring the development of the field of digital therapeutic devices, including for behavioral health care purposes. For example, VHA is providing digital behavioral health applications as self-help tools, not independent treatment interventions. The FDA has a regulatory framework, discussed in this section, to classify devices and review computerized behavioral therapy devices for psychiatric disorders.

b. Payment for Digital Mental Health Treatment (DMHT) Devices

We recognize that digital therapeutics may offer innovative means to access certain behavioral health care services. The FDA definition of devices encompasses software intended by the manufacturer to be used, alone or in combination, for the specific medical purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease and does not achieve its primary intended action by pharmacological, immunological or metabolic means.[166] SAMHSA has adopted the International Organization for Standardization's definition of DTx as ''health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.'' [167] SAMHSA also notes that ''DTx may be used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.'' Given nationwide behavioral health workforce shortages combined with increasing demand for behavioral health care services, some Medicare beneficiaries may have limited access to these services.[168] This proposal encompasses only part of what may be a spectrum of broadly similar products, most of which might require a new statutory Medicare benefit category. Specifically, we proposed in the CY 2025 PFS proposed rule to pay billing practitioners for DMHT devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care if that device had been cleared by FDA for use under 21 CFR 882.5801. Given that devices are not ''cleared'' by FDA for use under 21 CFR 882.5801, we clarify here that this proposed coding and payment policy would apply to DMHT devices that have been cleared under section 510(k) of the Food, Drug, and Cosmetics Act (FD&C Act) or granted De Novo authorization by FDA and classified under 21 CFR 882.5801, as discussed below. Many digital platforms and applications are marketed as behavioral health and wellness interventions; this proposal does not extend to such platforms and applications in part because other than some DTx, few at this time show evidence demonstrating improved behavioral health outcomes.[169]

We proposed to create three new HCPCS codes for DMHT devices modeled on coding for RTM services. Effective beginning in CY 2025, we proposed that physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness would be able to bill a new HCPCS code: G0552 (*Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan*) for furnishing a DMHT device. HCPCS code G0552 would be payable only if the DMHT device has been cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and classified under 21 CFR 882.5801 and the billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary. Furnishing of the DMHT device must be incident to the billing practitioner's professional services in association with ongoing treatment under a plan of care by the billing practitioner. The billing practitioner must diagnose the patient and prescribe or order the DMHT device. The patient could then use the DMHT device at home or perhaps in an office or other outpatient setting, if that is how the device has been classified by FDA for use under 21 CFR 882.5801. The DMHT device furnished must have demonstrated a reasonable assurance of safety and effectiveness. The FDA makes a determination of safety and effectiveness under 21 CFR 860.7. When making this determination, the FDA will consider a variety of factors including users, conditions of use, probable benefit to health weighed against probable injury, and reliability. The regulation at 21 CFR 860.7, states that ''[t]here is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.'' HCPCS code G0552 would not be payable in cases where the billing practitioner incurs no cost in acquiring and furnishing the DMHT device, or a patient procures the DMHT device independent of the practitioner. We will continue to monitor how DMHT devices are used as part of overall care.

We sought comment about other parameters that we should consider regarding the services described by HCPCS code G0552:

- Whether payment should be made if the practitioner furnishes a digital device that has not been classified by FDA for a specific use under 21 CFR 882.5801 for mental health treatment, even if the digital device has been classified by the FDA for another specific use under 21 CFR 882.5801;

[166] *https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.*

[167] *https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-health/pep23-06-00-001.*

[168] *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/behavioral-health-2013-2025.pdf.*

[169] *https://store.samhsa.gov/product/advisory-digital-therapeutics-management-and-treatment-behavioral-health/pep23-06-00-001.*

• Whether payment should be made for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and classified not only under 21 CFR 882.5801 but also under other regulations;
• Whether and how payment might be limited if a patient discontinues use of the DMHT device before completing a course of treatment; and
• Whether and how payment might be limited to a set number of DMHT devices per calendar month per patient.

In light of the pricing variability, as discussed previously, we proposed contractor pricing for HCPCS code G0552. We sought comment regarding what national pricing methodology we might consider, including what potential crosswalks would be appropriate.

We also proposed to establish payment for two additional new HCPCS codes. These codes are HCPCS code G0553 (*First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month*) and HCPCS code G0554 (*Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month).* Under this proposal, HCPCS code G0552 requires that the billing practitioner who diagnosed the patient and prescribed or ordered the DMHT device or that billing practitioner's clinical staff must monitor the patient's therapeutic response to the DMHT device and adjust the behavioral health therapy plan as needed. HCPCS codes G0553 and G0554 should only be billed when there is ongoing use of the DMHT device and should not be billed in cases where the patient discontinues use of the DMHT device.

For HCPCS code G0553 (first 20 minutes of monthly treatment management services directly related to use of the DMHT device), we proposed valuing the first 20 minutes of treatment management services based on a direct crosswalk to CPT code 98980 (remote therapeutic monitoring first 20 minutes), which is assigned a work RVU of .62. For HCPCS code G0554 (each additional 20 minutes of monthly treatment management services directly related to DMHT device), we proposed to value this code based on a crosswalk to CPT code 98981 (remote therapeutic monitoring each additional 20 minutes), which is assigned a work RVU of .61. We believe that the work and PE described by these crosswalk codes are analogous to the services described in HCPCS codes G0553 and G0554, respectively, because they include similar physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month. We welcomed comments on the proposed RVUs.

We received many public comments on these proposals. Most commenters expressed general support for our proposed coding. Only about a dozen expressed opposition or overall negative sentiment. Several dozen commenters expressed directional support but recommended significant refinements. The following is a summary of the comments we received and our responses.

Comment: Many commenters recommended we broaden our inclusion criteria for which devices would qualify for billing HCPCS code G0552. Some commenters felt that any product that had been classified as software as a medical device by the FDA under Section 201(h)(1) of the FD&C Act should be payable under our policy. Others opined that any remote therapeutic intervention based on medical devices as defined by FDA should be payable under HCPCS code G0552. Others felt that any digital therapeutic device for diagnosis or treatment of a behavioral health condition should be payable under HCPCS code G0552, and that clinicians may review the scientific literature around such devices and find them helpful and appropriate parts of certain behavioral health plans.

Other commenters recommended that we define ''mental health condition'' to explicitly include neurological conditions including dementia that are currently subject to treatment with effective FDA-authorized digital behavioral or psychological interventions. Many commenters advocated that we include medical and neurodevelopmental disorders to adequately cover the range of disorders treated by FDA-authorized products. Others recommended we clarify that all conditions in the DSM–5 are included, including SUD. Others asked that we make payment for evidenced-based psychotherapies for medical conditions that are not generally considered a mental health condition as defined by the DSM–5, for example, irritable bowel syndrome (IBS0, cancer care or obesity treatment. (Whether any of these may be classified as a ''somatic symptom disorder'' in the DSM–5 would be a matter for clinical judgement.)

Many supported payment for digital therapeutic devices specifically when they are furnished incident to a professional health service or ordered by a qualified health professional. Some commenters asked that we clarify which health professionals may report HCPCS code G0552 and asked whether auxiliary personnel such as peer support specialists and community health workers can bill the new codes because education and engagement are critical parts of successful use of digital mental health services.

Others, in response to our question about payment for devices classified by FDA under regulations besides 21 CFR 882.5801, Computerized behavioral therapy device for psychiatric disorders, offered that we should include devices for Gastrointestinal Conditions (21 CFR 876.5960), Attention Deficit Hyperactivity Disorder (21 CFR 882.5803), and Sleep Disturbance for Psychiatric Conditions (21 CFR 882.5705). Others recommended payment for Biofeedback (21 CFR 882.5050) devices.

Several commenters proposed that we adopt the definition provided in the Access to Prescription Digital Therapeutics Act of 2023, S723/HR1458: A product, device, internet application, or other technology that is cleared or approved under section 510(k), 513(f)(2), or 515 of the FD&C Act; has a cleared or approved indication for the prevention, management or treatment of a medical disease, condition or disorder; primarily uses software to achieve its intended result; and is a device that is exempt from section 502(f)(1) of the FD&C Act under 21 CFR 801.109.

On the other hand, some commenters expressed concern that FDA regulatory pathways are inadequate FD&C Act because many devices are authorized without having submitted rigorous studies demonstrating safety or effectiveness. Other commenters wanted to ensure that DMHT devices are safe and beneficial for clinicians and patients. Several commenters

recommended we define digital mental health treatment device independent of FDA regulatory classification pathways. Some commenters recommended that CMS create a registry of all eligible devices as a condition of payment or adopt a model developed by the American Psychiatric Association to evaluate their efficacy.

Other commenters supported our proposal's focus on digital interventions for behavioral health (including mental health and substance use disorders). Other commenters felt we should also include devices that are granted De Novo classification under section 513(f)(2) of the FD&C Act or granted Premarket Approval under section 515 of the FD&C Act. Others felt that DMHT devices do not always provide better health outcomes, and only high-quality, safe, and effective devices should be used. Others supported payment for DMHT devices as long as they are part of a physician-directed care plan. Another commenter supported our limited proposal because they believed DMHT applications are proliferating and their evidence base is minimal. Some referenced various efforts underway to develop an evidence-based evaluation framework for digital therapies. Another encouraged the continued evaluation of these services to ensure their efficacy in patient care. Another suggested CMS issue a broader RFI to gain stakeholder input on a fair and transparent process for evaluating ''Algorithm Based Health Services''. Another opined that CMS should identify opportunities and encourage vendors and billing practitioners to join in efforts to leverage interoperable DMHT data measure quality. Many commenters also recommended that DMHT devices and their technologies ensure or demonstrate data privacy and security. One commenter remarked about our inconsistent language in the proposal using the phrase ''incident to or integral to professional behavioral health services.''

Response: We appreciate all the comments and recommendations offered for our consideration. Commenters expressed wide ranging views about how broadly we should define DMHT devices for payment under HCPCS code G0552. First, we acknowledge the inconsistent use of the term ''incident to or integral to professional behavioral health services.'' We note that ''integral to'' is language reflected in one of the elements of the applicable regulation, 42 CFR 410.26(b)(2). We clarify that we were referencing 42 CFR 410.26 in the language ''incident to or integral to'' used in the proposed rule and that for clarity we are using ''incident to'' by itself in this section regarding DMHT devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health treatment under a behavioral health treatment plan of care. Second, as stated above, we wish to clarify that the definition of DMHT device as proposed would include devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA. In both instances, however, the device would need to be classified under 21 CFR 882.5801 to be payable under this policy.

We agree with commenters who expressed concern with ensuring that DMHT devices are not only safe for patients but also beneficial for patients. The technologies and platforms for digital therapeutics are evolving rapidly. We are at a starting point of Medicare payment for DMHT devices as supplies furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care and anticipate that this will be an iterative process. We are also cognizant that some of the definitions for DMHT devices that commenters proposed, or devices commenters recommended should be payable under HCPCS code G0552, including most Class I devices (exempt from 510(k)) may not be aligned with similar terms used by other agencies and may encompass devices not evaluated or authorized by the FDA. Commenters have noted the work of the American Psychiatric Association, and the Agency for Health Research and Quality (AHRQ), among others. Commenters have suggested CMS leverage its convening power to bring interested parties together to develop frameworks, quality measures, or DMHT device registries. Recommendations for CMS to do so are beyond the scope of the proposed policies in the CY 2025 PFS proposed rule. We do not have the capacity as some commenters have suggested to undertake evaluation of DMHT devices.

While partly in recognition of our inability to evaluate every DMHT device, we proposed to define DMHT device under the proposed codes as devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and classified under 21 CFR 882.5801 in an effort to ensure our payment policies for DMHT devices are aligned with devices the FDA classified with special controls requiring clinical data to validate the model of behavioral therapy as implemented by the device. We appreciate commenters concerns for patient privacy and data security. FDA's regulation of medical devices focuses on safety and effectiveness. Although loss of confidential health information is generally not considered to be a direct impact on safety and effectiveness, under Section 524B of the FD&C Act, a person who submits a 510(k), PMA, PDP, De Novo, or HDE for a device that meets the definition of a cyber device is required to submit information to ensure that cyber devices meet the cybersecurity requirements under section 524(b) of the FD&C Act.[170] FDA recommends that manufacturers submit their cybersecurity management plans as part of their premarket submissions so that FDA can assess whether the manufacturer has sufficiently addressed how to maintain the safety and effectiveness of the device after marketing authorization is achieved. Additionally, please note that manufacturers may be obligated to protect the confidentiality, integrity and availability of protected health information (PHI) throughout the product lifecycle in accordance with applicable federal and state laws, including the Health Insurance Portability and Accountability of 1996 (HIPAA).

We are finalizing payment under HCPCS code G0552 for DMHT devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health treatment under a behavioral health treatment plan of care. Specifically, we are finalizing that DMHT devices under this payment policy must be cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each case must be classified under 21 CFR 882.5801 for mental or behavioral health treatment. While presently use cases for insomnia, substance use disorder, depression and anxiety have been classified by the FDA under 21 CFR 882.5801, future use cases are not necessarily limited to these. Our objective in proposing that DMHT devices be classified under 21 CFR 882.5801 as a condition of payment was to set guardrails within our payment policy for patient safety and benefit. As clarified above, devices granted De Novo authorization by FDA if classified under 21 CFR 882.5801 would fall under the definition of DHMT device. We proposed to limit payment to

[170] Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff, issued September 27, 2023. *https://www.fda.gov/media/119933/download.*

devices classified under 21 CFR 882.5801 which are required to comply with the Class II special controls set forth at 21 CFR 882.5801(b), including clinical data to validate the model of behavioral therapy as implemented by the device.

Furthermore, we are finalizing that a physician or other practitioner who is authorized to diagnose, evaluate, and treat a mental health disorder may prescribe or order a DMHT device as permitted under the device's FDA clearance in accordance with State prescriptive authority and may report HCPCS code G0552. We are clarifying that auxiliary personnel meeting the requirements of 42 CFR 410.26(a)(1) may only provide part of the initial education and onboarding described in HCPCS code G0552, and cannot report HCPCS code G0552, as they do not have the statutory authority to serve as the billing practitioner. Additionally, we are clarifying that we do not define behavioral health services by HCPCS codes or by direct reference to the DSM–5. In the CY 2023 PFS final rule we did not propose to do so and did not do so when we finalized to allow behavioral health services to be furnished under the general supervision of a physician or NPP when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP (87 FR 69546). In general, we understand a behavioral health service to be any service furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders (SUD). However, we continue to believe individual practitioners are in the best position to determine whether particular services are behavioral health services. As stated in the CY 2022 PFS final rule (86 FR 65061), SUD services are considered mental health services for the purposes of the expanded definition of ''interactive telecommunications system.'' Moreover, in the CY 2010 PFS final rule (74 FR 61787), we referenced that the outpatient mental health treatment limitation, which was phased out as of 2014, applied to outpatient treatment of a mental, psychoneurotic, or personality disorders, identified under the International Classification of Diseases (ICD) diagnosis code range 290–319.

Comment: Several commenters recommended we refine the code descriptors of HCPCS codes G0552, G0553 and G0554. Some commenters suggested we define the course of treatment to be 30 days and allow HCPCS code G0552 to be billed in subsequent 30-day increments. For this purpose, they recommended that the work RVU for initial education and onboarding be removed from HCPCS code G0552 or that a second subsequent month per course of treatment device code could be created. Other commenters welcomed the inclusion of initial education and onboarding in HCPCS code G0552. While commenters generally supported the two HCPCS codes G0553 and G0554 for treatment management related to a patient's therapeutic use of a DMHT device, several commenters recommended that we acknowledge that many DMHT devices do not collect patient data. Many commenters recommended that we distinguish the treatment management codes from existing RTM codes by revising the descriptors for HCPCS codes G0553 and G0554 to replace the words: ''reviewing data generated from the DMHT device from'' with ''reviewing information related to the use of the DMHT device, including.'' In particular, some commenters who opposed our proposal thought that the RTM family of codes as revised effective January 1, 2024, by the AMA CPT Editorial Panel would overlap with HCPCS code G0552 and create confusion for practitioners.

Response: We thank commenters for their feedback about refining the descriptors for our proposed HCPCS codes G0552, G0553 and G0554. We are finalizing HCPCS code G0552 as proposed. We are finalizing HCPCS code G0553 with these refinements: G0553 (*First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month*). We are finalizing HCPCS code G0554 with the following refinements: (*Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month. (List separately in addition to HCPCS code G0553)*). We have noted that DMHT devices vary in the typical course of treatment and acknowledge that persons with mental health and behavioral health conditions may experience circumstances necessitating that their practitioners extend the time. As commenters noted, limiting HCPCS code G0552 to a monthly period would necessitate creating another code to account for a course of treatment beyond a month. As to commenters concerns for potential overlap, we believe that HCPCS code G0552 is specific enough that practitioners could determine when to use RTM coding instead of HCPCS code G0552. We are finalizing refinements to HCPCS codes G0553 and G0554 to clarify that these codes are for treatment management with a DMHT device which is intended as a therapeutic intervention as opposed to RTM devices which, beginning January 1, 2024, will describe devices that may have a digital therapeutic intent as well as be intended to monitor response to a therapeutic intervention not necessarily delivered by an RTM device. HCPCS code G0552 does not describe a device intended to monitor response to therapeutic intervention. We expect that practitioners will report the more specific HCPCS code G0552 when the DMHT device meets conditions of payment we are finalizing. We expect that practitioners will report the more specific HCPCS codes G0553 and G0554 when treatment management services are directly related to a DMHT device described by HCPCS code G0552 meeting these conditions of payment. HCPCS code G0552 would be payable only if:

- The DMHT device has been cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and classified under 21 CFR 882.5801 as described above.
- The billing practitioner is incurring the cost of furnishing the DMHT device to the beneficiary.
- Furnishing of the DMHT device is incident to the billing practitioner's professional services in association with ongoing behavioral health treatment under a plan of care by the billing practitioner.
- The billing practitioner diagnoses the patient with a mental health condition and prescribes or orders the DMHT device.

HCPCS code G0552 shall not be payable in cases where the billing practitioner incurs no cost in acquiring and furnishing the DMHT device, or a patient procures the DMHT device independent of the practitioner. One commenter noted an example of a

DMHT device classified by the FDA under 21 CFR 882.5801, that is prescribed by a practitioner, but the practitioner bears no cost for the device. In that case the commenter is correct that payment is not available to the practitioner. The benefit category for HCPCS code G0552 requires that payment for the DMHT device as a supply incident to a practitioner's professional services be a supply cost that the practitioner has incurred. We are aware this may be a limitation with respect to DMHT devices being payable under HCPCS code G0552.

Comment: In response to questions we raised in the proposed rule, commenters were divided among those concerned principally by greater access to treatment versus guarding against potential waste or misuse, and those concerned principally by patient safety. Some commenters felt that a practitioner and patient should determine whether to use a device ''off-label'' and whether it would be appropriate to use more than one device when the patient had more than one behavioral health condition. While others felt the risks for using a device for a different indication than for which it was authorized by FDA, or using more than one device at a time could pose unknown risks and furthermore that similar efficacy could not be inferred for these use cases. MedPAC suggested we consider giving the Parts A/B Medicare Administrative Contractors (MACs) the discretion to cover use of digital devices for purposes other than what has been approved by the FDA, similar to MACs' ability to cover non- cancer drugs for off-label indications.

Response: We agree with commenters who expressed concerns about unknown risks and that similar efficacy could not be inferred for cases using a device for a different indication than for which it was authorized. We are finalizing that payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated in their FDA classification under 21 CFR 882.5801.

Comment: Commenters generally supported payment for concurrent use of different DMHT devices used in the treatment of different mental health or behavioral health conditions. Some suggested heightened documentation requirements for such cases.

Response: We agree that many individuals with mental health or behavioral health conditions may have more than one co-occurring condition. We are not finalizing any limits in this regard.

Comment: Some commenters noted that practitioners who bore the cost of acquiring the device should not be liable for the cost of the device when a patient discontinued treatment given that patients with mental health conditions often go off treatment and return subsequently. Some commenters felt reduced payment was appropriate in those circumstance and suggested that Modifier-52 could be reported for reduced services.

Response: We agree with commenters who noted many individuals with certain behavioral health conditions are at a higher risk of not adhering to treatment or experiencing events that may necessitate temporary pauses in treatment. For these reasons, we are not finalizing a reduction in payment at this time for discontinued use of the treatment before the full course of treatment has been completed.

Comment: Some commenters urged us to set a national price based on invoices submitted to us or based on crosswalks to PE-only codes and codes with work RVUs for the initial education and onboarding. Some commenters recommended we adopt contractor pricing temporarily until we and our contractors have gained enough experience to adopt national pricing on product specific or product class specific codes. Some commenters noted that one device code was impractical for the range of devices they thought we intended and others recommended including that product classes be defined by treatment length, mechanism of action and hardware requirements. Most commenters supporting the proposal expressed no opinion about the proposed pricing. Some commenters recommended CM work with CMMI on developing a payment model. Finally, MedPAC recommended payment for the device be included in larger payment bundles.

Response: After consideration of public comments, we are finalizing to contractor price HCPCS code G0552, as proposed. We are also finalizing payment for HCPCS codes G0553 and G0554 as proposed. We note that the invoices we received vary considerably. At this time, we do not believe we can appropriately price all the DMHT devices for which we propose to make payment. As we have noted, the technologies and DMHT therapies are evolving rapidly. Given the dynamic nature of the development of these devices and the variation in methods of action for potential technology platforms, we do not have sufficient information needed to establish national pricing for devices under HCPCS code G0552 at this time. However, we continue to welcome information on this and may consider national pricing through future rulemaking.

3. Interprofessional Consultation Billed by Practitioners Authorized by Statute To Treat Behavioral Health Conditions

a. Background

In the CY 2019 PFS final rule (83 FR 59489), we finalized payment for six CPT codes regarding interprofessional consultations (99451, 99452, 99446, 99447, 99448, 99449). The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's condition without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. We established coding and payment for these services to reflect changing healthcare practices, technology, and the shift to treatment of chronic conditions in the Medicare population. In the CY 2019 PFS final rule (83 FR 59491), we established a policy to limit billing of these codes to the types of practitioners who can independently bill Medicare for E/M visits. We did not finalize the expansion of practitioners beyond those who can furnish E/M visits in the CY 2019 PFS final rule due to our belief that interprofessional consultations are primarily for the ongoing evaluation and management of the patient, including collaborative medical decision making among practitioners (83 FR 59491).

In the CY 2024 PFS proposed rule (88 FR 52369), we sought comment on expanding access to behavioral health services, including whether we should consider new coding to allow interprofessional consultation to be billed by practitioners in specialties whose covered services are limited by statute (Clinical psychologists at section 1861(ii) of the Act, Clinical social workers at section 1861(hh) of the Act, Marriage and Family Therapists and Mental Health Counselors at sections 1861(lll)(1) and 1861(lll)(3) of the Act, respectively) to services for the diagnosis and treatment of mental illness (which includes substance use disorders). The CPT codes describing interprofessional consultation (CPT codes 99451, 99452, 99446, 99447, 99448, 99449) are currently limited to being billed by practitioners who can

independently bill Medicare for E/M visits. As such, they cannot be billed by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors because these practitioners cannot independently bill Medicare for E/M visits. We proposed new codes that would allow clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors to bill for interprofessional consultations with other practitioners whose practice is similarly limited, as well as with physicians and practitioners who can bill Medicare for E/M services and would use the current CPT codes to bill for interpersonal consultations. These new codes would facilitate interprofessional consultations between treating/requesting practitioners and consultant practitioners, whether one or both of the practitioners is in a specialty whose practice is limited to the diagnosis and treatment of mental illness. When the treating/requesting practitioner or consultant practitioner is a physician or practitioner authorized to bill Medicare for E/M services, the practitioner will continue to bill using the current CPT codes that describe interprofessional consultation, listed previously in this section. Depending on which practitioner type is billing, and assuming all service requirements of the code descriptors are met, the consulting practitioner could bill the applicable codes, either HCPCS code (G0546–G0551) or CPT code (99451, 99446, 99447, 99448, 99449), determined by the amount of time spent on the consultation and whether a written and verbal consultation is provided or only a written consultation is provided. Similarly, depending on which practitioner type is billing, and assuming all service requirements of the code descriptors are met, the treating/requesting practitioner could bill either HCPCS code G0551 or CPT code 99452 for the time spent on their referral service.

We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or internet (including videoconference) is consistent with our ongoing efforts to appropriately recognize and reflect behavioral health care within the PFS. Currently, there is no payment mechanism to recognize the time and effort of performing these services by clinical psychologists, clinical social workers, marriage and family therapists, or mental health counselors. We have also previously received comments from interested parties that by not making separate payment for these services, CMS would not be accurately paying for the work of both the treating and consulting practitioner in a consultative scenario. With the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient will contribute to payment accuracy under the PFS for behavioral health services.

b. Coding

To further expand access to behavioral health services, we proposed payment for six new G codes: G0546 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 5–10 minutes of medical consultative discussion and review*), G0547 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 11–20 minutes of medical consultative discussion and review*), G0548 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 21–30 minutes of medical consultative discussion and review*), G0549 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a verbal and written report to the patient's treating/requesting practitioner; 31 or more minutes of medical consultative discussion and review*), G0550 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, including a written report to the patient's treating/requesting practitioner, 5 minutes or more of medical consultative time*), and G0551 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness, 30 minutes*). We welcomed comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported interprofessional consultations provided by a practitioner in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness. We also received comments requesting that instead of creating new HCPCS coding, we establish an exception to the interprofessional consultation CPT codes. Commenters cited potential confusion for having separate codes for the same service.

Response: In the CY 2019 PFS final rule (83 FR 59491), we established a policy to limit billing of the CPT interprofessional consultation codes to the types of practitioners who can independently bill Medicare for E/M visits since the text of these codes specifies that the practitioners involved in the consultation be physicians or other qualified health care professionals. We continue to believe that the CPT interprofessional consultation codes are most appropriate for physicians or other qualified health care professionals, and HCPCS G0546–G0551 are most appropriate for practitioners in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness.

Comment: Commenters requested clarification on whether the treating/requesting practitioner and the consulting provider must be in the same organization to bill interprofessional consultation codes.

Response: No, the treating/requesting practitioner and the consulting provider do not have to be in the same organization to furnish interprofessional consultation services.

After consideration of public comments, we are finalizing HCPCS G0546–G0551 codes as proposed.

Additionally, since these codes describe services that are furnished by the treating/requesting practitioner and the consultant practitioner without the

involvement of the patient, we proposed to require the treating practitioner to obtain the patient's consent in advance of these services, which would be documented by the treating practitioner in the medical record, similar to the conditions of payment associated with the CPT interprofessional consultation codes and certain other non-face-to-face services paid under the PFS. Obtaining advance patient consent includes ensuring that the patient is aware that Medicare cost sharing applies to these services, including informing the patient that there may be cost sharing for two services (one for the treating/requesting practitioner's service and another for the consultant practitioner's service). We welcomed comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported obtaining patient consent for these services, as they are usually furnished outside the presence of the patient. Some commenters requested that the requirement for consent not apply when the patient already has a relationship with the billing practitioner.

Response: We continue to believe that consent must be obtained for these services since they are furnished outside the presence of the patient. In addition, we continue to believe that it is important that patients are informed that they may be responsible for the cost sharing of two services.

After consideration of public comments, we are finalizing the consent requirements for HCPCS codes G0546–G0551 as proposed.

c. Valuation

We proposed to value the six proposed new G codes based on crosswalks to the six CPT codes for interprofessional consultations for practitioners who can independently bill Medicare for E/M visits (CPT codes 99451, 99452, 99446, 99447, 99448, 99449). We proposed a work RVU of 0.35 for G0546 based on a crosswalk to CPT code 99446, a work RVU of 0.70 for G0547 based on a crosswalk to CPT code 99447, a work RVU of 1.05 for G0548 based on a crosswalk to CPT code 99448), a work RVU of 1.40 for G0549 based on a crosswalk to CPT code 99449, a work RVU of 0.70 for G0550 based on a crosswalk to CPT code 99451, and a work RVU of 0.70 for G0551 based on a crosswalk to 99452. Since there are no direct PE inputs assigned to the six CPT codes describing interprofessional consultation services on which we are basing the proposed valuation for the new HCPCS codes G0546–G0551, we did not propose any direct PE inputs for these codes. We welcomed comments on this proposal.

Comment: Commenters were supportive of our proposed valuations for HCPCS codes G0546–G0551.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing HCPCS codes G0546–G0551 as proposed.

4. Comment Solicitation on Payment for Services Furnished in Additional Settings, Including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs)

In the CY 2024 OPPS final rule (88 FR 81809 through 81858), we finalized payment for Intensive Outpatient Program (IOP) services furnished in hospital outpatient departments (HOPDs), Community Mental Health Centers (CMHCs), Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs), and Opioid Treatment Programs (OTPs). We noted that Section 4124 of the Consolidated Appropriations Act (CAA), 2023, authorized payment for IOP services in HOPDs, CMHCs, FQHCs, RHCs, and that we additionally used existing statutory authority to propose and finalize payment for IOP services furnished in OTPs. CMS is monitoring utilization and uptake of IOP services in these settings. We have heard from other treatment settings that furnish IOP services that do not fall into the categories of HOPDs, CMHCs, FQHCs, RHCs, or OTPs, such as freestanding SUD facilities, that have an interest in billing Medicare for these services. In light of this, we sought comment on whether IOP services are furnished in other settings in order to determine whether potential coding and payment for IOP services under the PFS would facilitate these services being billed in additional settings.

In particular, we were interested in feedback on the following questions, as well as any other relevant feedback:

- To what extent do freestanding SUD facilities or other entities that furnish IOP services employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services? For example, do they typically employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general supervision to auxiliary personnel who furnish behavioral health services?
- Would bundled payments under the PFS similar to those finalized in the CY 2024 OPPS final rule (88 FR 81809–81858) better facilitate billing for IOP services in a broader range of settings?
- If CMS outlined how freestanding SUD facilities could bill Medicare under the PFS, would there be an impact in underserved areas?
- To what extent do freestanding SUD facilities see patients with Medicare or who are dually eligible for Medicare and Medicaid?

We received public comments on these questions. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated they believe that freestanding SUD facilities and other entities that furnish IOP services serve an important function in their communities and thus should have a sustainable payment structure because of their vital role in treatment engagement. Several commenters urged CMS to enable payment for freestanding facilities that furnish IOP services, as well as for other levels of care along the continuum of SUD treatment and recovery (including Level 0.5 early intervention and screening, Level 1 outpatient treatment, Level 2.5 high-intensity outpatient treatment (previously partial hospitalization (PHP)), and Level 2.7 medically managed intensive outpatient treatment) to facilitate greater access to and continuity of SUD care. Absent statutory changes, the commenters encouraged CMS to adopt an ''incident to'' billing model for freestanding SUD treatment facilities for all of these levels of care, so long as (1) the reimbursement rate is no lower than the hospital outpatient department rate, (2) an add-on code is developed to appropriately compensate the billing practitioner—especially if they are external to the facility—in a way that does not dilute the rate for the freestanding SUD treatment facility; and (3) the billing practitioner is able to perform their duties via telemedicine so as not to delay or deter access to care where appropriate. One commenter from a provider of SUD services noted that according to their internal data, they had to turn away approximately 3,000 Medicare beneficiaries who called seeking services because they are not an approved setting for Medicare services and urged CMS to expand the Medicare provider type definition to include non-hospital based state licensed freestanding or standalone SUD treatment centers to ensure that participation under Medicare does not

exclude high-quality facilities that are not classified as an OTP, HOPD, CMHS, FQHC, or RHC. One commenter stated that CMS should only expand IOP services to other types of entities if they follow the same rules that apply for the approved entities now in place, including regulatory requirements from State licensing and accreditation bodies that create a layer of accountability. This commenter supported having a physician (or equivalent) guiding and directing all admissions, treatment planning, and discharges for IOP regardless of the type of organization providing the services. AABH also strongly advocates for the use of a multi-disciplinary team to provide the level of care that should be provided and billed as an IOP.

Response: We thank the commenters for the detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

Comment: Some commenters noted that CCBHCs are able to provide services that typically comprise an IOP program, noting that based on the community needs assessment, this may look different across the country as CCBHCs can respond with the level of intensity of care that is responsive and personalized to an individual's need in the community, and ultimately the care provided could rise to a level of care similar to what an IOP program might consist of at a community mental health center (CMHC). However, the commenter urged CMS' caution in pursuing this benefit at CCBHCs, stating that CMHCs appear to face challenges in providing the IOP benefit under Medicare because the Medicare CMHC Conditions of Participation (CoPs) pose challenges and significant administrative burden for provider organizations.

Response: We thank the commenters for the detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

Additionally, we sought comment on entities that offer community-based crisis stabilization, including 24/7 receiving and short-term stabilization centers, that provide immediate access to voluntary and/or involuntary care, without the need for a referral. Regarding such crisis stabilization units, we were interested in feedback on the following questions, as well as any other relevant feedback:

- What kind of services do crisis stabilization units provide? Do crisis stabilization units provide services similar to those described by the psychotherapy for crisis codes (CPT codes 90839 and 90840)?
- Does the definition of crisis stabilization unit vary by State? If so, what are the variations and similarities across States?
- If CMS outlined how crisis stabilization units could bill Medicare under the PFS, would there be an impact in underserved areas?
- To what extent do crisis stabilization units see patients with Medicare or who are dually eligible for Medicare and Medicaid?
- To what extent do crisis stabilization units employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services. For example, do crisis stabilization units typically employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general to auxiliary personnel who furnish behavioral health services?

We received public comments on these questions. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that innovative approaches such as crisis stabilization units have helped communities improve coordination of emergency psychiatric care, and they can serve as models for other communities to implement and build upon to help alleviate the overall load on the mental health care system and emergency psychiatric boarding. Another commenter stated that payment for mental health and SUD services in these settings would greatly expand access to care in the midst of the ongoing overdose epidemic and mental health crisis, which has been exacerbated by workforce shortages. This commenter noted that especially with the increased access to crisis services through the 988 crisis line and the new mobile crisis psychotherapy code, expanding access to crisis receiving and crisis stabilization services at these settings would ensure that Medicare beneficiaries have access to the full continuum of crisis services and supports they need. One commenter stated that the definition of crisis stabilization, as well as ''sobering care,'' can vary from state to state, and noted that variations can include: acceptance of involuntary admissions, referring parties (law enforcement, EMS, walk-in, etc.), length of stay, environment, staffing levels and qualifications, etc.

Response: We thank the commenters for the detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

Additionally, as a separate example, we have received information from interested parties that there is a similar concern regarding urgent care centers more broadly. These interested parties note that hospital emergency departments are often used by beneficiaries to address non-emergent urgent care needs that could be appropriately served in less acute settings, but where other settings, such as physician offices, urgent care centers or other clinics, are not available or readily accessible. Patients enter EDs to treat common conditions like allergic reactions, lacerations, sprains and fractures, common respiratory illnesses (for example, flu or RSV), and bacterial infections (for example, strep throat, urinary tract infections or foodborne illness). Conditions like these often can be treated in less acute settings. We are interested in system capacity and workforce issues broadly and are interested in hearing more on those issues, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments. In particular, we were interested in feedback on the following questions, as well as any other relevant feedback:

- What types of services would alternative settings to EDs need to offer to meet beneficiaries' non-emergent, urgent care needs?
- Does the current ''Urgent Care Facility'' Place of Service code (POS 20) adequately identify and define the scope of services furnished in such settings? Is this place of service code sufficiently distinct from others such as ''Walk-in Retail Health Clinic (POS 17) and ''Office'' (POS 11)? If not, how might these Place of Service code definitions be modified?
- Does the existing code set accurately describe and value services personally performed by professionals and costs incurred by the facility in these settings?
- How might potential strategies to reduce overcrowding and wait times in EDs advance equity in access to health care services?

We received public comments on these questions. The following is a summary of the comments we received and our responses.

Comment: One commenter suggested that CMS create a payment structure in which urgent care centers are differentially compensated. In response to our question about the existing place of service codes, they stated that the current place of service (POS) definitions are inadequately

differentiated, especially if CMS wishes to encourage proliferation of the type of urgent care centers that can provide suitable alternatives to EDs, noting that POS 11 generally refers to physician offices that provide diagnostic and therapeutic care in an office setting, by appointment, typically during regular business hours; POS 17 generally refers to clinics that are attached to retail operations, such as pharmacies, grocery stores or big box stores, and provide low-acuity primary and preventive health care, such as vaccinations; and POS 20 refers to UCCs but does not adequately differentiate between those that offer services more akin to the typical general practitioner's office and those that offer enhanced diagnostic and therapeutic services and extended hours. They suggested that the creation of a new POS code describing ''enhanced'' urgent care centers that offer specific diagnostic and therapeutic services and that operate outside typical business hours could fill this need. In response to our question about the existing code set and valuation, they stated that Medicare's fee-for-service payment systems do not recognize and adequately value services furnished in UCCs and stated that while there is some overlap in the types of professional services furnished in UCCs and physician offices, UCCs that operate for extended hours and that have enhanced diagnostic and therapeutic capabilities incur additional costs to provide these services.

One commenter stated they appreciate the important role that non-emergency facilities, such as urgent care centers, can play treating patients, but emphasized that it is essential to preserve the fundamental right for patients to seek emergency care when they think they are experiencing a medical emergency. They encouraged CMS to consider how best to educate beneficiaries about when they should seek emergency treatment, their right to do so, and when another setting such as an urgent care center may be appropriate to address their health care needs. The commenter stated they believe that physician-led care teams offer the highest quality of care, and every urgent care should seek to have an emergency physician on staff and that in the setting of physician-led teams, urgent care should be capable of caring for the full range of non-life-threatening conditions. Another commenter noted that many urgent care centers and retail clinics do not accept public insurance (*i.e.,* Medicare, Medicaid, CHIP, Tricare) due to low reimbursement rates, stating that this disproportionately impacts the ability for underserved patient populations to access non-ED services for acute, unscheduled care. The commenter stated that improving Medicare and Medicaid reimbursement for urgent care services would advance equity and access for acute care amongst this patient population.

Response: We thank the commenters for the detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

Lastly, we sought comment regarding Certified Community Behavioral Health Clinics (CCBHCs). Specifically, we were interested in feedback on the following questions:

- What kind of services do CCBHCs provide? Do they provide IOP services, services for the treatment of substance use disorders, psychotherapy, behavioral health integration, community health integration, or principal illness navigation services to patients with either Medicare or another payer?
- If CMS outlined how CCBHCs could bill Medicare under the PFS, would there be an impact in underserved areas?
- To what extent do CCBHCs see patients with Medicare or who are dually eligible for Medicare and Medicaid?
- To what extent do CCBHCs employ practitioner types who can supervise auxiliary personnel and bill Medicare for their services? For example, do CCBHCs employ physicians, clinical psychologists, nurse practitioners, clinical nurse specialists, certified nurse midwives and physician assistants who are eligible to provide general supervision to auxiliary personnel who furnish behavioral health services?

We received public comments on these questions. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they understand that CCBHCs can bill Medicare if they are registered as a different provider type such as an Office or CMHC but noted that Medicare does not cover all required CCBHC services. They also noted that CCBHCs are already certified per federal and state Medicaid criteria and to the extent Medicare were to allow CCBHCs as a Medicare provider, they encouraged alignment of any potential future Medicare CCBHC conditions of payment with existing Medicaid and state certification requirements.

A joint comment letter submitted by several specialty societies and interested parties also described the history of CCBHCs, noting that most recently, the Consolidated Appropriations Act, 2024 (CAA 2024) provided a definition for CCBHCs in Medicaid statute, permanently establishing CCBHCs as an optional Medicaid benefit. They stated that CCBHCs can be implemented and funded through the Section 223 Medicaid Demonstration, CCBHC Expansion Grants administered by SAMHSA, or through independent state programs and noted that states participating in the Demonstration select one of four Medicaid Prospective Payment System (PPS) rate methodologies to establish payment rates for CCBHCs based on the expected cost of delivering care.[171] They stated there are currently nearly 500 CCBHCs across 46 states and territories (offering services in 40 percent of all U.S. counties, covering 62 percent of the nation's population), serving an estimated 3 million people nationwide.[172] A regularly updated list of CCBHCs across the country can be found on National Council for Mental Wellbeing's website.[173]

Response: We thank the commenters for the detailed comments received on these topics and note that we may consider this input for potential policy proposals through future rulemaking.

J. Provisions on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Other Covered Services

1. Medicare Payment for Dental Services

a. Overview

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at § 411.15(i)

[171] *https://www.medicaid.gov/medicaid/financial-management/downloads/section-223-ccbh-pps-prop-updates-022024.pdf.*

[172] *https://www.thenationalcouncil.org/resources/2024-ccbhc-impact-report/.*

[173] *https://www.thenationalcouncil.org/program/ccbhc-success-center/ccbhc-locator/.*

similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under § 411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029).

In the CY 2023 PFS final rule, we also established a process whereby we accept and consider submissions from the public (the ''public submission process'') to assist us to identify additional dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered services (87 FR 69663 through 69688). Hereafter in this section we will refer to these services as dental services that are ''inextricably linked to other covered services.''

We also note that the examples provided in our regulation at § 411.15(i)(3)(i) are not exclusive. Medicare administrative contractors (MACs) retain discretion to determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exceptions specified in section 1862(a)(12) of the Act and § 411.15(i).

In the CY 2024 PFS final rule, we discussed our plans to issue educational and outreach materials to inform billing and payment for finalized policies for dental services. We reiterated our commitment to review submissions we receive through the public submissions process. We also expressed our intention to continue to engage in discussions with the public on a wide spectrum of issues relating to Medicare payment for dental services that may be inextricably linked to other covered services. We also described our partnership with the Agency for Healthcare Research and Quality (AHRQ) to assist us to review available clinical evidence and consider the relationship between dental services and specific covered medical services and to identify other potential clinical circumstances in which dental services are inextricably linked to other covered services (88 FR 79029).

In the CY 2025 PFS proposed rule (89 FR 61747 through 61765), we: (1) described recent rapid response reports conducted by our partner agency, AHRQ, on the potential connection between sickle cell disease and hemophilia and dental services; (2) summarized submissions we received through the public submission process that we considered for CY 2025 rulemaking; (3) proposed to amend section § 411.15(i)(3)(i) to permit payment for certain dental services that are inextricably linked to other covered services (certain dental services for patients receiving dialysis services to treat end-stage renal disease (ESRD)); (4) requested public comment and information related to other clinical scenarios that may involve dental services that are inextricably linked to other covered services; and (5) are included proposals related to Medicare billing and payment policy for dental services. We also included a request for information regarding oral sleep apnea appliances.

b. Consideration of Dental Services That May Be Inextricably Linked to Other Covered Services

We received several nominations through our public submission process and have partnered with AHRQ to help us consider the evidence supporting the relationship between dental services and other specific covered services. Specifically, AHRQ reviews available clinical evidence regarding this relationship and provides analysis of clinical scenarios where dental services may be inextricably linked to other covered services. To better address the public's immediate dental needs, AHRQ conducted rapid response reports instead of systematic reviews. With these rapid response reports, we can better specify which payments can be made under Medicare Parts A and B for specific dental services that are inextricably linked to other covered services.

Through the public submissions process for consideration in CY 2024 rulemaking, interested parties nominated dental services for individuals living with sickle cell disease (SCD) or hemophilia, urging us to consider adding payment for these services. Acknowledging the importance of dental health to overall well-being of patients with these two types of diseases, in the CY 2024 proposed rule, we summarized information provided by submitters utilizing the public submission process and solicited comment on whether certain dental services are inextricably linked to covered services in the treatment of SCD (88 FR 52374).

In the CY 2024 PFS final rule, we discuss the comments received from commenters suggesting to expand dental service coverage for individuals with SCD. We concluded that the information provided by commenters did not sufficiently demonstrate that dental services are essential to the clinical success of treatments for SCD, including hydroxyurea therapy. Therefore, we did not expand the examples under § 411.15(i)(3)(i) to include additional covered medical services for SCD. Please refer to the CY 2024 PFS final rule (88 FR 79031 through 79032) for more detailed information.

In the CY 2024 PFS proposed rule, we similarly solicited comments on hemophilia regarding whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services for individuals with hemophilia (88 FR 52382). In the CY 2024 PFS final rule, we discuss the comments received from commenters advocating Medicare Part A and Part B payment for dental services for individuals with hemophilia, citing guidelines from Hemophilia Treatment Centers (HTCs), the Centers for Disease Control and Prevention (CDC), and the World Federation of Hemophilia (WFH). While we acknowledged the importance of maintaining oral health to prevent complications such as serious gum bleeding, especially problematic for those with hemophilia, we also reiterated that for the purposes of the PFS payment policy for dental services inextricably linked to covered medical services, our statute and regulations require that specific evidence supports the integral connection between dental services and clinical success in managing hemophilia-related medical services, and, therefore, we did not expand the examples under § 411.15(i)(3)(i) to include additional covered medical services for hemophilia. Please refer to the CY 2024 PFS final rule (88 FR 79032 through 79033) for more detailed information.

In the CY 2025 PFS proposed rule, we noted that while interested parties have suggested the interaction of oral health

care for SCD or hemophilia, further research was necessary to find specific evidence supporting specific medical services for which dental services are inextricably linked to their clinical success. We explained, to gain further understanding of any potential relationship between dental services and specific covered SCD or hemophilia medical services, we again partnered with researchers at AHRQ to review available clinical evidence regarding the relationship between dental services and covered SCD or hemophilia medical services. As a result, AHRQ created two rapid response reports, which summarized recent evidence, aiming to inform CMS policy development related to the possible linkage between dental services and treatment modalities and services for SCD or hemophilia patients (89 FR 61748). For more detailed information about the search strategies and findings, please refer to the two AHRQ rapid response reports available at *https://effectivehealthcare.ahrq.gov/products/sickle-cell-dental/research* and *https://effectivehealthcare.ahrq.gov/products/hemophilia-dental/research*.

In the CY 2025 PFS proposed rule, we gave a detailed discussion and summary of these two rapid response reports provided by AHRQ. We explained that after reviewing AHRQ's rapid response reports both SCD and hemophilia, we found the evidence related to the linkage between dental services and outcomes for covered medical services for both SCD and hemophilia lacking in the current research and literature. Both rapid responses noted a limited number of studies examining the impact of dental care on outcomes for individuals with SCD or hemophilia. Currently, the evidence base does not appear to support that dental services may be inextricably linked to covered services for SCD or hemophilia. Also, the body of evidence evaluating dental services before, during, or after the treatment of SCD and hemophilia lacks primary clinical data and relies on available guidelines and reviews. We stated, however, that the limited information in both the SCD and hemophilia rapid responses did support the need for preventive care and patient education as essential practices for both SCD and hemophilia patients to minimize the likelihood of oral infections, periodontal disease, and major dental procedures. In addition, both rapid response reports recommend collaborative efforts between dentists, hematologists, and specialized clinics as crucial for improved patient care, despite the lack of primary evidence informing the potential effect of dental care on treatment. While both rapid response reports discuss their findings on the importance of a multidisciplinary approach, both rapid response reports also found that the current reviews and guidelines do not address dental care as a standard of care that is inextricably linked to hemophilia or SCD treatment. Instead, their focus was on managing the respective conditions during dental services, not on the inextricable linkage between dental and medical services. Please refer to the CY 2025 PFS proposed rule (89 FR 61748 through 61749) for a more detailed discussion of the two rapid response reports provided by AHRQ for both SCD and hemophilia.

In the CY 2025 PFS proposed rule, we stated that interested parties had asked us to consider the conditions of SCD and hemophilia for the purposes of the Medicare Parts A and B payment policy for dental services that are inextricably linked to other covered services. We then explored the inextricable link between dental and covered services associated with SCD and hemophilia by partnering with AHRQ to generate rapid responses on these topics. However, we did not find the evidence base to support that dental services may be inextricably linked to services for SCD or hemophilia within the meaning of the standard at § 411.15(i)(3). We stated that given the new and evolving therapies and treatments in this space, we will consider conducting additional evaluations as new studies are carried out to examine the impact of dental services on SCD and hemophilia outcomes and will take any future studies into consideration. We noted that we continue to seek clinical evidence demonstrating the integral connection between dental services and other covered services for SCD and hemophilia, and we welcomed any comments or literature regarding these two conditions. We explained that we did not propose to amend § 411.15(i)(3)(i) since we have not identified additional dental services that are inextricably linked to certain services associated with SCD or hemophilia. We stated that we remain open to considering any such services identified by public commenters, and, if sufficient evidence is presented, we may consider adding such services to our regulations in the final rule. In addition, we encouraged interested parties to supply additional submissions for consideration in future PFS rulemaking through the public submission process, which may include relevant medical evidence, peer-reviewed literature, clinical guidelines, or supporting documentation as described in section II.J.1.c. of this final rule (89 FR 61750).

We received 9 public comments on our consideration of dental services that may be inextricably linked to covered services for the treatment of SCD and hemophilia. Commenters included patient advocacy organizations, hospital associations, medical and dental associations representing several different specialties and specialty societies, and dental plan associations. The following is a summary of the comments we received and our responses.

Comment: A few commenters provided information on beneficiaries with SCD. The commenters explained that these individuals represent a particularly vulnerable group since it is an inherited blood disorder primarily affecting individuals of African descent. The commenters stated that beneficiaries with SCD have significant healthcare needs due to the complex nature of their condition. For example, these individuals may experience chronic complications such as pain crises, organ damage, and an increased risk of infections, as well as have comorbidity conditions such as chronic kidney disease, heart failure, and depression, which further complicates their care. The commenters also indicated that these individuals are at risk for oral health complications, including infections that could trigger a sickle cell crisis. The commenters explained that beneficiaries with SCD often experience higher rates of emergency department visits and hospitalizations. This commenter also stated that approximately half of individuals with SCD are enrolled in Medicaid, while 11 percent are enrolled in Medicare, often as dually eligible beneficiaries and that research indicates that SCD patients who are enrolled in both Medicare and Medicaid experience worse survival outcomes compared to those with single coverage.

A few commenters provided information on beneficiaries who have hemophilia. The commenters explained that these individuals also represent a particularly vulnerable group since advancements in medical care have extended their life expectancy and now living longer, they often face multiple comorbidities such as hepatitis C, human immunodeficiency virus, hypertension, and diabetes, which can further complicate their overall health management. The commenters explained that the need for dental management is heightened due to the increased risk of bleeding during and after dental procedures, especially in those with severe hemophilia. One

commenter stated that individuals living with bleeding disorders such as hemophilia are often hesitant to perform normal oral hygiene practices due to the fear of a bleed, which can make these individuals more susceptible to oral diseases and conditions, such as gingivitis, dental caries, and periodontal disease. This commenter also stated that if an individual with a bleeding disorder does require an oral procedure or surgery, it is typical that a large amount of clotting factor would be needed to control the bleeding during such a procedure or surgery. Other commenters stated that while hemophilia is rare, managing severe hemophilia A presents a significant economic burden, with annual treatment costs ranging from approximately $600,000 to over $900,000, depending on the type of prophylactic therapy used.

Some commenters referenced CMS' partnership with AHRQ to conduct response reports on both SCD and hemophilia. One commenter expressed their appreciation for this arrangement but conveyed that they disagreed with CMS' assessment that there is a lack of literature to support coverage of dental services for these conditions. The commenter specifically pointed to the Kawar study from AHRQ's report on SCD which clearly states that ''standard of care for dental management of sickle cell disease patients'' includes ''prevention and early intervention . . . routine dental visits . . . collaboration between healthcare team (including hematologist) and dentist is important''.[174] A different commenter agreed with CMS's assessment that the cited sources in AHRQ's report do not demonstrate that dental services are inextricably linked to covered medical services for SCD and that, based on the available evidence, dental services are not inextricably linked to covered medical services for hemophilia. Another commenter acknowledged that while dental care is essential for managing complications associated with hemophilia, current evidence may not be sufficient to support expanding Medicare coverage beyond the existing provisions since the focus remains on preventing bleeding complications rather than enhancing hemophilia treatment outcomes through dental interventions.

Commenters stated that they recognize that CMS is only able to pay for dental services when the services are inextricably linked to an already covered Medicare service and that, to date, there is not enough evidence to support the need to pay for dental services that are inextricably linked to services for SCD or hemophilia. The commenters then concluded that the broader impact of expanded dental benefits remains an area for further research which they believe reflects the complex relationship between dental health and overall care, suggesting that more exploration is needed without endorsing specific policy changes.

Many commenters supported CMS's commitment to continue seeking clinical evidence regarding circumstances in which dental services are inextricably linked to treatments for SCD and hemophilia. One commenter explained that there are significant racial disparities in the incidence and severity of these health conditions that coverage of dental services would improve. Another commenter appreciated CMS' ongoing commitment to allowing stakeholders to continue presenting evidence that they believe can support policy coverage changes for these critical conditions. However, one commenter thanked CMS for thoroughly reviewing their request to consider coverage for dental services linked to Medicare services for the treatment of SCD. This commenter explained that while they understand that CMS did not believe that the data and other evidence submitted met the threshold, in their members' experience caring for individuals living with SCD, they find that dental health is indeed inextricably linked to their overall health and treatment.

Lastly, we received several recommendations from commenters. Several commenters requested that CMS continue to partner with researchers to monitor the literature related to dental services to obtain additional evidence that may support payment for dental and oral health treatments and ancillary services that improve the affordability, access, and treatments for sickle cell and hemophilia. Another commenter suggested that CMS actively collaborate with organized dentistry and medicine in their scientific review process that goes into coverage determinations.

Response: We thank commenters for their feedback. The information commenters provided did not support a finding that dental services are inextricably linked to a covered medical service for SCD or that the standard of SCD care would be compromised without dental services or that the standard of SCD care would require dental services to be performed in conjunction with treatments for SCD. We also found the same with regard to the information commenters provided for hemophilia.

As we stated in the CY 2024 PFS final rule, in order for us to find that dental services are inextricably linked to, and substantially related and integral to the clinical success of treatments for SCD or hemophilia, we would need clinical evidence to demonstrate that the standard of care would be not to proceed with the other covered services without providing the dental services in conjunction with the treatment for SCD or hemophilia (88 FR 79032 through 79033). As discussed below in section II.J.1.c. of this final rule, to consider whether certain dental services are inextricably linked to the clinical success of other covered services, we need to identify specific covered medical services for which there is medical evidence that certain dental services are so integral to their clinical success that they are inextricably linked to the covered service. Based on the information provided, we have not been able to identify such a specific covered medical service for SCD or hemophilia, and thus we are unable to evaluate whether any medical evidence would support an inextricable linkage to certain dental services.

We thank the commenters for their perspectives and we agree that maintaining good oral health and preventing dental problems is highly important in the prevention of oral diseases that can lead to serious complications for beneficiaries with SCD or hemophilia. However, the information generally provided by commenters did not establish an inextricable link between dental services and a covered medical service. Because the Medicare statute generally prohibits payment for dental services, payment may be made in limited situations such as when the dental services are inextricably linked to, and substantially related and integral to the clinical success of certain other covered services as provided by our regulations at § 411.15(i)(3)(i), or under the exceptions provided by section 1862(a)(12) of the Act and codified at § 411.15(i)(2).

After consideration of public comments, we are not expanding the examples of clinical scenarios under § 411.15(i)(3)(i) to include additional covered medical services for SCD or hemophilia. We remain committed to exploring whether there is an inextricable link between dental services and other covered services associated with SCD and hemophilia.

We plan to continue reviewing the clinical evidence on this topic and

[174] Kawar N., Alrayyes S., Yang B., Aljewari H. Oral health management considerations for patients with sickle cell disease. Dis. Mon. 2018;64(6):296–301. (In eng). DOI: 10.1016/j.disamonth.2017.12.005.

welcome continued engagement from the public.

c. Submissions Received Through Public Submission Process

As we have in the CY 2023 and CY 2024 PFS final rules, we continue to encourage interested parties to engage with us regularly and to submit recommendations through our public submissions process for our consideration of additional clinical scenarios where dental services may be inextricably linked to covered services under § 411.15(i)(3)(i). Through our annual public submissions process, interested parties should provide clinical evidence and other documentation to support their recommendations (87 FR 69685). We are using the PFS annual rulemaking process to discuss public submissions and to consider whether the clinical scenario described in the submissions should be added to § 411.15(i)(3)(i) as an example of a circumstance where payment can be made for dental services inextricably linked to other covered services. Using our annual notice and comment rulemaking process to discuss submitted recommendations allows the public to comment and submit further medical evidence and important feedback to assist us in evaluating whether certain dental services furnished in certain clinical scenarios would meet the standard to permit Medicare payment for the dental services.

Through this process, we review clinical evidence included in submissions and public comments in rulemaking, as well as information and analysis provided by AHRQ in rapid response reports, to assess whether there is an inextricable link between certain dental services and certain covered services. We would find that there is an inextricable link where the standard of care for a service is such that the practitioner would not proceed with the procedure or service without performing the dental service(s), for example, because the covered services would or could be significantly and materially compromised absent the provision of the inextricably-linked dental services, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. As such, documentation accompanying recommendations should include medical evidence to support that certain dental services are inextricably linked to certain covered services. Specifically, as we specified in the CY 2023 PFS final rule, we request that the medical evidence included in submissions through the public submissions process should:

(1) Provide support that the provision of certain dental services leads to improved healing, improved quality of surgery outcomes, and the reduced likelihood of readmission and/or surgical revisions because an infection has interfered with the integration of the medical implant and/or interfered with the medical implant to the skeletal structure;

(2) Be clinically meaningful and demonstrate that the dental services result in a material difference in terms of the clinical outcomes and success of the procedure such that the dental services are inextricably linked to other covered services; and,

(3) Be compelling to support that certain dental services would result in clinically significant improvements in quality and safety outcomes (for example, fewer revisions, fewer readmissions, more rapid healing, quicker discharge, and quicker rehabilitation for the patient) (87 FR 69686).

This evidence should include at least one of the following:

(1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;

(2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario;

(3) Other ancillary services that may be integral to the covered services; and/or

(4) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services (87 FR 69686).

Submissions should focus on the inextricably linked relationship between dental services and other services necessary to diagnose and treat the individual's underlying medical condition and clinical status, and whether it would not be clinically advisable to move forward with the other covered services without performing certain dental services. To be considered for purposes of CY 2026 PFS rulemaking, submissions through our public submissions process should be received by February 10, 2025, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov*. To facilitate processing, interested parties should include the words ''dental recommendations for CY 2026 review'' in the subject line of their email submission. We continue to stress to submitters that recommendations must include at least one of the types of evidence listed earlier. We further note that we may also consider recommendations that are submitted as public comments during the comment period following the annual publication of the PFS proposed rule.

In the CY 2025 PFS proposed rule, we discussed the 13 public submissions received from various organizations and individuals on or before February 10, 2024, with recommendations for additional clinical scenarios for which they believe Medicare payment for dental services would be consistent with the policies we codified at § 411.15(i)(3)(i). The clinical scenarios discussed include hematologic disorders, blood cancers, chronic graft versus host disease, post-treatment for head and neck cancer, autoimmune diseases, renal diseases, and diabetes Several submitters represented dozens or hundreds of other organizations in making these recommendations. We noted one submission was received after the deadline that presented nominations for clinical scenarios addressed by other submitters and a proposal outside the scope of clinical scenarios where dental services may be inextricably linked to covered medical services under § 411.15(i)(3)(i). Please refer to the CY 2025 PFS proposed rule (89 FR 61751 through 61752) for a more detailed discussion of the public submissions received for CY 2025 rulemaking consideration.

2. Additions to Current Policies Permitting Payment for Dental Services Inextricably Linked to Other Covered Services

In the CY 2025 PFS proposed rule, we explained that we have received information and requests from interested parties, including entities submitting information through the public submissions process as well as organizations providing comments in response to prior rulemaking efforts, that an inextricable linkage exists between dental services and dialysis treatment services for individuals diagnosed with end-stage renal disease (ESRD) who are receiving dialysis services, particularly those experiencing comorbidities. Commenters and submitters have stated that dental treatment is inextricably linked and integral, and substantially related to the clinical success and outcomes of covered dialysis medical services (89 FR 61752).

In the CY 2024 PFS final rule, we stated that commenters had provided comments in response to the CY 2024 PFS proposed rule supporting the coverage of annual dental examinations, and treatment as clinically indicated, for individuals with chronic kidney disease and ESRD. The commenters stated that

chronic immunosuppression increases the risk of dental infections leading to potentially deadly complications including BSI, peritoneal dialysis-associated peritonitis, and the exacerbation of chronic cardiovascular conditions. They also stated that when established by patient-specific medical and dental parameters, dental services can be unquestionably integral to the outcome of covered medical procedures. We thanked the commenters for the information they submitted regarding these suggestions; however, at that time, commenters did not provide sufficient evidence to support an inextricable link between certain dental services and certain covered services for chronic kidney disease and ESRD (88 FR 79034).

Subsequent to the issuance of the CY 2024 PFS final rule and as we discuss in section II.J.1.c. of this final rule, we received recommendations through the public submissions process for our consideration in CY 2025 rulemaking. That is, the submitters stated that there is a connection between dental services to identify and address dental or oral infections and covered medical services for individuals receiving dialysis in the treatment of ESRD. In the CY 2025 PFS proposed rule (89 FR 61752 through 61756), as well as in the following paragraphs of this final rule, we discuss the research and recommendations provided by the public through the submission process and our analyses of the studies and research available regarding the connection between dental services and the clinical success of dialysis services for individuals with ESRD.

ESRD is a medical condition in which a patient's kidneys successively experience loss of functionality on a permanent basis, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.[175]

Chronic kidney disease (CKD) is a progressively debilitating disease and is marked by the presence of kidney damage or reduction in the kidneys' filtration rate. CKD is a state of progressive loss of kidney function, in that the disease worsens over time and cannot be reversed, ultimately resulting in the need for renal replacement therapy, generally dialysis or transplantation.[176] The Kidney Disease Improving Global Outcomes (KDIGO) Organization established guidelines that define five stages of CKD using kidney damage markers, including factors that determine proteinuria (level of protein in the urine) and glomerular filtration rate (level of kidney function/filtration) in its KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.[177] Chronic kidney disease is generally defined as the presence of two factors (glomerular filtration rate [GFR] less than 60 mL/min and albumin greater than 30 mg per gram of creatinine) along with abnormalities of kidney structure or function for greater than three months. Stage 5 of CKD is labeled end-stage renal disease (ESRD) with a GFR of less than 15 mL/min.[178] According to the National Institutes of Health (NIH), more than 500,000 people in the United States live with ESRD.[179]

Per the American Academy of Family Physicians, individuals with ESRD are typically referred to nephrologists for the development of treatment plans. Collectively the various modalities utilized to replicate kidney function are referred to as renal replacement therapy (RRT). Most ESRD patients are treated with dialysis, regardless of whether transplantation ultimately occurs. Generally, kidney transplantation typically yields the best patient outcomes; however, not all patients with ESRD are eligible for or able to undergo transplantation, and some therefore continue dialysis treatment.[180] Standards of medical care for CKD outline the need for monitoring for signs of progression of the disease and early referral to specialists for RRT.[181] Dialysis is generally supplied via two primary modes: hemodialysis or peritoneal dialysis. In hemodialysis, blood is filtered through a dialyzer, outside of the body. A dialyzer is sometimes referred to as an ''artificial kidney.'' [182] To access the circulatory system, several access points may be placed and utilized, including an arteriovenous (AV) fistula, AV graft, and in some cases a central venous catheter.[183] [184] [185] In peritoneal dialysis, a fixed catheter is placed in the abdomen, and dialysis solution is administered into the abdomen. The solution absorbs wastes and excess fluid from the patient's body.[186] [187]

Submissions we received through the public submissions process for consideration in CY 2025 rulemaking provided information regarding the potential linkage between dental services and specific covered medical services associated with ESRD and dialysis including:

- CPT codes 36901–36906: Dialysis circuit procedures;
- CPT codes 90935, 90937, 90940: Hemodialysis procedures;
- CPT code 90961: Physician or other qualified healthcare professional visits for ESRD;
- CPT codes 90989–90999: Other dialysis procedures; and,
- DRG code 872: Hospitalization for septicemia or severe sepsis.

We noted that Medicare provides coverage for individuals with ESRD, regardless of age, when certain requirements are met.[188]

We also noted that dialysis procedures may be utilized for individuals who do not have ESRD in the treatment of acute intoxication or poisoning. For example, in the case of a patient experiencing poisoning, dialysis hemoperfusion may be employed, which passes the blood through a column packed with granules that include a resin that act as absorbents. In this procedure, physicochemical properties of an absorbent are used to remove toxins. Conversely, in hemodialysis utilized in the treatment of ESRD, there is a concentration gradient between the blood and the solvent across the dialysis membrane.[189] We noted that the patient accessing dialysis treatment for the treatment of acute intoxication or poisoning would not present with the same diagnostic profile, treatment needs, nor face the same risks of immunodeficiency and infection as individuals with ESRD as described below.[190]

[175] *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[176] *https://www.ncbi.nlm.nih.gov/books/NBK535404/.*

[177] *https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf.*

[178] *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[179] *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[180] Am. Fam. Physician. 2021;104(5):493–499. *https://www.aafp.org/pubs/afp/issues/2021/1100/p493.html.*

[181] *https://pubmed.ncbi.nlm.nih.gov/29763036/.*

[182] *https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis.*

[183] *https://www.ncbi.nlm.nih.gov/books/NBK563296/.*

[184] *https://www.mayoclinic.org/tests-procedures/hemodialysis/about/pac-20384824.*

[185] *https://www.cdc.gov/dialysis/patient/.*

[186] *https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725.*

[187] *https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis.*

[188] *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[189] Durakovic Z. Combined hemoperfusion and hemodialysis treatment of poisoning with cholinesterase inhibitors. Korean J Intern Med. 1993 Jul;8(2):99–102. *doi: 10.3904/kjim.1993.8.2.99.* PMID: 8031730; PMCID: PMC4532091. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4532091.*

[190] Ouellet G, Bouchard J, Ghannoum M, Decker BS. Available extracorporeal treatments for poisoning: overview and limitations. Semin Dial.

Continued

Periodontal diseases and dental caries are the main chronic infectious diseases of the oral cavity. Periodontal diseases include a group of chronic inflammatory diseases that affect the periodontal supporting tissues of teeth and encompass destructive and nondestructive diseases. Gingivitis is inflammation of the soft tissue without apical migration of the junctional epithelium. It is a reversible, nondestructive disease that does not involve loss of periodontal tissues. Periodontitis is inflammation of the periodontium that is accompanied by apical migration of the junctional epithelium, leading to destruction of the connective tissue attachment and alveolar bone loss.[191]

Periodontitis serves as a prime example of a disrupted balance between the local microbiome and the host's inflammatory response, a condition known as dysbiosis. Although the inflammatory response is ostensibly triggered to manage the microbial threat, it proves to be ineffective and inadequately regulated in individuals prone to the condition. This leads to the inflammatory destruction of the periodontium, which encompasses the tissues that encase and support the teeth, including the gingiva, periodontal ligament, and alveolar bone. Without appropriate treatment, this disease can progress to tooth loss, adversely affecting chewing, appearance, and overall quality of life.[192]

In 2017, the American Academy of Periodontology (AAP) and the European Federation of Periodontology (EFP) co-presented the 2017 Classification of Periodontal and Peri-Implant Diseases and Conditions. This disease classification framework serves to guide treatment planning for periodontitis and aims to support customized approaches to patient care. The revised classification includes a multi-dimensional staging and grading system for periodontitis classification, a recategorization of various forms of periodontitis, and a classification for peri-implant diseases and conditions.[193]

Individuals with ESRD experience compromised immune systems as the immune system and the kidneys are closely integrated and interdependent. In healthy individuals, the kidneys contribute to immune homeostasis and regulation, while components of the immune system mediate many acute forms of renal disease and play a central role in the progression of chronic kidney disease. A dysregulated immune system can have either direct or indirect renal effects.[194] Moreover, uremia, the buildup of waste products in the blood that occurs as a result of declining or decreasing kidney function, can lead to inflammation and reduction in the immune system's ability to function as evidenced by an increased risk of viral-associated cancers, increased susceptibility to infections, and decreased vaccination responses in patients with ESRD.[195] ESRD is also characterized by diminished endocrine and metabolic functions of the kidney with subsequent retention and accumulation of toxic metabolites.[196] Additionally, the presence of indwelling catheters and grafts utilized for the administration of dialysis, malnutrition, dysregulated inflammation, and acquired immune dysfunction due to uremia contribute to the immune deficiency in ESRD and increase susceptibility to infection.[197] Notably, infection is the second leading cause of death in hemodialysis patients.[198] [199]

Several submitters providing information through the public submissions process stated that comorbidities frequently occur in the ESRD patient population and can cause complications for the patient, potentially jeopardizing the outcomes of the dialysis treatment. For example, submitters stated that comorbid diabetes can result in clinical complications for individuals receiving dialysis services in the treatment of ESRD, stating that periodontitis can worsen blood glucose control in diabetics by increasing levels of inflammatory mediators and may interfere with insulin, resulting in clinical complications. Additionally, periodontitis is associated with oral health-related quality of life in individuals with ESRD. One study evaluated whether periodontitis may be independently associated with oral health-related quality of life (OHRQoL) in individuals with ESRD. Researchers assessed 180 adults with ESRD and evaluated for impacts on various domains, and found that periodontitis exerts an influence on OHRQoL in individuals with ESRD, with a more severe condition impacting different domains.[200] Moreover, a prospective cohort study aimed to determine the association between an index of radiographically assessed oral health, Panoramic Tomographic Index (PTI), and cardiovascular and all-cause mortality, major adverse cardiovascular events (MACEs) and episodes of bacteremia and laboratory measurements during a three-year prospective follow-up in chronic kidney disease (CKD) stage 4–5 patients not on maintenance dialysis at baseline. The study showed that radiographically assessed and indexed dental health is independently associated with all-cause and cardiovascular mortality and MACEs in CKD stage 4–5 patients transitioning to maintenance dialysis and renal transplantation during follow-up (but not with the incidence of bacteremia).[201]

Submitters providing information through the public process also stated that BSI, poor glycemic control, and other complications arising from dental infection can jeopardize the clinical success of medical therapies employed to manage ESRD. Research provided by submitters described that issues and changes in the mouth and oral cavity, such as periodontitis and other consequences of poor oral health, frequently occur in patients with CKD and may contribute to increased morbidity and mortality because of

2014 Jul;27(4):342–9. *https://pubmed.ncbi.nlm.nih.gov/24697909/.*

[191] Albandar, J.M. (2005). Epidemiology and risk factors of periodontal diseases. *Dent Clin North Am, 49*(3), 517–532, v–vi. *doi:10.1016/j.cden.2005.03.003.*

[192] Hajishengallis, G., & Chavakis, T. (2021). Local and systemic mechanisms linking periodontal disease and inflammatory comorbidities. *Nature Reviews Immunology, 21*(7), 426–440. *doi:10.1038/s41577-020-00488-6.*

[193] *https://www.perio.org/wp-content/uploads/2019/08/Staging-and-Grading-Periodontitis.pdf.*

[194] Tecklenborg J, Clayton D, Siebert S, Coley SM. The role of the immune system in kidney disease. Clin Exp Immunol. 2018 May;192(2):142–150. *doi: 10.1111/cei.13119.* Epub 2018 Mar 24. PMID: 29453850; PMCID: PMC5904695.

[195] Betjes MG. Immune cell dysfunction and inflammation in end-stage renal disease. Nat Rev Nephrol. 2013 May;9(5):255–65. doi: 10.1038/nrneph.2013.44. Epub 2013 Mar 19. PMID: 23507826. *https://pubmed.ncbi.nlm.nih.gov/23507826/.*

[196] Costantinides F, Castronovo G, Vettori E, Frattini C, Artero ML, Bevilacqua L, Berton F, Nicolin V, Di Lenarda R. Dental Care for Patients with End-Stage Renal Disease and Undergoing Hemodialysis. Int J Dent. 2018 Nov 13;2018:9610892. *doi: 10.1155/2018/9610892.* PMID: 30538746; PMCID: PMC6258100.

[197] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7404977/.*

[198] U.S. Renal Data System. USRDS 2015 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, Bethesda, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2015.

[199] Dalrymple LS, et al. Infection-related hospitalizations in older patients with ESRD. Am. J. Kidney Dis. 2010;56:522–530. *doi: 10.1053/j.ajkd.2010.04.016.*

[200] Oliveira, L.M., Sari, D., Schoffer, C., Santi, S.S., Antoniazzi, R.P., & Zanatta, F.B. (2020). Periodontitis is associated with oral health-related quality of life in individuals with end-stage renal disease. Journal of Clinical Periodontology, 47(3), 319–329. *doi:10.1111/jcpe.13233.*

[201] Jarvisalo, M.J., Jokihaka, V., Hakamaki, M., Lankinen, R., Helin, H., Koivuviita, N.S., . . . Metsarinne, K. (2021). Dental health assessed using panoramic radiograph and adverse events in chronic kidney disease stage 4–5 patients transitioning to dialysis and transplantation—A prospective cohort study. PLOS ONE, 16(9), e0258055. *doi:10.1371/journal.pone.*0258055.

systemic consequences such as inflammation, infections, protein-energy wasting, and atherosclerotic complications.[202]

Several submitters also stated that addressing oral health issues, including identifying and resolving dental infections through the provision of dental and oral services, can be inextricably linked and integral and related to the clinical success of Medicare covered dialysis services for the treatment of ESRD. The submitters stated that the consequences of poor oral health are worse for ESRD patients than for the general population due to ESRD patient characteristics such as advanced age, higher prevalence of comorbid diabetes, polypharmacy, and impaired immune function, and that medically necessary dental care may improve the clinical success of the dialysis services.

A few submitters supplied a general position paper on the need for dental care and services in the ESRD patient population receiving dialysis services, describing the unique risks for individuals with ESRD and the increased risk of infection from oral sources. Specifically, the position paper states that ''oral diseases represent a potential and preventable cause of poor health outcomes in people with ESRD due to their relation to infection, inflammation, and malnutrition. Oral health represents a potential determinant of health outcomes in patients with end-stage renal diseases (ESRD).'' [203] Several submitters also provided a cohort outcomes study of 675 randomly selected individuals receiving peritoneal dialysis services.[204] The study outcomes described that ''poor oral health was associated with lower educational levels, diabetes, older age, marriage, and worse nutritional indicators (including lower time-averaged serum albumin and phosphate concentrations).'' [205]

The research further isolated that poor oral health is independently associated with an increased risk of peritonitis, an infection of the peritoneum where the peritoneal access graft is placed, and mortality in patients receiving peritoneal dialysis. The authors describe that ''after adjusting for age, sex, comorbidities, serum albumin, shared frailty by study sites, and PD vintage, poor oral health was associated with increased risks of peritonitis (adjusted hazard ratio [HR] = 1.45, 95 percent confidence interval [CI]: 1.06–2.00) and all-cause mortality (adjusted HR = 1.55, 95 percent CI: 1.04–2.32) but not hemodialysis (HD) transfer (adjusted HR = 1.89, 95 percent CI: 0.87–4.10) compared to participants with good oral health.'' Furthermore, the study explained that ''poor oral health status was present in one-fourth of peritoneal dialysis patients and was independently associated with a higher risk of peritonitis and death.'' [206] Moreover, submitters provided information that suggests that patients with ESRD receiving hemodialysis services and receiving preventive oral and dental services experience increased survival while those not receiving dental services were associated with increased mortality. A prospective cohort outcomes study of 4,205 hemodialysis patients assessed the impact of dental health on mortality from 2010 to 2012. The study described that ''in adults treated with hemodialysis, poorer dental health was associated with early death, whereas preventive dental health practices were associated with longer survival.'' [207]

Additionally, in a systematic review supplied by several submitters, studies show that patients on RRT (for example hemodialysis, peritoneal dialysis, and/or transplantation) experience a high prevalence of dental caries, a common chronic infectious disease resulting from tooth-adherent cariogenic bacteria.[208] The observational data presented in the review suggests a link between oral health and mortality in patients on RRT.[209] The review highlighted the need for further research in this area but also stated that improved, multidisciplinary, patient-centered dental care concepts are required to support dental and overall oral health in individuals on RRT.

Several submitters also noted that the Society for Vascular Surgery has stated that transient bacteremia from dental infections can seed hemodialysis access grafts. Among strategies to prevent infection of vascular grafts, recommended preoperative measures include identifying and treating remote site infections, including dental or oral sites of infection.[210] [211] Statements regarding best practices for managing infection control advise that sources of infection, including those within the oral cavity, should be addressed in order to minimize the risk of broader infection in the ESRD patient receiving hemodialysis.[212]

We concluded that the evidence base indicates that evaluation for and treatment of oral infection leads to improved outcomes and reduced risk of mortality for individuals with ESRD receiving covered dialysis services (89 FR 61755).

We noted that in the CY 2023 PFS final rule, we agreed with commenters that there is clinical evidence to support that medically necessary dental care may advance the clinical success of organ transplants and finalized that payment can be made under Medicare Parts A and B for dental services such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery and medically necessary diagnostic and treatment services immediately necessary to eliminate or eradicate the infection or its source that are provided before transplantation because such services are inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant procedure (87 FR 69676).

Furthermore, we stated that we appreciated commenters' feedback regarding those individuals who are awaiting organ transplantation and the commenters' request that Medicare provide payment for medically necessary dental services prior to transplantation. We described that in a case where an individual is awaiting organ transplantation, we believe that it is appropriate for Medicare to provide payment for, including but not limited to, an oral or dental examination, and

[202] Harun Akar, Gulcan Coskun Akar, Juan Jesus Carrero, Peter Stenvinkel, and Bengt Lindholm. Systemic Consequences of Poor Oral Health in Chronic Kidney Disease Patients, Clin J Am Soc Nephrol 6: 218–226, 2011. *doi: 10.2215/CJN.05470610.*

[203] Costantinides F, Castronovo G, Vettori E, Frattini C, Artero ML, Bevilacqua L, Berton F, Nicolin V, Di Lenarda R. Dental Care for Patients with End-Stage Renal Disease and Undergoing Hemodialysis. Int J Dent. 2018 Nov 13;2018:9610892. *doi: 10.1155/2018/9610892.* PMID: 30538746; PMCID: PMC6258100.

[204] Sirirat Purisinsith, Patnarin Kanjanabuch, Jeerath Phannajit, Bruce Robinson, Kriang Tungsanga, et al. ''Oral Health-Related Quality of Life, A Proxy of Poor Outcomes in Patients on Peritoneal Dialysis.'' *doi: https://doi.org/10.1016/j.ekir.2022.07.008* (August 5, 2022).

[205] Ibid.

[206] Ibid.

[207] See, for example, Palmer S.C., Ruospo M., Wong G., et al. Oral-D study investigators. Dental health and mortality in people with end-stage kidney disease treated with hemodialysis: a multinational cohort study. American Journal of Kidney Diseases. 2015;66:666–676.

[208] *https://www.ncbi.nlm.nih.gov/books/NBK551699/.*

[209] Deborah Kreher et.al., Prevalence of Dental Caries in Patients on Renal Replacement Therapy—A Systematic Review J. Clin. Med. 2023, 12, 1507. *https://doi.org/10.3390/jcm12041507.*

[210] Surgical Site Infection Toolkit, CDC, SSI Toolkit Activity C: ELC Prevention Collaboratives (*cdc.gov*).

[211] Pear S, Patient Risk Factors and Best Practices for Surgical Site Infection Prevention, *https://www.halyardhealth.com/wp-content/uploads/patient_risk_factors_best_practices_ssi.pdf.*

[212] Ibid.

medically necessary diagnosis and treatment for only those services that are considered immediately necessary to eliminate or eradicate the infection or its source prior to the organ transplant (87 FR 69676).

In the CY 2025 PFS proposed rule, we stated, in consideration of research and recommendations provided by the public and our analyses of the studies and research available regarding the connection between dental services and the clinical success of dialysis services for individuals with ESRD, that we believe that dental services to diagnose and treat infection prior to dialysis services in the treatment of ESRD represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the inpatient or outpatient setting, such as prior to organ transplant. The clinical evidence supports that the medically necessary dental care may similarly advance the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present substantial risk to the success and outcomes of these procedures (including the risk of systemic infection, BSI, sepsis, and death) (89 FR 61755 through 61756).

As such, we stated in the proposed rule that we believe that if a patient requiring dialysis services in the treatment of ESRD has an oral infection, the success of those dialysis services could be compromised if the infection is not properly diagnosed and treated prior to the covered medical services. Without an oral or dental examination to identify such an infection and the provision of necessary treatment, such as restorative dental services, to eradicate the infection prior to the dialysis procedure, the patient's ability to complete the dialysis services could be seriously complicated or compromised and the risk of infection would further increase the risk of mortality for the patient (89 FR 61756).

We provided examples of restorative dental services to eradicate infection: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999) (89 FR 61756).

We explained that if such an infection is not treated prior to dialysis services in the treatment of ESRD, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to BSI and sepsis. Likewise, we stated that we believe that infections occurring during the course of dialysis treatment should similarly be addressed and resolved in order to minimize the risk of infection and death for the patient with ESRD receiving dialysis services (89 FR 61756).

We stated that because an oral or dental infection can present substantial risk to the success of dialysis treatment for ESRD, we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to or contemporaneously with dialysis services in the treatment of ESRD are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, these other covered medical services. We noted that, in these circumstances, the necessary treatment to eradicate an infection may not be the totality of recommended dental services for a given patient. For example, if an infected tooth is identified in a patient requiring dialysis services in the treatment of ESRD, the necessary treatment would be to eradicate the infection, which could result in the tooth being extracted. Additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source prior to surgery. Therefore, such additional services would not be inextricably linked to, and substantially related and integral to, the clinical success of Medicare-covered dialysis services when used in the treatment of ESRD. As such, no Medicare payment would be made for the additional services that are not immediately necessary prior to or contemporaneously with dialysis for ESRD to eliminate or eradicate the infection (89 FR 61756).

In consideration of the concerns discussed above in this section, we proposed to add this clinical scenario to the examples of clinical scenarios under which payment can be made for certain dental services in our regulation at § 411.15(i)(3)(i)(A). Specifically, we proposed to amend the regulation in paragraph A to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with Medicare-covered dialysis services when used in the treatment of ESRD. We sought comments on all aspects of this proposal (89 FR 61756).

a. Consideration of Dental Services That May Be Inextricably Linked to Covered Services for the Treatment of Chronic Kidney Disease

In section II.J.1.b. of this final rule, we discuss that we have partnered with AHRQ to help us consider the relationship between dental services and other specific covered services. Specifically, AHRQ reviews available clinical evidence regarding this relationship and provides analysis of clinical scenarios where dental services may be inextricably linked to other covered services. To better address the public's immediate dental needs, AHRQ conducts rapid response reports instead of systematic reviews. With these rapid response reports, we can better specify which payments can be made under Medicare Parts A and B for certain dental services that are inextricably linked to other covered services.

In the CY 2025 PFS proposed rule (89 FR 61752), we provided an overview of the information we received from the public through the submission process. In that discussion, we summarized the submissions received from interested parties asserting that dental treatments can be integral to the clinical success of covered nephrology-related medical services. We found the evidence submitted through the submission process compelling with respect to dental services furnished to identify, diagnose, and treat oral or dental infections prior to or contemporaneously with dialysis services in the treatment of ESRD, which led to our proposal discussed above.

We acknowledge the importance of dental health to overall well-being of patients with kidney related diseases, such as, CKD. To gain further understanding of potential relationships between dental services and specific covered CKD medical services, we partnered with researchers at AHRQ to review available clinical evidence regarding this topic.

AHRQ created a rapid response report, which was not available at the time of the proposed rule's publication, that summarized recent evidence, aiming to inform CMS policy

development related to the possible linkage between dental services and treatment modalities and services for CKD patients. Specifically, the report reviewed the available clinical evidence on the efficacy of dental services in improving health outcomes for patients with CKD across different treatment modalities and stages of the disease. For more detailed information about the search strategies and findings, please refer to the AHRQ rapid response report available at *https://effectivehealthcare.ahrq.gov/products/treatment-outcomes-chronic-kidney/rapid-research*.

CKD affects around 14 percent of American adults [213] and 850 million people globally,[214] and its prevalence is rising faster than that of other major diseases like diabetes and heart disease.[215] As stated in the AHRQ rapid response report, CKD is a condition characterized by impaired kidney function, which leads to the accumulation of excess fluid and toxic waste. This impairment can result in various health complications, including high blood pressure, heart disease, and stroke. AHRQ stated that assessing kidney function and damage involves the use of several biomarkers, with serum creatinine and other serum indicators employed to estimate the estimated glomerular filtration rate (eGFR). CKD is classified into five stages based on eGFR levels and evidence of kidney damage.[216] According to the rapid response report, stages 1, 2, 3 and 4 have eGFR values of >90, 60–89, 30–59 and 15–29 mL/min/1.73m^2 respectively. CKD stage 4 represents severe kidney damage. CKD stage 5 represents severe kidney damage or failing kidneys and is also termed end-stage renal disease (ESRD), which is defined by eGFR below 15 mL/min/1.73m^2. For individuals in Stage 5, treatment options include dialysis (for example, hemodialysis and peritoneal dialysis) or kidney replacement therapy.

AHRQ's rapid response report highlights that chronic oral diseases (COD), such as dental caries, gingival infection, periodontal disease, and tooth loss,[217] are common in the United States and can significantly impact overall health. Periodontitis, in particular, is a condition that can cause systemic inflammation, which can worsen CKD. According to the rapid response review, the prevalence of periodontitis approaches 100 percent in patients on dialysis in some studies,[218] suggesting that this is a near-ubiquitous comorbidity with severe CKD. A recent study finding identified that dental intervention may reduce total medical treatment for these patients by delaying or preventing disease progression.[219] Additionally, periodontitis may also significantly exacerbate cardiovascular risk and total mortality in patients with CKD at all severity levels.[220]

In their rapid response, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram, used in systematic reviews and meta-analyses to describe the review's findings, revealed that 515 records were initially identified from two large databases, of which 23 relevant articles met the study's eligibility criteria for inclusion. Of these 23 articles, 7 were systematic reviews and/or meta-analyses, 15 were randomized clinical trials, non-controlled clinical trials, or observational studies, and 1 article related to practice guidelines.

Based on the report, no evidence is available regarding the impact of dental services on health outcomes, specifically for individuals with stage 4 CKD alone. However, the report found evidence suggesting improved outcomes for all-cause mortality for hemodialysis patients after nonsurgical periodontal therapy (NSPT), as well as evidence indicating a decreased risk of cardiovascular events with NSPT or endodontic treatment for hemodialysis patients. A single study in their report suggested a decrease in all-cause mortality among ESRD patients undergoing either hemodialysis or peritoneal dialysis. The report also found that there is insufficient evidence suggesting that NSPT leads to lower rates of bacteremia, pneumonia, osteomyelitis, brain abscess, or renal and perinephric abscess outcomes. Additionally, the report found that the evidence regarding the effect of dental services on all-cause mortality in patients undergoing hemodialysis or peritoneal dialysis is inconsistent.

The rapid response report noted several limitations in the evidence base, including varying severities of periodontitis among patient populations and differences in study designs, which affect the overall quality of the findings. Additionally, follow-up periods were generally short, limiting the ability to assess long-term effects. Furthermore, no recent trials or cohort studies have been conducted in the U.S., making it unclear to what extent this evidence is generalizable to the U.S. population.

The findings of the AHRQ rapid responses highlight that this area merits further study by researchers and industry to explore potential connections between dental services and improved outcomes for individuals with CKD. Specifically, the body of evidence evaluating dental services before, during, or after the initiation of dialysis lacks primary clinical data. Additionally, the current literature lacks comprehensive guidance and evidence-based protocols for addressing the diverse oral health needs of CKD patients, including the appropriate frequency and duration of dental services for patients at any stage of CKD.

We received 54 public comments on the proposal to amend the regulation at § 411.15(i)(3)(i)(A) to include dental or oral examination performed as part of a comprehensive workup in either the inpatient or outpatient setting prior to Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with Medicare-covered dialysis services when used in the treatment of ESRD. Commenters included members of Congress, patient advocacy organizations, hospitals and hospital associations, medical and dental associations representing several different specialties and specialty societies, dialysis organizations, dental plan associations, and health insurance companies, among others. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposal. Commenters stated they agree with CMS's conclusion that the clinical evidence indicates that

[213] American Kidney Fund. All about the kidneys. Stages of kidney disease (CKD). *https://www.kidneyfund.org/all-about-kidneys/stages-kidney-disease* (accessed 2024–07–21).

[214] Centers for Disease Control and Prevention. About Post-Streptococcal Glomerulonephritis. *https://www.cdc.gov/group-a-strep/about/post-streptococcal-glomerulonephritis.html*.

[215] Ibid.

[216] American Kidney Fund. All about the kidneys. Stages of kidney disease (CKD). *https://www.kidneyfund.org/all-about-kidneys/stages-kidney-disease* (accessed 2024–07–21).

[217] Centers for Disease Control and Prevention. About Post-Streptococcal Glomerulonephritis. *https://www.cdc.gov/group-a-strep/about/post-streptococcal-glomerulonephritis.html*.

[218] Craig, R.G. Interactions between Chronic Renal Disease and Periodontal Disease. Oral Dis 2008, 14 (1), 1–7. *https://doi.org/10.1111/j.1601-0825.2007.01430.x*.

[219] Grubbs, V.; Vittinghoff, E.; Beck, J.D.; Kshirsagar, A.V.; Wang, W.; Griswold, M.E.; Powe, N.R.; Correa, A.; Young, B. Association Between Periodontal Disease and Kidney Function Decline in African Americans: The Jackson Heart Study. Journal of Periodontology 2015, 86 (10), 1126–1132. *https://doi.org/10.1902/jop.2015.150195*.

[220] Sharma, P.; Dietrich, T.; Ferro, C.J.; Cockwell, P.; Chapple, I. L. C. Association between Periodontitis and Mortality in Stages 3–5 Chronic Kidney Disease: NHANES III and Linked Mortality Study. J Clin Periodontol 2016, 43 (2), 104–113. *https://doi.org/10.1111/jcpe.12502*.

medically necessary dental care may advance the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present a substantial risk to the success and outcomes of these procedures. Commenters offered many ways that dental and oral care play a critical role in the success and outcomes of dialysis for individuals living with kidney failure. For example, they explained that dental services furnished to identify, diagnose, and treat oral or dental infections may enhance access to kidney transplants, lessen the risk of morbidity, mortality, and negative cardiovascular events, protect against peritoneal dialysis associated peritonitis, prevent hospitalizations, improve overall health and prognosis of individuals with ESRD, prevent complications including bloodstream infections and poor glycemic control, improve quality of life, and keep patients stable on their current dialysis modality.

Commenters stated that the proposal is a crucial step towards addressing health disparities and enhancing access to transplantation services. They explained that without Medicare coverage, many beneficiaries on dialysis may not have access to dental services, which serves as a serious health equity issue and a real barrier to care and applauded CMS for taking an important step to close a real health equity gap for Americans living with kidney disease. Commenters explained that oral health related infections result in worse prognoses for ESRD patients and perpetuate disparities based on race. The commenters discussed how kidney disease disproportionately affects communities of color and explained that Black people are nearly four times more likely to be affected by kidney disease than white people, and more than one-third of people with ESRD come from neighborhoods that are disproportionately impoverished. These commenters stated that expanding access to these services would address these disparities in communities that have long been underserved by medical and dental care.

One commenter stated that the proposal, if finalized, would improve the health outcomes of pediatric patients who are receiving dialysis. The commenter also offered to work with CMS to explore other policies that would ensure pediatric patients have access to these services. Other commenters shared their support of the proposal and noted that many residents of nursing homes and assisted living residences with ESRD requiring dialysis also have dental diseases that may result in infections and other complications that can impair the effectiveness of the dialysis intervention.

Commenters had different interpretations of the proposal with regard to the population of beneficiaries with ESRD for which Medicare would cover dental services as well as the scope and frequency of such services. Most commenters described the proposal as providing that for individuals with ESRD receiving Medicare-covered dialysis, since these treatments are not a one-time procedure like an organ transplant but instead are ongoing and life-sustaining, the duration of dental services should be the same as for dialysis sessions, because the policy's premise is that they are inextricably linked to the dialysis services. Other descriptions that commenters used included casting the proposed policy as offering comprehensive dental care and an expansion of dental benefits. However, some commenters conveyed their understanding that the oral examinations would be covered only before the onset of dialysis, that is, the time an individual initiates the first dialysis treatment. Some commenters requested clarity on the allowable frequency of dental services.

One commenter restated the proposal as permitting payment for dental exams prior to or contemporaneously with dialysis services, while another commenter described the dental services as reliable which could suggest that they are consistent or planned. A different commenter restated the proposal as permitting payment for periodic dental care and later in their comment referred to regular dental care and how these services can identify and reduce the occurrence of infections.

One commenter restated the proposal as permitting payment for oral evaluations for ESRD patients prior to commencing dialysis, while another commenter described the services as an oral examination performed as part of a comprehensive workup prior to the initiation of Medicare-covered dialysis to treat ESRD. A different commenter stated that a comprehensive workup prior to the initiation of dialysis services does not routinely include a dental and oral examination. The commenter also referenced the Conditions for Coverage for ESRD Facilities (CfCs) at § 494.80, where it states that an ESRD facility's interdisciplinary team conducts an ''individualized and comprehensive assessment'' of the patient's needs, which is then used to develop and implement a comprehensive plan of care. The commenter stated that while the initial assessment might identify a patient's oral health needs, an ESRD facility has no ability or financing with which to incorporate such into the plan of care except perhaps through referral to outside dental services. Likewise, dental issues may surface throughout dialysis treatment, when a patient may relay dental pain or discomfort to a health care provider. The commenter stated that, at that point, too, if a patient and/or health provider realize dental or oral services are needed, the only recourse would be referral.

One commenter stated that it is unclear whether the proposal would permit payment for a dental exam prior to each dialysis session, since dialysis services can be frequent and long-lasting. The commenter stated that ESRD patients often receive dialysis up to three times per week. One commenter requested additional information to understand the proposal. The commenter requested a detailed definition of what constitutes a medically necessary dental or oral examination and asked that we provide the criteria or guidelines that will be used to determine the necessity of such examinations. The commenter also requested clarification on the specific diagnostic and treatment services considered medically necessary, as well as any relevant criteria or thresholds that will determine the necessity for these services.

Commenters expressed appreciation for CMS listening to recommendations provided by the kidney community and evaluating the clinical research that demonstrates the connection between dental services and the clinical success of dialysis services for individuals with ESRD. One commenter stated the proposal aligns with CMS's longstanding policy of covering treatments related to ESRD, including dialysis services and kidney transplant surgeries. The commenter stated that given the critical role of dialysis in managing ESRD and the importance of oral health in these patients, expanding coverage for dental services linked to dialysis is a logical progression. A different commenter stated that they were pleased to see CMS expand access to dental services for individuals with kidney failure seeking transplants in the CY 2023 PFS rule and believe this further expansion to all beneficiaries with ESRD is incredibly positive. The commenter stated that all beneficiaries who require dialysis, including in-center, home peritoneal, and home hemodialysis patients, should have access to dental services. A different commenter was pleased that this year's proposal would be another significant step to ensure another high-risk patient

population can access medically necessary dental services. This commenter stated that they are root canal specialists and witness firsthand the severe consequences of untreated dental infections, which can rapidly spread, exacerbating existing health conditions and potentially become life-threatening.

Several commenters urged CMS to ensure that payment is permitted for dental services not only for patients diagnosed with ESRD (ICD–10 code N18.6) but also for patients diagnosed with stage 5 CKD (ICD–10 code N18.5) who have not yet initiated dialysis, stating that these patients should receive the dental care needed to prevent infections that exacerbate diabetes and kidney disease. These commenters further requested that the policy apply to claims for patients with a diagnosis encompassing one of those conditions, such as Hypertensive Chronic Kidney Disease with stage 5 CKD or ESRD (ICD–10 code I12.0).

Several commenters also urged CMS to reconsider whether certain dental services may be inextricably linked to treatment for stage 4 CKD (ICD–10 code N18.4). They explained that when a patient is at CKD stage 4, they have severe kidney damage, and it is critical to slow the loss of kidney function by managing health problems, such as oral/dental infection, that directly complicate and are complicated by their kidney disease. They further explained that resolving dental infections in patients at that stage can improve eGFR, inflammatory markers, erythrocyte count, and nutrition, as well as reduce the risk of cardiovascular and other serious medical events. They stated that these clinical factors are commonly exacerbated by CKD and negatively impact CKD outcomes, and since dental care can play a substantial role in addressing these factors in patients with stage 4 CKD, it can help to delay or avoid progression to stage 5 and ESRD, and the consequent need for dialysis or kidney transplantation.

One commenter also requested that CMS consider expanding the proposed policy to stage 4 CKD, stating that it is critical that CMS go upstream to address the needs of patients with advanced CKD who may not yet be starting dialysis, but whose eGFR points to a likely start in the near future. The commenter explained that this can be a critical time for a patient—whether in preparation for transplant or transition to dialysis—to address, in collaboration with their nephrologist, dental and/or oral health challenges in a comprehensive manner. Access to necessary oral and dental care is one means of doing so. The commenter asked CMS to clarify that its expansion of dental coverage as related and integral to treatment of kidney disease includes those patients whose course of treatment may not yet have started but is anticipated in the near term. The commenter agreed with our statement in the proposed rule, that the evidence indicates that evaluation for and treatment of oral infections lead to improved outcomes and reduced risk of mortality for individuals with ESRD receiving covered dialysis services and further noted that not only does dental and oral care have the potential to improve kidney care outcomes, but it also has the potential to ultimately generate cost savings.

Response: We agree with commenters that there is evidence to support that dental services are inextricably linked to, and substantially related and integral to the clinical success of dialysis services in the treatment of ESRD. We note that the two leading causes of death in the dialysis patient population are cardiovascular disease and infection. The AHRQ rapid response report identified a high-quality retrospective cohort study comparing 3613 patients who received hemodialysis and intensive periodontal disease treatment to patients on hemodialysis without periodontal disease treatment. The treatment cohort exhibited significantly lower cumulative incidences of cardiovascular disease events and all-cause mortality.[221] The AHRQ rapid response report also identified a high-quality retrospective cohort study that followed 12,454 patients receiving either hemodialysis or peritoneal dialysis over the course of 16 years. From this population, two subgroups were further defined, those that received root canal therapy and those that did not. The results showed that members of the non-root canal therapy group had a significantly higher mortality rate than those of the root canal therapy group. This study suggested that patients on either hemodialysis or peritoneal dialysis who received root canal therapy had a lower risk of death than patients who did not receive root canal therapy. The study also noted infectious diseases had a significant role in mortality among dialysis patients who did not receive root canal therapy.[222]

As earlier stated, we also found submitter information compelling. Specifically, submitters provided a cohort outcomes study of 675 randomly selected individuals receiving peritoneal dialysis services.[223] After adjusting for age, sex, comorbidities, serum albumin, shared frailty by study sites, and peritoneal dialysis vintage, poor oral health was associated with increased risks of peritonitis and all-cause mortality compared to participants with good oral health. While we do note that a specific dental treatment service was not part of this study design, we still find the increased risk of peritonitis in the poor oral health population, which likely would affect the ability to perform and the clinical success of peritoneal dialysis, compelling evidence in support of the assertion that dental services are inextricably linked to, and substantially related, and integral to the clinical success of dialysis services in the treatment of ESRD.

In consideration of the submissions and comments provided by the public and the research conducted by AHRQ, we find that the clinical evidence supports that the medically necessary dental care are inextricably linked to, and substantially related, and integral to the clinical success of dialysis services in the treatment of ESRD because an oral or dental infection can present a substantial risk to the success and outcomes of these procedures (including the risk of systemic infection, BSI, sepsis, and death). Therefore, the dental services are so integral to medically necessary dialysis services in the treatment of ESRD that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of the medical service and are substantially related and integral to the covered medical service of dialysis. We note that these medical services include either modality of dialysis that a beneficiary is receiving,

[221] Huang, S.-T.; Yu, T.-M.; Ke, T.-Y.; Wu, M.-J.; Chuang, Y.-W.; Li, C.-Y.; Chiu, C.-W.; Lin, C.-L.; Liang, W.-M.; Chou, T.-C.; Kao, C.-H. Intensive Periodontal Treatment Reduces Risks of Hospitalization for Cardiovascular Disease and All-Cause Mortality in the Hemodialysis Population. J Clin Med 2018, 7 (10), 344. *https://doi.org/10.3390/jcm7100344.*

[222] Chiu, C.-C.; Chang, Y.-C.; Huang, R.-Y.; Chan, J.-S.; Chung, C.-H.; Chien, W.-C.; Kao, Y.-H.; Hsiao, P.-J. Investigation of the Impact of Endodontic Therapy on Survival among Dialysis Patients in Taiwan: A Nationwide Population-Based Cohort Study. Int J Environ Res Public Health 2021, 18 (1), 326. *https://doi.org/10.3390/ijerph18010326.*

[223] Sirirat Purisinsith, Patnarin Kanjanabuch, Jeerath Phannajit, Bruce Robinson, Kriang Tungsanga, et al. ''Oral Health-Related Quality of Life, A Proxy of Poor Outcomes in Patients on Peritoneal Dialysis.'' *doi: https://doi.org/10.1016/j.ekir.2022.07.008* (August 5, 2022).

hemodialysis or peritoneal dialysis—and whether or not it is administered in the home or in-center at an ESRD facility. As such, we are finalizing our proposal that Medicare Part A and Part B payment can be made for certain dental services, such as a dental or oral examination performed as part of a comprehensive workup prior to dialysis services in the treatment of ESRD, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, dialysis services in the treatment of ESRD.

We note that we are finalizing the proposal with modifications, as discussed below, after consideration of public comments to reflect the duration of dialysis services for the treatment of ESRD. The clinical evidence demonstrates that if an infection is not treated prior to, or contemporaneously with dialysis services in the treatment of ESRD, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to BSI and sepsis. Likewise, infections occurring during the course of dialysis treatment should similarly be addressed and resolved in order to minimize the risk of infection and death for the patient with ESRD receiving dialysis services.

Some of the commenters appear to have interpreted the proposal as an expansion of Medicare coverage of dental services. This was not our intention. As we explained in the CY 2023 PFS final rule, under our interpretation of section 1862(a)(12) of the Act, items and services furnished in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth generally are not covered by Medicare, and no payment may be made for them under either Medicare Part A or Part B, subject to certain exceptions specified in the statute (87 FR 69664). The proposal would not expand Medicare coverage of dental services. Rather, it would add certain dental services that are inextricably linked to Medicare-covered dialysis services used in the treatment of ESRD to the non-exhaustive list of examples of clinical scenarios under § 411.15(i)(3)(i) in which Medicare may pay for certain specified dental services.

With regard to the comments on the population for which Medicare would pay for dental or oral examinations before dialysis, we note payment under Medicare Part A and B may be made for dental services that are inextricably linked to other covered services only for individuals who are entitled to and enrolled in Medicare. To clarify, individuals of any age with ESRD who receive dialysis on a regular basis or a kidney transplant are entitled to Medicare if they file an application and meet certain requirements. Entitlement usually begins after a 3-month waiting period has been served.[224] [225] [226] While the proposal references payment for dental or oral examination performed as part of a comprehensive workup prior to Medicare-covered dialysis services when used in the treatment of ESRD, it does not change the existing terms of Medicare entitlement. We agree with commenters that the proposal would allow for payment for oral evaluations prior to the onset of dialysis, that is, the initial treatment furnished to a patient with ESRD. We also agree with commenters that the proposal would allow for payment for dental services that identify, diagnose, and treat the occurrence of infections for the duration that a beneficiary with ESRD is on dialysis, because dialysis is ongoing and life-sustaining unless a kidney transplant occurs. This means that the duration of the provision of dental services that are inextricably linked to dialysis services for these beneficiaries with ESRD may be ongoing but still would have to be medically reasonable and necessary.

After consideration of these comments, we are finalizing the proposal with a modification to address the duration of the provision of dental services that are inextricably linked to dialysis services for the treatment of ESRD. We are finalizing the addition of new paragraph (F) to the regulation at § 411.15(i)(3)(i) to include dental or oral examination performed as part of a comprehensive workup prior to, or contemporaneously with, Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, Medicare-covered dialysis services when used in the treatment of ESRD.

With regard to commenters' concerns about how frequently the dental services can be furnished and paid for under Medicare Part A and B and the comment requesting detail on what constitutes dental services that are medically necessary, MACs retain discretion to decide that payment can be made for dental services in accordance with the regulation on a claim-by-claim basis.

With regards to the comments requesting that the policy extend to beneficiaries that are in the earlier stages of CKD, we agree that dental services may improve outcomes for such individuals; however, the clinical evidence available to us does not demonstrate an inextricable link between dental services and other covered medical services that such individuals may receive.

We appreciate the comment referencing the CfCs at § 494.80. We believe that the provisions discussed under this regulation are outside the scope of the proposals for this rule, since they outline the conditions that dialysis facilities must meet to be certified under the Medicare program. We note, as discussed in the CY 2023 PFS final rule (87 FR 69663 through 69688), that we believe the dental services and the other covered services related to the treatment of ESRD would most often be furnished by different professionals and that in order for the dental services to be inextricably linked to the other covered services such that Medicare payment can be made, there must be coordination between these professionals. This coordination should occur between the practitioners furnishing the dental and covered services regardless of whether both individuals are affiliated with or employed by the same entity. This coordination can occur in various forms, such as, but not limited to, a referral or exchange of information between the practitioners furnishing the dental and other covered services. Additionally, any evidence of coordination between the professionals furnishing the primary medical service and dental services should be documented. If there is no evidence to support the exchange of information, or integration, between the professionals furnishing the primary medical service and the dental services, then there would not be an inextricable link between the dental and other covered services within the meaning of our regulation at § 411.15(i)(3)(i). As such, Medicare payment for the dental services would be excluded under section 1862(a)(12) of the Act (though payment for the dental services might be available through supplemental health or dental coverage).

Comment: Commenters urged CMS to be careful not to suggest a preference for tooth extraction as ''the necessary treatment'' for eradicating infections despite our listing of other restorative (and tooth-sparing) services provided in the proposed rule that may be paid for. The commenters explained that doing so could lead MACs to improperly impose an extra burden on health care

[224] Section 226A of the Act.

[225] 42 CFR 406.13.

[226] Pub. 100–01 Medicare General Information, Eligibility and Entitlement Manual, Chapter 2 Hospital Insurance and Supplementary Medical Insurance, Sections 10.4 and 10.4.2.

providers to justify choosing a procedure other than an extraction in a particular instance. The commenters had the same concern with how CMS discusses additional services by using crowns as an example of a service that may not be paid and expressed concern that these types of statements should be approached with ample clinical basis, since the standard of care in certain root canal procedures, among other situations, requires application of a crown to prevent root canal failure, fracture, infection, and other complications in the immediate and longer term. One commenter recognized that implants or crowns may not be immediately necessary on their own to address an acute oral infection but explained that these services become necessary once treatment to extract a tooth is initiated. The commenter expressed the concern that since dialysis for ESRD is a long-term, rather than an acute treatment, the removal of teeth without associated restoration of the mouth and oral structures to function and allow for healthy chewing and eating will have reverberating effects on dialysis treatment outcomes. A different commenter explained that despite the availability of tooth-saving and oral health preservation options such as fluoride applications or restoration of the teeth that are salvageable through root canal treatment or fillings, beneficiaries end up living with fewer natural teeth. They further explained that this partial or complete edentulism impairs their ability to eat healthy food, maintain a social life, and keep an esthetic facial profile and can impair the healing and health maintenance activities that are often necessary to manage the underlying medical condition.

Conversely, one commenter did not believe the proposal properly delineated those dental services that would be deemed inextricably linked to Medicare-covered dialysis treatments for ESRD patients, and, as a result, is concerned with CMS's open-ended proposal to cover many complex dental services which they believe are not warranted. The commenter explained that although CMS mentions several restorative dental services in the preamble of the proposed rule, these are only examples, since a MAC would not be precluded from allowing Medicare payment for other dental services. The commenter also stated that the proposed coverage of endodontics (root canals), which would warrant related restorative treatment, represents a significant expansion, as CMS would only customarily cover an extraction of an infected tooth. In addition, the commenter questioned CMS' logic of covering root canals while excluding implants and crowns as ''not immediately necessary.'' The commenter requested that CMS consider defining infection for this purpose as an acute infection, limit covered dental services to extractions, and provide clarification on the specific dental services that would qualify as restorative dental services to eradicate infection.

Response: In the CY 2025 PFS proposed rule we stated that examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth—for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings—for example, CDT D2000–2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning—for example, CDT D4000–4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal—for example, CDT D3000–3999) (89 FR 61756). Because an oral or dental infection can present substantial risk to the success of dialysis treatment for ESRD, payment under Medicare Part A and B is permitted for only those dental services furnished to identify, diagnose, and treat the infection. We gave the example of dental implants or crowns as additional dental services that might not be considered immediately necessary to eliminate or eradicate the infection or its source because these types of services may have other uses in the dental space.

Comment: One commenter stated that while linking dental services to other services such as a stent for hemodialysis, or a vascular access graft would be a benefit for ESRD patients, receipt of dental services is not a clinical requirement in order to receive dialysis. The commenter said that beneficiaries with ESRD should have access to dental services when necessary, and dental services should not become a requirement that precludes a patient from receiving another important service.

Response: We thank the commenter for their perspective and sharing of clinical insight.

3. Request for Comment on Dental Services Integral to Specific Covered Services To Treat Diabetes

We have received information from interested parties, including submitters providing evidence through the public submissions process as well as commenters on prior proposed rules suggesting that dental services are inextricably linked to treatment services for individuals with diabetes mellitus. As we discussed in the CY 2025 PFS proposed rule (89 FR 61752), several interested parties using the public submissions process have urged us to provide Medicare payment for dental services for individuals diagnosed with diabetes for consideration in CY 2025 rule making. These submissions included information and references supporting oral and dental treatment of advanced periodontitis among individuals with diabetes to improve markers related to management of the diabetes.

Submitters stated that clinical studies demonstrate that dental treatments for oral infections, such as advanced periodontitis and related inflammation, meaningfully advance and improve the treatment of, management of, and outcomes for patients with diabetes. Submitters also stated that conversely, the absence of treatment of chronic dental infections in turn complicates covered medical treatment for the management of diabetes and potentially exacerbates insulin resistance, worsens glycemic control, and other diabetes-related complications, leading to poor outcomes for the individuals with diabetes. Submitters also noted that studies demonstrate cost savings when dental services are employed in the treatment of individuals with diabetes and also serve to advance health equity among vulnerable populations.

Submitters provided information detailing the increased risk of dental caries and periodontal disease in people with diabetes, many of whom lose teeth, which greatly limits nutrition, general well-being, and overall quality of life. Submitted studies demonstrated the bidirectional nature of periodontal disease and diabetes, suggesting that both conditions influence each other and can worsen or conversely improve outcomes.

As described by submitters, numerous basic and clinical studies describe the relationship between oral diseases and inflammation in persons with diabetes, which increases risks for micro- and macrovascular complications including retinopathy, nephropathy, neuropathy, cardiovascular diseases, and stroke. Several submitters stated that there is a documented reduction in hospitalizations in persons with diabetes who receive conservative periodontal treatment. Consequently, submitters stated that periodontal treatment is recommended for patients

with diabetes by the American Diabetes Association Clinical Guidelines and is also promoted by the American Association of Clinical Endocrinologists and others.[227]

Diabetes mellitus is a chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which, over time, may lead to serious damage to the heart, blood vessels, eyes, kidneys, and nerves. Type 2 diabetes, which usually occurs in adults, causes the body to become resistant to insulin or not to make enough insulin. Type 1 diabetes, previously referred to as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin.[228]

A primary goal for diabetes treatment is glycemic control and requires accurate individualization and customization of available treatment options. Interventions to address lipoproteins, blood pressure, weight control, mental health, and lifestyle are important factors that contribute to quality of life and the frequency of diabetes-associated complications.[229] According to recent statistics from the Centers for Disease Control and Prevention, approximately 38 million people in the United States may have diabetes, and the CDC estimates that 1 in 5 of them do not know they have the condition. Approximately 98 million U.S. adults likely have prediabetes, and more than 8 in 10 of them may not know they have prediabetes. Notably, diabetes is the eighth leading cause of death in the United States (and maybe underreported). Type 2 diabetes accounts for approximately 90 to 95 percent of all diagnosed cases of diabetes, while Type 1 diabetes accounts for approximately 5–10 percent. The CDC reports that over the last 20 years, the number of adults diagnosed with diabetes has more than doubled as the overweight and obesity have become more prevalent in the American population.[230] [231]

One key marker for the measurement of glycemic control, a key goal in the treatment of diabetes, in individuals with diabetes is the hemoglobin A1c test. The hemoglobin A1c (also referred to as glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c) test is used to evaluate a person's level of glucose control and shows an average of the blood sugar level over the past 90 days and represents a percentage.[232]

Submitters through the public submissions process provided multiple research studies regarding the interaction between dental services and outcomes for medical services to treat diabetes. The Cochrane Library (ISSN 1465–1858) is a collection of databases that contain high-quality, independent evidence to inform healthcare decision-making. The Cochrane Library is owned by Cochrane and published by Wiley.[233] In the Cochrane Review entitled *Treatment of periodontitis for glycemic control in people with diabetes mellitus,* evidence from 30 trials (results from 2,443 participants) showed that periodontitis treatment reduces blood sugar levels (measured by HbA1c) in diabetic patients on average by 0.43 percentage points (for example, from 7.43 to 7 percent; 4.7 mmol/mol) 3 to 4 months after receiving the treatment compared with no active treatment or usual care. A difference of 0.30 percent (3.3 mmol/mol) was seen after 6 months (12 studies), and 0.50 percent (5.4 mmol/mol) at 12 months (one study).[234] All studies in the review used a parallel randomized controlled trials (RCT) design and followed participants for between 3 and 12 months. The studies generally focused on people with type 2 diabetes, save one study that included participants with type 1 or type 2 diabetes. Most studies were mixed in terms of whether metabolic control of participants at baseline was good, fair, or poor and were carried out in secondary care. Researchers compared periodontitis treatment with control, which could be no (or delayed) treatment or usual care (oral hygiene instruction (OHI) or supragingival scaling with or without OHI). The degree and nature of advanced periodontitis were not specifically defined in the context of the studies. Additionally, the studies did not control for other types of interventions deployed in the treatment of diabetes (that is, strategies used to manage glycemic control), so patients may have been receiving other types of treatment during the study periods.

The types of periodontal treatment provided covered a wide range of oral services: subgingival instrumentation, surgical periodontitis treatment—flap surgery or gingivectomy; antimicrobial therapy (encompassing antibacterials and antibiotics), either locally applied (including mouth rinses, gels, or dentifrices) or systemically administered; other drug therapy with a possible benefit of improving the periodontal health of the participant; other novel interventions to manage periodontitis; supragingival scaling (also known as professional mechanical plaque removal (PMPR)); oral hygiene instruction; and/or, education or support sessions to improve self-help or self-awareness of oral hygiene.

In summary, the Cochrane review demonstrated that individuals with diabetes who have periodontitis who receive dental services for the treatment of the periodontitis experience a statistically significant reduction of HbA1c. Again, measurement of HbA1c is a metric for gauging glycemic control which is a primary goal of treatment for all individuals with diabetes. The study suggests that individuals with diabetes who also have a diagnosis of periodontitis who receive treatment to address the periodontitis subsequently experience a reduction in HbA1c. The study authors described the clinical outcomes related to preventive dental care, conservative periodontal treatment, and reduction in HbA1c as statistically and clinically significant. Moreover, the authors of the research stated that ''further trials evaluating no treatment vs usual care are unlikely to change this conclusion.'' [235]

Submitters providing information through the public submissions process suggested that dental services could be inextricably linked to the following specific medical services in the treatment of diabetes:

- CPT 36901–36906: Dialysis circuit procedures.
- CPT 82947: Chemistry procedures, blood glucose testing.

[227] Nuha A. El Sayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M. Brown, Dennis Bruemmer, Billy S. Collins, Kenneth Cusi, Sandeep R. Das, Christopher H. Gibbons, John M. Giurini, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott Kahan, Kamlesh Khunti, Mikhail Kosiborod, Jose Leon, Sarah K. Lyons, Lisa Murdock, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, Jennifer K. Sun, Crystal C. Woodward, Deborah Young-Hyman, Robert A. Gabbay; on behalf of the American Diabetes Association, Summary of Revisions: Standards of Care in Diabetes—2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S5–S9. *https://doi.org/10.2337/dc23-Srev.*

[228] *https://www.who.int/health-topics/diabetes.*

[229] Melmer A, Laimer M. Treatment Goals in Diabetes. Endocr Dev. 2016;31:1–27. doi: 10.1159/000439364. Epub 2016 Jan 19. PMID: 26824869. *https://pubmed.ncbi.nlm.nih.gov/26824869/.*

[230] *https://www.cdc.gov/diabetes/basics/quick-facts.html.*

[231] *https://www.cdc.gov/ncbddd/disabilityandhealth/materials/factsheets/fs-communicating-with-people.html.*

[232] *https://www.ncbi.nlm.nih.gov/books/NBK549816/.*

[233] *https://www.cochranelibrary.com/about/about-cochrane-library.*

[234] Simpson TC, et al. Treatment of periodontitis for glycaemic control in people with diabetes mellitus. Cochrane Database Syst Rev. 2022;4:CD004714 *https://www.ncbi.nlm.nih.gov/pubmed/35420698.*

[235] Simpson TC, et al. Treatment of periodontitis for glycaemic control in people with diabetes mellitus. Cochrane Database Syst Rev. 2022;4:CD004714 *https://www.ncbi.nlm.nih.gov/pubmed/35420698.*

- CPT 83036: Hemoglobin A1C testing.
- CPT 90935, 90937, 90940: Hemodialysis procedures.
- CPT 90961: Physician or other qualified healthcare professional visits for ESRD.
- CPT 90989–90999: Other dialysis procedures.
- CPT 92227–92229: Diabetic retinopathy screening.
- CPT 99091: Collection and interpretation of physiologic data.
- CPT 99202–99215: Evaluation and Management (E/M) Services.
- CPT 99211: Office visit for an established patient.
- CPT 99487: Complex chronic care management services.
- CPT 99490–99491: Chronic care management services.
- CPT 99497: Remote physiologic monitoring services.
- CPT 99605–99607: Medication Management.
- CPT 99802–99804: Assessment, Intervention, Face to Face (F2F).
- DRG 637: Hospitalization for diabetes with major complications.
- G0108: Diabetes Self-Management Training.
- G0109: Group Diabetes Self-Management Training.
- G0270: Nutrition Therapy.
- G0466: FQHC visit new patient.
- G0467: FQHC visit established patient.

In the CY 2025 PFS proposed rule (89 FR 61758), we discussed how the research provided by submitters suggests that periodontal treatment for an individual with both a diagnosis of diabetes and periodontitis led to improved HbA1c measures.

We stated in the proposed rule that in the case of an individual with diabetes who also has a diagnosis of periodontitis, oral services and treatment to address the periodontitis potentially lead to a reduction in HbA1c, a marker of glycemic control that may be used to determine the effectiveness of interventions for treatment of diabetes. We noted that in the description of the studies submitted, the research seems to indicate that the improvement of glycemic control as evidenced by the HbA1c is due to the provision of treatment for the periodontitis. The dental and oral services may not be integral to other specific medically necessary, covered services, but rather the dental and oral services may serve to influence clinical outcomes directly. The studies compare the impact of the treatment for the periodontitis to the impact of pharmacological interventions.

We recognized that evidence submitted by interested parties demonstrates that an individual with both a diagnosis of diabetes and a diagnosis of periodontitis who in turn receives periodontal treatment services may experience improvements in markers for HbA1c, which is a key target outcome for the patient population with diabetes. However, the interaction between these diagnoses and the potential improvements due to periodontal treatment services does not appear to align with the framework we have established to pay for dental services inextricably linked to covered services; in our framework, the delivery of certain dental services are integral to the successful completion of or outcomes related to the covered services.

We stated that under § 411.15(i)(3), we have specified that payment can be made for certain dental services that are inextricably linked to other services when the specific covered services with which the dental services are inextricably linked are identified. The studies that have been provided to CMS through submissions have not identified any specific covered services for the treatment of diabetes to which dental services are inextricably linked. Rather, the studies indicate that the primary treatment of periodontal disease in patients with diabetes generally leads to better outcomes in the management of the patients' diabetes. While the research makes the case that the dental services are medically necessary for patients with diabetes, medical necessity alone does not permit payment for dental services given the broad statutory prohibition under section 1862(a)(12) on payment for services ''in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth.'' In the case of patients with diabetes, the research does not appear to show that certain dental services are inextricably linked with certain other covered services for the treatment of diabetes, in accordance with our regulation at § 411.15(i)(3) such that the statutory prohibition under section 1862(a)(12) does not apply.

We noted that some of the examples of medical services for diabetes treatment provided by submitters are general in nature and not specific to patients with diabetes who may also have periodontal disease, including CPT codes 99202–99215: Evaluation and Management (E/M) Services that broadly describe outpatient office visits for the diagnosis and medical management of practically any illness, disease, or condition.

Additionally, we noted that submitters providing evidence for our consideration suggested that the services described by codes for diabetes self-management training (for example, G0108: *Diabetes Self-Management Training,* and G0109: *Group Diabetes Self-Management Training*) are services with which dental services may be inextricably linked. However, we were not persuaded by this evidence and do not believe that dental services would be inextricably linked to improved outcomes for services for diabetes self-management training.

In the CY 2025 PFS proposed rule (89 FR 61758 through 61760) we sought comment from the public regarding specific covered services for management of patients with diabetes with which dental services may be inextricably linked. We stated that we did not propose to amend § 411.15(i)(3)(i) since we had not identified additional dental services that are inextricably linked to certain services in the treatment of diabetes. However, we noted that we remain open to considering any such services identified by public commenters, and, if sufficient evidence is presented, we may consider adding such services to our regulations in this final rule.

In the context of payment for dental services for an individual with diabetes, we sought information from the public regarding what the coordination between a medical and dental professional would entail in the scenario where an individual with a diagnosis of diabetes presents with suspected periodontitis. In the CY 2023 PFS final rule, we explained that we would make payment when a doctor of dental medicine or dental surgery (referred to as a dentist) furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician, or non-physician practitioner, treating the primary medical illness. However, if there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) in regard to the primary medical service and the dentist in regard to the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3). Without both integration between the Medicare enrolled medical and dental professional, and the inextricable link between the dental and covered services, Medicare payment for dental services would be prohibited under section 1862(a)(12) because the services are in connection with the care,

treatment, filling, removal, or replacement of teeth or structures directly supporting teeth; though they may be covered by types of supplemental health or dental coverage (87 FR 69687 through 69688).

We asked, in a situation where a medical professional believes that an individual with a diagnosis of diabetes may also have a diagnosis of periodontitis, how are recommendations conveyed between the medical and dental professionals? What coordination, if any, occurs between the medical and dental professionals? We noted that we expect that inextricably linked services related to the treatment of periodontitis in an individual with diabetes would require significant communication between the medical and dental professionals.

We mentioned that we have stated previously that an inextricable linkage may exist between dental services and covered services when the standard of care for the medical service is such that the practitioner would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially compromised, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment (87 FR 69669). While evidence supports that individuals with diabetes and periodontitis who receive periodontal treatment experience improvements in their HbA1c markers, dental services do not appear to serve as a precondition to overall treatment for the diabetes. We sought information from the public on how oral treatment services may be a clinical prerequisite in the treatment protocol for the care of individuals with diabetes.

We noted that there does not appear to be a clear or singular definitional framework for categorizing the state of diabetes, such as ''controlled'' or ''uncontrolled'' diabetes. Research submitted by the public discusses improvements in glycemic control as evidence by HbA1c markers, but does not delineate the characteristics of a patient that would require direct clinical intervention (pharmacological, behavioral, usage of DME such as insulin pumps, etc.) versus a patient that would not require interventions given that their disease state is not within a concerning range requiring direct medical treatment.

Additionally, we noted that in the current literature, there are two types of severity measures that can help categorizing the state of diabetes: the severity of diabetes itself and the severity of periodontal disease among individuals with diabetes. With respect to the severity of diabetes, the American Diabetes Association recommends that most adults with diabetes aim for a HbA1c level below 7.0% (<53 mmol/mol), along with other recommended targets such as blood pressure below 130/80 mmHg and LDL cholesterol below 100 mg/dL.[236] In the current literature, uncontrolled hyperglycemia is typically defined as an HbA1c level above 8.0% (>64 mmol/mol), according to guidelines from various medical organizations, including the ADA, American College of Physicians, Association of Clinical Endocrinologists, and American College of Endocrinology.[237] [238] [239] [240] Based on the literature, this threshold serves as a ''take action'' point in managing diabetes and has been used in previous studies to indicate poor glycemic control. Achieving and maintaining target HbA1c levels is essential for individuals with diabetes (as well as the general population) and is a key goal of treatment. Moreover, we noted that for the purposes of Quality Payment Program (QPP) measures, CMS has issued measures for diabetes (for example, Quality ID #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)).[241] The measure is described as ''Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0% during the measurement period.'' Furthermore, measures of HbA1c may fluctuate over time; therefore, a strict threshold could lead to incentives for multiple rounds of testing to aim for the levels established. In general, guidelines exist, but standards vary for defining diabetes states based on multiple severity measures.

In addition, the severity of periodontal disease is not uniformly defined. ICD–10 codes, such as K05.2 for Aggressive Periodontitis and K05.3 for Chronic Periodontitis may be utilized to describe more severe instances of periodontitis (and in this instance when such diagnosis codes are also partnered with diagnoses related to diabetes for a particular individual). Another approach involves using the Armitage criteria for periodontal diagnosis.[242] [243] Severity assessment can be based on the clinical attachment level (CAL), with CAL between 1 mm and 2 mm classified as slight, 3 mm and 4 mm as moderate, and ≥5 mm as severe.[244] Again, some standards exist relative to the staging of periodontitis, but such criteria vary. Additionally, we believe that the current practice of medicine would allow for variation in clinical attributes as well as judgment and discernment by the referring practitioner regarding the clinical status of the individual when determining the need for consultation with other practitioner types, including the dentist. We sought comment on whether clinical standards exist that describe and define the disease state of diabetes that would serve to inform the selection of treatment modalities, including potential referrals to dental professionals with respect to concerns related to oral health. We also sought comment from the public regarding the ways that CMS could ensure that practitioners do not decrease the quality of diabetes treatment in an effort to maintain a beneficiary's potential access to Medicare payment for dental services.

We explained that the evidence supplied by submitters also described periodontitis but without a clear and consistent definitional structure. The 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions resulted in a new classification of periodontitis characterized by a multidimensional staging and grading system. The staging considers the aspects of severity, complexity, extent,

[236] American Diabetes Association. ''Standards of medical care in diabetes—2011.'' Diabetes care vol. 34 Suppl 1,Suppl 1 (2011): S11–61. *doi:10.2337/dc11-S011.*

[237] Liu, Longjian et al. ''Burden of Uncontrolled Hyperglycemia and Its Association with Patients Characteristics and Socioeconomic Status in Philadelphia, USA.'' Health equity vol. 4,1 525–532. 30 Dec. 2020, *doi:10.1089/heq.2020.0076.*

[238] Qaseem, Amir et al. ''Glycemic control and type 2 diabetes mellitus: the optimal hemoglobin A1c targets. A guidance statement from the American College of Physicians.'' Annals of internal medicine vol. 147,6 (2007): 417–22. *doi:10.7326/0003-4819-147-6-200709180-00012.*

[239] Cortez-Espinosa, Nancy et al. ''Abnormal expression and function of Dectin-1 receptor in type 2 diabetes mellitus patients with poor glycemic control (HbA1c>8%).'' Metabolism: clinical and experimental vol. 61,11 (2012): 1538–46. *doi:10.1016/j.metabol.2012.03.020.*

[240] Hu, Huanhuan et al. ''Hba1c, Blood Pressure, and Lipid Control in People with Diabetes: Japan Epidemiology Collaboration on Occupational Health Study.'' PloS one vol. 11,7 e0159071. 20 Jul. 2016, *doi:10.1371/journal.pone.0159071.*

[241] *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_001_MIPSCQM.pdf.*

[242] Armitage, G C. ''Development of a classification system for periodontal diseases and conditions.'' Annals of periodontology vol. 4,1 (1999): 1–6. *doi:10.1902/annals.1999.4.1.1.*

[243] Caton, Jack G et al. ''A new classification scheme for periodontal and peri-implant diseases and conditions—Introduction and key changes from the 1999 classification.'' Journal of clinical periodontology vol. 45 Suppl 20 (2018): S1–S8. *doi:10.1111/jcpe.12935.*

[244] Pinho, M Morado et al. ''Periodontitis and atherosclerosis: an observational study.'' Journal of periodontal research vol. 48,4 (2013): 452–7. *doi:10.1111/jre.12026.*

and distribution while the grading contemplates primary criteria such as progression and grade modifiers, including risk factors such as smoking and diabetes.[245]

For the purposes of our consideration of medical services for the treatment of diabetes for individuals with diabetes who have periodontitis, we sought comment from the public on clinical criteria that will determine eligibility for the effectiveness of periodontal treatment as described in the Cochrane review and other studies. We do not believe that a condition such as gingivitis or early stages of periodontitis will require oral treatment that, in turn, will influence the outcomes for an individual with diabetes. However, we sought information to address the following questions. At what stages and grading will the periodontitis be considered advanced and/or requiring dental and oral treatment intervention? What types of practitioners are able to make determinations regarding the staging of periodontitis? We also sought comment on patient eligibility. What determines patient eligibility for treatment for advanced periodontitis? Are there other criteria for consideration?

Additionally, we sought comment on the duration of potential periodontal treatment. How is the length of treatment determined? If a patient's clinical status improves with respect to the periodontal disease, what factors determine when periodontal treatment comes to an end? What does maintenance treatment entail? What services are provided in the treatment of advanced periodontal disease? What is the service definition? Are services bundled? If yes, what is included in the bundle? When are the services provided and over what period? Is it provided over a calendar month period? A single day? Multiple days? Are services timed? Who provides the services? What specific terminology is involved? Are these services ever provided under supervision? Or ''incident to'' by other clinical staff?

We also sought information on how services for advanced periodontal disease are provided. Where and how are services for treatment of advanced periodontal disease provided? Are there any special rules, such as obtaining advance consent or performance of an initiating visit?

We also sought information regarding coding and billing of periodontal services. What coding is utilized for the treatment services for advanced periodontal disease? What claims format is employed for the submission of claims with related oral and dental services (for example, 837D and/or 837P)?

Additionally, we sought comment from the public regarding the risk of recurrence of periodontal disease for this patient population. What is the level of risk for re-development of advanced periodontitis and likelihood of recurrence?

We also sought information regarding the role of caries in management of diabetes. What is the prevalence of caries in this patient population? What is the impact of caries on management of diabetes?

We also sought information regarding the disease state of the diabetes itself and its interaction with dental services. Does evidence exist to support that certain characteristics related to diabetes management (for example, maintenance of HbA1c) are more closely tied to certain oral interventions' ability to yield clinical improvements?

We reiterated that section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Thus, payment is permitted only where the dental services are inextricably linked to covered medical services. We believe that general maintenance and management of oral disease processes clearly falls within the statutory exclusion, and therefore, Medicare would not permit payment for routine dental and oral services.

We noted that many submitters stated that good dental and oral health benefits a patient's overall health in general. Several commenters responding to the CY 2023 PFS proposed rule also expressed that good oral hygiene, along with routine dental services, contributes to better outcomes for patients. We recognized in the CY 2023 PFS final rule in response to those comments that there is a great deal of evidence suggesting that dental health is generally an important component of overall health; however, we are interested in comments on whether certain dental services are considered so integral to the primary covered services that the necessary dental interventions are inextricably linked to, and substantially related and integral to clinical success of, the primary covered services such that they are not subject to the statutory preclusion on Medicare payment for dental services under section 1862(a)(12) of the Act (88 FR 79033).

In summary, we sought comment on whether certain dental services are inextricably linked to certain other covered services for diabetes, supported by clinical evidence as outlined in section II.J.1.c. of this final rule. We also sought comment specifically on whether dental services such as prophylaxis are a standard of care in the management of diabetes. We stated that we are committed to continuing to explore the potential inextricable relationship between dental services and covered medical services utilized in treatment for individuals with diabetes. We thanked submitters for the information they provided through the public submissions process and indicated that may consider revisions to the clinical examples codified in our regulations at § 411.15(i)(3)(i) based upon additional data and information received in response to the proposed rule.

a. Consideration of Dental Services That May Be Inextricably Linked to Covered Services for the Treatment of Diabetes

In section II.J.1.b. of this final rule, we discuss that we have partnered with AHRQ tohelp us consider the relationship between dental services and other specific covered services. In the CY 2025 PFS proposed rule (89 FR 61752), we provided an overview of the information we received from the public through the submission process.

We acknowledge the importance of dental health to overall well-being of patients with diabetes. We believe that further research is necessary to find specific evidence supporting specific medical services for which dental services are inextricably linked to their clinical success. To gain further understanding of any potential relationship between dental services and specific covered diabetes medical services, we partnered with researchers at AHRQ to review available clinical evidence regarding the relationship between dental services and covered diabetes medical services.

AHRQ created a rapid response report, which was not available at the time of the proposed rule's publication, which summarized recent evidence, aiming to inform CMS policy development related to the possible linkage between dental services and treatment modalities and services for diabetes patients. The AHRQ report reviewed the available clinical evidence on the efficacy of dental services in improving health outcomes for patients with diabetes mellitus (type 1 and 2). For more detailed information about the search strategies and findings, please

[245] Tables from Tonetti, Greenwell, Kornman. J Periodontol 2018;89 (Suppl 1): S159–S172. *https://www.perio.org/wp-content/uploads/2019/08/Staging-and-Grading-Periodontitis.pdf.*

refer to the AHRQ rapid response report available at *https://effectivehealthcare.ahrq.gov/products/treatment-outcomes-diabetes/rapid-research*.

According to the response report, diabetes mellitus (DM) characterized by high blood sugar levels (HbA1c >6.5 percent) affects approximately 37 million adults in the United States [246] and 500 million globally.[247] [248] Diabetes is a chronic metabolic disease that can lead to severe health complications, including lower limb amputations, blindness, chronic kidney disease, and cardiovascular diseases. As stated in the report, Type II DM is a highly prevalent metabolic disorder characterized by the loss of ability to adequately control blood glucose levels due to insulin resistance in body tissues and typically emerges in adulthood. On the other hand, Type I DM (formerly commonly known as juvenile diabetes), where an autoimmune response results in the destruction of insulin-secreting β cells in the pancreas, requires life-long insulin therapy.

Notably, chronic oral diseases (COD) including dental caries, gingival infection, periodontal disease, and tooth loss are significantly more common and more severe in diabetic patients.[249] As stated in the rapid response report, emerging evidence shows a complex relationship between diabetes and oral health (see Figure 1 in the AHRQ report). Increasing COD severity results in greater systemic inflammation, reducing glycemic control [250] and worsening diabetes outcomes. Conversely, poorly controlled diabetes can lead to increased severity of oral diseases such as periodontitis,[251] creating a cycle that negatively impacts overall health. The report also highlights a growing body of data indicating that oral inflammation affects general diseases.[252] According to the findings, diabetes patients with severe COD can have a significantly increased risk of all-cause mortality, underscoring the impact of oral health on cardiovascular, immune, and renal function.

The relationship between oral health treatment and diabetes management has been investigated in several studies; however, the exact correlation between oral health management and diabetes (both Type 1 and Type 2) has not been comprehensively addressed. Thus, the rapid response report conducted literature searches using large databases. As presented in the PRISMA diagram, the search identified 601 studies, of which 27 met the inclusion and exclusion criteria for the current review. Of these 27 articles, 16 were randomized clinical trials or non-randomized controlled observational studies, 6 were systematic reviews or meta-analyses, 3 were reviews of reviews, and 2 were practice guidelines.

The report found that there is consistent evidence that non-surgical periodontal therapy (NSPT) can improve glycemic control in diabetic patients, as measured by HbA1c. In the report, a subgroup analysis that divided patients into different baseline HbA1c groups suggested that dental care treatments may lead to greater improvement in glycemic control for patients with higher baseline HbA1c levels. Additionally, three primary studies show a statistically significant reduction in inflammatory markers, such as C-reactive protein and TNF-alpha, with the use of NSPT. Based on the report, guidelines reflected the available literature, demonstrating the effectiveness of NSPT in improving glycemic control in people with diabetes. There is also concordance in these guidelines regarding the need for an integrated care approach that includes dental health as part of comprehensive diabetes management.

The report also provided a few equivocal findings. The report found insufficient evidence to determine whether periodontal treatment sustains glycemic improvement or reduces inflammatory status for periods longer than 6 months. Outcomes related to mortality, hospitalizations, cardiovascular events, and quality of life (QoL) have been variable across studies. Additionally, a significant reduction in HbA1c levels in patients with type 2 DM after dental prophylaxis alone has not been consistently demonstrated. Furthermore, no significant changes in non-diabetes-specific metrics, such as inflammation and lipid markers, have been observed following non-periodontal dental services.

The report highlights three major limitations in the evidence: a lack of comprehensive reporting on important factors such as insulin resistance and additional inflammatory mediators beyond C-reactive protein (CRP); a limited follow-up duration of most interventional studies, typically capped at six months; and the generalizability of the current evidence to the U.S. population is unknown.

The findings of the AHRQ rapid response reports underscore that this area warrants further investigation by researchers and industry to explore potential connections between dental services and improved outcomes for individuals with diabetes. Specifically, future research can focus on identifying which subgroups of diabetic patients, and with what degree of periodontal disease, are most likely to experience significant improvements in glycemic control through concurrent treatment of their periodontal disease. Additionally, research is needed to determine whether recurring periodontal treatments, or a combination of periodontal and non-periodontal dental services, are necessary to sustain glycemic improvements and/or reductions in inflammatory status for periods longer than six months. Such studies could provide valuable insights for policymakers when assessing whether there is an inextricable link between certain dental and covered services for patients with diabetes.

We received 23 public comments responding to the request for information on whether certain dental services are inextricably linked to certain other covered services for diabetes. The following is a summary of the comments we received and our responses.

Comment: Commenters provided information and references supporting oral and dental treatment of periodontal disease among individuals with diabetes to improve markers related to management of the diabetes (mainly,

[246] Cho, N.H.; Shaw, J.E.; Karuranga, S.; Huang, Y.; Da Rocha Fernandes, J.D.; Ohlrogge, A.W.; Malanda, B. IDF Diabetes Atlas: Global Estimates of Diabetes Prevalence for 2017 and Projections for 2045. Diabetes Research and Clinical Practice 2018, 138, 271–281. *https://doi.org/10.1016/j.diabres.2018.02.023*.

[247] Tsalamandris, S.; Antonopoulos, A.S.; Oikonomou, E.; Papamikroulis, G.-A.; Vogiatzi, G.; Papaioannou, S.; Deftereos, S.; Tousoulis, D. The Role of Inflammation in Diabetes: Current Concepts and Future Perspectives. Eur Cardiol 2019, 14 (1), 50–59. *https://doi.org/10.15420/ecr.2018.33.1*.

[248] Heydari, M.-H.; Sharifi, F.; Sobhaninejad, S.; Sharifi, A.; Alizadeh, L.; Darmiani, S.; Bijari, S.; Parvaie, P.; Bakhshandeh, S.; Shoaee, S.; Khoshnevisan, M.-H. The Association between Dental Caries, Periodontal Diseases, and Tooth Loss with Diabetes Mellitus among the Elderly Population. J Diabetes Metab Disord 2024, 23(1), 1371–1380. *https://doi.org/10.1007/s40200-024-01434-2*.

[249] Triebl, Z.; Bencze, B.; Bányai, D.; Rózsa, N.; Hermann, P.; Végh, D. Poor Glycemic Control Impairs Oral Health in Children with Type 1 Diabetes Mellitus—a Systematic Review and Meta-Analysis. BMC Oral Health 2024, 24(1), 748.

[250] Tsalamandris, S.; Antonopoulos, A.S.; Oikonomou, E.; Papamikroulis, G.-A.; Vogiatzi, G.; Papaioannou, S.; Deftereos, S.; Tousoulis, D. The Role of Inflammation in Diabetes: Current Concepts and Future Perspectives. Eur Cardiol 2019, 14(1), 50–59. *https://doi.org/10.15420/ecr.2018.33.1*.

[251] Löe, H. Periodontal Disease: The Sixth Complication of Diabetes Mellitus. Diabetes Care 1993, 16(1), 329–334. *https://doi.org/10.2337/diacare.16.1.329*.

[252] National Institutes of Health. Oral Health Care in America: Advances and Challenges. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Dental and Craniofacial Research.; 2021.

glycemic control). Some commenters urged us to continue to review findings, work within our authority and with stakeholders to support policies for individuals with diabetes to receive appropriate dental care while others recommended that we continue a judicious approach in consideration of expanding the policy for Medicare payment for dental services. One commenter stated that an act of Congress is required to further expand coverage to manage life-long chronic conditions because there are no specific medical services that can be used to qualify payment for dental services under the policy's framework. Commenters expressed concern about the broad application of the policy, and some suggested that CMS assess the similar standards of care found within the Veterans Health Administration and within Medicare Advantage.

Response: We thank commenters for their thoughtful feedback on the requests for information and note that we will take these comments into consideration for the future. The information provided to CMS through public comment did not identify any specific covered services for the treatment of diabetes to which dental services are inextricably linked. Rather, the information indicates that the primary treatment of periodontal disease in patients with diabetes generally leads to better outcomes in the management of the patients' diabetes, which is consistent with information provided through the public submission process. We continue to believe that while the research makes the case that the dental services are medically necessary for patients with diabetes, medical necessity alone does not permit payment for dental services given the broad statutory prohibition under section 1862(a)(12) of payment for services ''in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth.''

While the AHRQ rapid response report and the public comments we received provided more information regarding the standard of care and severity levels of diabetes along with severity levels of periodontitis and certain dental services that may improve clinical outcomes, this information lacks evidence that supports an inextricable link between dental services and certain other covered services for the treatment of diabetes. We will continue to engage with interested parties on this topic and are interested in information that could assist us in identifying specific covered medical services that the dental services are inextricably linked to. We believe that the list of services identified by submitters provided above in section II.J.3 of this final rule may be a good starting point in considering how to apply the inextricably linked standard to chronic disease management. Are there codes that describe specific services that align to patients with these conditions or needs (for example, an uncontrolled diabetic that has periodontitis)? Are there physicians' services that dental services would be inextricably linked to for beneficiaries with these needs?

4. Request for Comment on Dental Services Integral to Specific Covered Services To Treat Systemic Autoimmune Disease Requiring Immunosuppressive Therapies

We have received information from interested parties, including submitters providing evidence through the public submissions process as well as commenters on prior proposed rules suggesting that certain dental services are inextricably linked to immunosuppressive therapies for individuals with autoimmune disorders.

According to the NIH's National Institute of Environmental Health Sciences, a healthy immune system is able to defend the body against disease and infection. However, if the immune system malfunctions, it may mistakenly attack healthy cells, tissues, and organs. This scenario is called autoimmune disease, and these attacks can affect any part of the body, weaken bodily function, and in some cases become life-threatening.[253] There are over 100 autoimmune diseases, including Type 1 diabetes, multiple sclerosis, lupus, rheumatoid arthritis, and inflammatory bowel disease. There are also other autoimmune diseases that are rare and difficult to diagnose. In some cases, patients may suffer for years before receiving a proper diagnosis, and most of these diseases have no cure. Additionally, some autoimmune diseases require lifelong treatment for system management.[254]

Autoimmune diseases are continuously affecting more people. Estimates indicate that as many as 50 million people in the U.S. have an autoimmune disease, making it the third most prevalent disease category, surpassed only by cancer and cardiac disease. Generally speaking, a person's genes, in combination with infections and other environmental exposures, likely play a significant role in disease development, though in some instances, the pathology may be unknown. Additionally, nearly 80 percent of people with a chronic autoimmune condition are women.[255] Symptoms of autoimmune diseases can include: fatigue, pain, dermatologic manifestations, weight loss or gain, insomnia, fever, and a myriad of other symptoms.[256]

Many treatment modalities are employed in the management of autoimmune diseases. Treatments could include use of oral medications, including steroids, anti-inflammatory medications, as well as infusion immunotherapy. Some autoimmune conditions may present in a localized fashion, such as Sjogren's, and many of the independent organ inflammations require immunosuppressive therapies, and may progress to a more systemic involvement. Conversely, some systemic autoimmune diseases, like sarcoidosis, may not require immunosuppression in mild cases.

Submissions through the public submissions process urged us to provide that payment can be made for dental services for individuals with autoimmune diseases receiving immunosuppressive therapy. In submissions, several interested parties have asserted that immunosuppressive therapies utilized in the treatment of autoimmune disease have similar immunosuppressive effects as those of toxic chemotherapy utilized in the treatment of cancer and that these treatments are analogous to the clinical examples finalized in CY 2024 PFS rulemaking for dental services inextricably linked to covered medical services in the treatment of cancer.

Submitters stated that oral and dental treatment is also often integral to the successful care and management of beneficiaries with autoimmune diseases who are initiating or undergoing immunosuppressive or immunomodulator therapy because the absence of medically necessary oral and dental treatment can pose serious complications to those beneficiaries and the covered medical services they receive. Submitters state that, for example, dental infections can spread quickly when host immunity is compromised by immunosuppressing or immunomodulating drugs utilized in treatment. As such, submitters note that the American College of Physicians has described that the implications of dental disease in patients who are undergoing immunosuppressive therapy extend

[253] *https://www.niehs.nih.gov/health/topics/conditions/autoimmune.*

[254] Ibid.

[255] Ibid.

[256] *https://www.womenshealth.gov/a-z-topics/autoimmune-diseases.*

beyond their oral disease, with potentially life-threatening complications if the dental problems are not treated. For these reasons, submitters state that the covered services upon which immunocompromised patients depend (for example, immunosuppressive therapy) should not proceed until a dental or oral exam is performed to address the oral complications and/or clear the patient of an oral or dental infection.

Submitters provided information regarding specific covered services that they believe could be associated with treatments for immunosuppressive therapy for the treatment of autoimmune disease and that may increase infection risk, such as:

- CPT codes 99212–99215: Evaluation and Management (E/M) Services.
- CPT codes 96365–96368: Infusion services.

Submitters also provided coding information related to drug therapies, such as CPT codes for immunosuppressant drugs, including:

- J0129: Abatacept (Orencia) for Rheumatoid Arthritis.
- J0135: Adalimumad (Humira) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis.
- J0490: Belimumab (Benlysta) for systemic lupus erythematosus (SLE), Lupus Nephritis, and Sjögren's.
- J0491: Anifrolumab-fnia (Saphnelo) for systemic lupus erythematosus (SLE).
- J1303: Ravulizumab-cwvz (Ultomiris) for Generalized Myasthenia Gravis.
- J1438: Etanercept (Enbrel) for Rheumatoid Arthritis, Ankylosing Spondylitis.
- J1595: Glatiramer (Copaxone) for Multiple Sclerosis.
- J1602: Golimumab (Simponi) for Rheumatoid Arthritis, UC, Ankylosing Spondylitis.
- J1745: Infliximab (Remicade) for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis.
- J2250: Upadacitinib (Rinvoq) for Rheumatoid Arthritis, Ulcerative Colitis, Crohn's.
- J2323: Natalizumab (Tysabri) for Multiple Sclerosis.
- J2350: Ocrelizumab (Ocrevus) for Multiple Sclerosis.
- J3262: Tocilizumab (Actemra) for Scleroderma-associated lung fibrosis.
- J3357: Ustekinumab (Stelara) for Crohn's, Ulcerative Colitis, Psoriatic Arthritis.
- J3380: Vedolizumab (Entyvio) for Crohn's, Ulcerative Colitis.
- J3590: Secukinumab (Cosentyx) for Plaque Psoriasis.
- J7500: Azathioprine (Imuran) for Lupus, Crohn's, Sjögren's.
- J7517: Mycophenolate (Cellcept) for Lupus, Sjögren's.
- J9070: Cyclophosphamide (Cytoxan) for Sjögren's, Vasculitis.
- J9250: Methotrexate for Sjögren's, Rheumatoid Arthritis (unresponsive to other treatment).
- J9302: Ofatumumab (Kesimpta) for Multiple Sclerosis.
- J9312: Rituximab (Rituxan) for Rheumatoid Arthritis, Sjögren's.
- J9332: Efgartigimod (Vyvgart) for Myasthenia Gravis.

Submitters also provided coding information for potential medical services for medical treatment for pulmonary diseases when aspiration of dental pathogens risk or cause the initiation and/or recurrence of complications, such as:

- CPT codes 99212–99215: Evaluation and Management (E/M) Services.
- CPT code 99291: Critical Care Services.
- DRG code 177: Hospitalization for respiratory infections and inflammation.
- DRG code 190: COPD with complications.

Submitters also provided coding regarding medical treatment for dentally sourced dissecting maxillofacial space infections:

- CPT 41000: Intraoral incision and drainage of abscess.
- CPT 87181: Antibiotic susceptibility study.
- CPT 96365: Infusion of antibiotic.
- CPT codes 99281–99285: Emergency department services.
- CPT codes 99291–99292: Critical care services.
- DRG code 135: Sinus procedures with CC/MCC.
- DRG code 141: Major head and neck procedures with CC.
- DRG code 872: Hospitalization for septicemia or severe sepsis.

Submitters providing information through the public submissions process stated that if dental or oral infections are left undetected or untreated in the population of individuals undergoing immunosuppressive therapy for autoimmune disease, serious complications may occur and negatively impact the course and outcome of the covered medical procedures, which submitters state is analogous to previously finalized policies for dental services inextricably linked to covered cancer treatment for the patient. Several submitters pointed out that we stated in the CY 2024 PFS final rule that proceeding without a dental or oral exam of the mouth prior to chemotherapy could lead to systemic infection or sepsis, among other complications, and that similar outcomes can follow for those receiving immunosuppressive therapy to treat autoimmune diseases.

The submitters noted that in the CY 2024 PFS final rule, we described that AHRQ identified evidence to support that dental evaluation/treatment prior to cancer treatment led to decreased incidence and/or less severity of serious oral infections and complications like oral mucositis and encouraged CMS to explore this connection to confirm that dental evaluations and treatment prior to immunosuppressive therapy would lead to decreased incidence of serious oral infections in a similar fashion. The submitters also stated that they believe it is critical that beneficiaries with an autoimmune disease that requires immunosuppressive therapy have access to necessary dental services, as proper dental care for this population can reduce the incidence of serious infection and improve overall patient outcomes for the covered service.

In the CY 2025 PFS proposed rule (89 FR 61762), we stated that we appreciate the evidence and information provided by submitters and agree that we should continue to research whether there is a connection between dental and oral evaluations and treatment prior to immunosuppressive therapy and outcomes for said therapies, including the potential decreased incidence of serious oral infections.

However, we sought comment on whether the level of immunosuppression utilized in the treatment of autoimmune diseases is analogous to the immunosuppression levels employed in the treatment of cancer. We believe that the level of immunosuppression for systemic autoimmune disease has different characteristics versus therapies utilized in chemotherapy for the treatment of cancer. For example, the usage of monoclonal antibodies in the treatment of autoimmune disease may not render the same level of immunosuppression and subsequent susceptibility to infection as chemotherapy used in the treatment of cancer.

We also sought information on the connection between immunosuppressive therapy in the treatment of autoimmune disease and the likelihood of systemic infection and sepsis. Specifically, we sought information regarding the likelihood of dental and oral sources as the locus of the seeding of infection in this patient population. Additionally, we sought information regarding standards of care or clinical guidelines that recommend that a dental infection be addressed

before proceeding with the immunosuppressive treatment or the administration of drugs or whether oral antibiotics would be prescribed to resolve the infection and that the therapy would advance without direct dental or oral services to address the infection.

We also sought information regarding whether there is differential impact between drugs that are administered in an office setting or similar versus those medications that are taken in an oral fashion.

We thanked submitters for the information they provided through the public submissions process. We explained that we believe that additional information is necessary to consider whether there is an inextricable link between dental services and covered services to treat systemic autoimmune disease requiring immunosuppressive therapies and sought comment from the public. We indicated that we remain open to considering any such services identified by public commenters, and if sufficient evidence is presented, we may consider adding such services to § 411.15(i)(3) in this final rule.

a. Consideration of Dental Services That May Be Inextricably Linked to Covered Services for the Treatment of Systemic Autoimmune Disease Requiring Immunosuppressive Therapies

In section II.J.1.b. of this final rule, we discuss that we have partnered with AHRQ to help us consider the relationship between dental services and other specific covered services. In the CY 2025 PFS proposed rule (89 FR 61752), we provided an overview of the information we received from the public through the submission process.

We acknowledge the importance of dental health to overall well-being of patients with autoimmune disease. We believe that further research is necessary to find specific evidence supporting specific medical services for which dental services are inextricably linked to their clinical success. To gain further understanding of any potential relationship between dental services and specific covered autoimmune disease medical services, we again partnered with researchers at AHRQ to review available clinical evidence regarding the relationship between dental services and covered autoimmune disease medical services.

AHRQ created a rapid response report, which was not available at the time of the proposed rule's publication, which summarized recent evidence, aiming to inform CMS policy development related to the possible linkage between dental services and treatment modalities and services for patients with autoimmune conditions. The AHRQ report reviewed the available clinical evidence on the efficacy of dental services in improving health outcomes for patients with autoimmune (AI) diseases treated with biologics and other immunosuppressants. For more detailed information about the search strategies and findings, please refer to the AHRQ rapid response report available at *https://effectivehealthcare.ahrq.gov/products/autoimmune-disease/rapid-research*.

As stated in the AHRQ rapid response report, AI, such as systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and limited cutaneous systemic sclerosis (lcSSc), affect over 50 million people in the United States,[257] with oral symptoms often serving as early indicators of AI disease.[258] Patients with autoimmune conditions frequently experience poor oral health (for example, increased plaque index, gum disease, and edentulism) compared to healthy individuals.[259] [260] [261] [262] Additionally, as chronic autoimmune and inflammatory diseases are correlated with an elevated risk of periodontitis, patients with both periodontitis and lcSSc exhibited greater arterial stiffness and disease activity compared to healthy individuals with periodontitis,[263] a gum disease that damages local tissue and can promote systemic inflammation.[264] The rapid response underscores a bidirectional relationship for autoimmune diseases, including SLE, where the dysregulated immune system exacerbates oral inflammation and dysbiosis of the oral microbiota. In turn, oral infections contribute to systemic inflammation and the progression of SLE.[265] For more details on the causal model depicting the relationship between rheumatoid arthritis and oral disease, please refer to Figure 1 in the AHRQ report.

Given a bidirectional relationship between oral health and autoimmune disease, the Centers for Disease Control and Prevention (CDC) emphasizes the importance of daily oral hygiene and professional dental care, which reduce rates of tooth decay and oral inflammation.[266] Maintaining good oral health and reducing overall plaque may be especially beneficial to AI patients with dysregulated inflammatory responses.

According to the report, there are various therapies available for treating RA and other autoimmune diseases. One key group of treatments, disease-modifying anti-rheumatic drugs (DMARDs), has been used effectively for multiple autoimmune conditions. DMARDs are divided into two main types: conventional small molecule drugs like methotrexate, and biologics, which are more targeted therapies. Both types work by suppressing the immune system but through different mechanisms. Conventional DMARDs inhibit inflammatory pathways broadly, while biologics are more selective, targeting specific immune components such as cytokines or B-cells.

As stated in the AHRQ rapid response report, an electronic database search conducted in Medline and Embase yielded 127 records, of which 38 articles were assessed for eligibility. Of the 38 full-text articles retrieved and reviewed for eligibility, 25 articles were excluded. In total, 13 unique publications—

[257] About Autoimmunity. Autoimmune Association. *https://autoimmune.org/resource-center/about-autoimmunity/*.

[258] Mays, J.W.; Sarmadi, M.; Moutsopoulos, N.M. Oral Manifestations of Systemic Autoimmune and Inflammatory Diseases: Diagnosis and Clinical Management. J Evid Based Dent Pract 2012, 12 (3 Suppl), 265–282. *https://doi.org/10.1016/S1532-3382(12)70051-9*.

[259] Julkunen, A.; Heikkinen, A. M.; Söder, B.; Söder, P.-Ö.; Toppila-Salmi, S.; Meurman, J.H. Autoimmune Diseases and Oral Health: 30-Year Follow-Up of a Swedish Cohort. Dent J (Basel) 2017, 6 (1), 1. *https://doi.org/10.3390/dj6010001*.

[260] Rodríguez-Lozano, B.; González Febles, J.; Sánchez Alonso, F.; Garnier Rodríguez, J.L.; Dadlani, S.; Barrios, Y.; Sanz Alonso, M.; Díaz González, F. Is There an Association between Periodontitis and Levels of Anti-Citrullinated Peptides Antibodies in Rheumatoid Arthritis? Annals of the Rheumatic Diseases 2017, 76, 1115. *https://doi.org/10.1136/annrheumdis-2017-eular.4420*.

[261] de Pablo, P.; Dietrich, T.; McAlindon, T.E. Association of Periodontal Disease and Tooth Loss with Rheumatoid Arthritis in the US Population. J Rheumatol 2008, 35 (1), 70–76.

[262] Yang, B.; Pang, X.; Guan, J.; Liu, X.; Li, X.; Wang, Y.; Chen, Z.; Cheng, B. The Association of Periodontal Diseases and Sjogren's Syndrome: A Systematic Review and Meta-Analysis. Front Med (Lausanne) 2023, 9, 904638. *https://doi.org/10.3389/fmed.2022.904638*.

[263] Jud, P.; Wimmer, G.; Meinitzer, A.; Strohmaier, H.; Schwantzer, G.; Moazedi-Fürst, F.; Schweiger, L.; Brodmann, M.; Hafner, F.; Arefnia, B. Periodontal Disease and Its Association to Endothelial Dysfunction and Clinical Changes in Limited Systemic Sclerosis: A Case-Control Study. *J Periodontal Res* 2023, *58* (3), 621–633. *https://doi.org/10.1111/jre.13111*.

[264] Hajishengallis, G.; Chavakis, T. Local and Systemic Mechanisms Linking Periodontal Disease and Inflammatory Comorbidities. Nat Rev Immunol 2021, 21 (7), 426–440. *https://doi.org/10.1038/s41577-020-00488-6*.

[265] Sojod, B.; Pidorodeski Nagano, C.; Garcia Lopez, G.M.; Zalcberg, A.; Dridi, S. M.; Anagnostou, F. Systemic Lupus Erythematosus and Periodontal Disease: A Complex Clinical and Biological Interplay. J Clin Med 2021, 10 (9), 1957. *https://doi.org/10.3390/jcm10091957*.

[266] CDC. About Tooth Loss. Oral Health. *https://www.cdc.gov/oral-health/about/about-tooth-loss.html* (accessed 2024–08–29).

including 10 primary studies and 3 systematic reviews with meta-analyses—were included, extracted, and synthesized in this rapid response review.

The evidence reviewed on the impact of dental services on autoimmune disease outcomes primarily focused on patients with RA receiving non-surgical periodontal treatment (NSPT). There is limited evidence for other autoimmune diseases and no studies assessing the effect of other dental services. Additionally, all studies examined NSPT during autoimmune treatments, with no evidence available on the impact of NSPT prior to immunosuppressive therapy. The report found that the evidence generally supports the effectiveness of NSPT in reducing disease activity scores for RA and psoriasis, with follow-up times ranging from 6 weeks to 6 months. Additionally, there is moderate evidence that C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) levels decrease post-NSPT in patients with RA and SLE.

The report also provided a few equivocal findings. There is a lack of evidence regarding dental services other than NSPT. Findings on the reduction of the number of tender or swollen joints in RA patients after NSPT are inconsistent. Additionally, there is inconsistent evidence showing that NSPT had no significant effect on quality of life (QoL) measures for RA and psoriasis. The report found insufficient evidence of any effect of NSPT on disease activity in SLE. Also, there has been no reported impact of NSPT on adverse effects related to therapies for autoimmune conditions. A guidance article on RA published by the American Dental Association included recommendations for oral health management,[267] and of the 30 clinical practice guidelines on autoimmune diseases, only one—focused on Sjogren's syndrome—provided recommendations for dental care.

The report found that there are several limitations to the current body of evidence. Most studies had short follow-up periods (typically 3 months or less), preventing a full assessment of NSPT's long-term effects on autoimmune disease outcomes. The report also highlighted high variability across studies, making it difficult to draw definitive conclusions about the benefits of periodontal therapy. Additionally, most research focuses on rheumatoid arthritis, leaving gaps in understanding of other autoimmune conditions and dental services beyond non-surgical periodontal treatment. Finally, the generalizability to diverse populations, particularly in the U.S., remains uncertain.

Based on this report, several future research areas can be identified. More studies could focus on examining the impact of dental services on autoimmune conditions beyond RA. Additionally, researchers could evaluate whether improvements in disease activity scores are appropriate metrics for clinical improvement in RA, especially when these scores do not appear to correlate with improvements in clinical joint inflammation. Furthermore, it may be necessary to subdivide DMARDs, used to treat RA and other autoimmune diseases, into categories such as corticosteroids, biologics, and antimetabolites to better assess their specific impacts on treatment outcomes.

We received 22 public comments in response to the request for information on whether certain dental services are inextricably linked to certain other covered services for individuals with autoimmune disorders requiring immunosuppressive therapies. The following is a summary of the comments we received and our responses.

Comment: Commenters provided information on the value of dental services, both prior to and during, for beneficiaries undergoing immunosuppressive therapy due to their compromised immune system. Commenters stated that immunosuppressive therapies, used to treat conditions such as autoimmune diseases and certain cancers, often exacerbate oral health problems. Commenters stated that the level of immunosuppression for systemic autoimmune disease has different characteristics versus therapies used in chemotherapy in the treatment of cancer. Commenters stated the variability in therapies, severity levels of dental disease, and severity levels of compromised immunity but urged CMS to recognize that the risk of immunosuppression is real, as is the associated risk for infection-related complications. Some commenters urged us to continue to review findings, work within our authority and with stakeholders to support policies for individuals with autoimmune disease who are undergoing immunosuppressive therapy to receive appropriate dental care while others recommended that we continue a judicious approach in consideration of expanding the policy for Medicare payment for dental services. Some commenters suggested that CMS assess the similar standards of care for immunocompromised individuals found within the Veterans Health Administration.

Response: We thank commenters for their thoughtful feedback on the requests for information and note that we will take these comments into consideration for the future. We agree with commenters that people who are immunocompromised due to receiving immunosuppressive therapies may be prone to serious infection. We also believe that information provided by commenters further supports the idea that, broadly, dental health is an important component of good overall health. However, we reiterate that dental services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth are statutorily excluded from payment under Medicare Parts A and B unless a specific exception applies.

We agree with commenters that comparing autoimmune diseases and cancer as related to immunosuppression is difficult due to several factors such as the location of cancer and the modality of treatment. We also agree that in order to make a meaningful comparison, it would be necessary to identify the specific autoimmune disease and immunosuppressive therapy, or both.

While the AHRQ rapid response report and the public comments we received provided more information regarding certain autoimmune diseases and therapies and certain dental services that may improve clinical outcomes, this information lacks evidence to help us determine whether there is an inextricable link between dental services and covered services for treating autoimmune disease. Specifically, we believe that we need more clinical evidence to help us identify whether there are clinical scenarios where dental services are inextricably linked with specific clinical outcomes of a medical service for people with immunosuppression.

We will continue to engage with interested parties on this topic and are interested in information that could assist us in identifying specific clinical scenarios and the covered medical services that the dental services are inextricably linked to. Similarly, with what we stated for diabetes, we believe that the list of services identified by submitters provided above in section II.J.4 of this final rule may be a good starting point in considering how to apply the inextricably linked standard to chronic disease management. In

[267] De Rossi, S.S.; Ciarrocca, K.N. Autoimmune and Connective Tissue Diseases. In The ADA Practical Guide to Patients with Medical Conditions; John Wiley & Sons, Ltd, 2015; pp 201–229. *https://doi.org/10.1002/9781119121039.ch10.*

addition, we are interested in information on specific autoimmune diseases, level of severity, and the extent to which there is a linkage of an autoimmune disease to dental infection. Are there metrics available to indicate the depth and breadth of immunosuppression? If so, what could be the level of immunosuppression that creates susceptibility to infection? How do the different therapies impact immunosuppression levels and health outcomes? Are there specific immunosuppressive therapies that pose higher risks to patients? Does the duration of use for a particular immunosuppressant play a role and if so how? What are the clinical scenarios where an immunosuppressive must be stopped because they are placing the individual's health and continued treatment at risk?

5. Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services

In the CY 2024 PFS final rule (88 FR 79035 through 79039), we solicited comments on whether we should provide additional guidance that would aid in processing claims for dental services that are inextricably linked to a Medicare-covered medical service. Some commenters suggested the usage of a modifier on the dental claim format that would better identify when dental services are inextricably linked to specific covered medical services. As we continue to consider improvements to our payment policies and have gained experience around the provision of dental services inextricably linked to covered medical services, we have explored tools and resources that may help to facilitate the implementation and coordination of dental services that are currently covered under Medicare, including the possible usage of modifiers and diagnosis codes. The usage of modifiers on a dental claim would seek to identify the dental service as a service the billing practitioner identifies as inextricably linked to a specific covered medical service and for which there was an exchange of information, or integration, between the medical and dental professional (physician, including a dentist, or other non-physician practitioner) as specified in the CY 2023 PFS final rule (87 FR 69663 through 69688). We have explained that if there is no exchange of information, or integration, between the medical professional (physician or other non-physician practitioner) regarding the primary medical service and the practitioner furnishing the dental services, then there would not be an inextricable link between the dental and covered medical service within the meaning of our regulation at § 411.15(i)(3). Furthermore, integration between medical and dental professionals can occur when these professionals coordinate care. This level of coordination can occur in various forms such as, but not limited to, a referral or exchange of information between the medical professional (physician or non-physician practitioner) and the dentist. This coordination should occur between a dentist and another medical professional (physician or other non-physician practitioner) regardless of whether both individuals are affiliated with or employed by the same entity.

In the CY 2025 PFS proposed rule, we explained that the KX modifier is currently submitted on a Medicare Part B claim to indicate that the service or item is medically necessary, and that the healthcare provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. We stated that we believe that usage of the KX modifier in the context of claims for dental services inextricably linked to covered services would be appropriate and support claims processing and program integrity efforts.

We further explained that based on comments received and summarized in the CY 2024 PFS final rule (88 FR 79037), interested parties requested that we provide more guidance on how a practitioner submitting claims for dental services can attest that the dental and medical services are inextricably linked, and that the criteria have been met to support payment. We believe that the use of the KX modifier would allow practitioners to signal that the dental services meet the criteria to support payment. We also noted that the use of the KX modifier may improve the MACs' ability to ascertain the volume of claims that are being submitted for dental services inextricably linked to covered services.

Therefore, we proposed that, effective January 1, 2025, the KX modifier will be required for claims submission for dental services inextricably linked to covered medical services on both the dental claim format 837D and the professional claim format 837P. We proposed that practitioners who bill for dental services for which they seek payment in accordance with § 411.15(i)(3) must include the KX modifier on the 837D or 837P claim to indicate that they believe that the dental service meets the established payment criteria; that the practitioner has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item and that demonstrates the inextricable linkage to covered medical services; and that coordination of care between the medical and dental practitioners has occurred.

We discussed how practitioners now have the option to utilize the KX modifier as proposed, for services with dates of service in CY 2024 as a way to help with this transition to potentially requiring use of the KX modifier for claims submission beginning in 2025. We stated that this optional usage in CY 2024 will not be mandatory and will serve to support both clinician and MAC claims processing activities. We noted our intent to provide additional instruction and education through subregulatory guidance regarding this voluntary phase of the usage of the KX modifier on claims submitted for dental services inextricably linked to covered medical services. We sought comment on all aspects of this proposal. (89 FR 61762 through 61763)

In the CY 2025 PFS proposed rule, we also discussed that while the KX modifier indicates that the services are medically necessary, the GY modifier (along with three other HCPCS denial modifiers) serves to indicate that a service is not covered because it is outside of the scope of Medicare coverage authorized by the statute. We reiterated that denial modifiers should be used when physicians, practitioners, or suppliers want to indicate that the item or service is statutorily non-covered.

We explained that the use of the GY modifier could support MAC efforts to adjudicate claims and remove from the claims processing pipeline those claims that do not require further processing. We sought comment on whether we should recommend the usage of the GY modifier on the 837D or 837P dental claim format in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the service does not fit within a Medicare benefit category and is statutorily excluded from coverage.

Additionally, we stated that in general, the Act and our regulations mandate the submission of diagnostic coding (for example, ICD–10 codes) on Medicare claims. Section 1842(p)(1) of the Act states that ''each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.'' Under this section, each bill or request for payment for

physicians' services under Medicare Part B must include the appropriate diagnostic code ''as established by the Secretary'' for each item or service for which the Medicare beneficiary received treatment. We noted that in the March 4, 1994 final rule entitled *Medicare Program; Diagnosis Codes on Physician Bills,* we codified that each bill or request for payment for a service furnished by a physician under Medicare Part B must include appropriate diagnostic coding for the diagnosis or the symptoms of the illness or injury for which the Medicare beneficiary received care and revised our regulations at § 424.32, *Basic requirements for all claims,* to state specifically that a claim for physician services must include appropriate diagnostic coding using diagnostic information (59 FR 10290).

We noted that in the CY 2023 PFS final rule, we stated that dentists are included in the statutory definition of physician at section 1861(r)(2) of the Act and would generally be considered and treated as a physician for purposes of enrollment, compliance, and other administrative programs (87 FR 69673). Therefore, dentists, who are physicians for the purposes of the Medicare program, are required to submit diagnosis codes on claims for physician services as described in the statute and regulations. Furthermore, we noted that diagnosis code information is currently required on the submission of the professional claim form 837P; professional claims lacking such information are returned to the healthcare provider and are not processed.

We also noted that in the CY 2023 PFS final rule (87 FR 69679 through 69680), we acknowledged the need to address and clarify certain operational issues related to Medicare payment for dental services inextricably linked to covered services and noted that we were working to address these issues, including claims processing questions raised by the commenters. We stated that we anticipated resolving many of the additional operational issues raised by commenters potentially as soon as CY 2024, including efforts to adopt the dental claim form (837D). Similarly, in the CY 2024 PFS final rule (88 FR 79036), we stated that we continue to work to address issues raised by commenters, such as questions related to claims processing and efforts to accommodate the dental claim form within our claims processing systems, effective 2024. The efforts related to adopting the dental claim form are ongoing, and as efforts advance to address the implementation and functionality of claims processing systems for the dental claim form, we intend to provide appropriate guidance and education to interested parties. (89 FR 61763)

In the CY 2025 PFS proposed rule, we explained that we anticipate that our systems will be able to process claims submitted using the dental claim form 837D (OMB Control No. 0938–1471) by January 1, 2025. We stated that consistent with the statutory and regulatory requirements discussed above, we intend to require a diagnosis code to be included on claims submitted for physicians' services for dental services inextricably linked to covered medical services on both the 837P and 837D formats, beginning on January 1, 2025. However, given the complexities related to the operational launch of and transition to the 837D dental claims format, we also considered further delaying the requirement to include a diagnosis code on the 837D form. For example, interested parties have indicated that in current dental practice, claims processing systems may not require the submission of a diagnosis code on claims for dental services, and therefore, dental practices may need time to adjust to this requirement for the 837D form. We also stated that we believe that it may be appropriate to delay this requirement for a limited time to support clinicians and billing entities as they seek to change their workflows and transition to using the 837D form. We sought comment on our intention to require the inclusion of a diagnosis code on the 837D form beginning on January 1, 2025. We were particularly interested in any operational challenges that interested parties may face in attempting to comply, as well as other considerations that we should take into account with regard to the timing of this requirement. (89 FR 61763)

We received 25 public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to require the KX modifier for claims submission of dental services inextricably linked to covered medical services on both the dental claim format 837D and the professional claim format 837P. One commenter stated they support the use of the KX modifier to indicate that a dental service is inextricably linked to a covered medical service and that there has been integration between the medical and dental providers. The commenter stated that a patient's provider is well positioned to determine that a KX modifier should or should not be added.

Overall, commenters responded favorably to our comment solicitation on whether we should recommend the usage of the GY modifier on the 837D or 837P dental claim format in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the service does not fit within a Medicare benefit category and is statutorily excluded from coverage. Most commenters supporting the proposed use of the KX modifier also supported usage of the GY modifier in this context. These commenters indicated that the KX and GY modifiers would streamline and improve claim submission and generally help to establish a more clear, transparent standard to help ensure coordination between the dental and clinical professional and agree that it will help to demonstrate when dental services are inextricably linked to Medicare covered services. One commenter supported the use of both modifiers, stating that this will ensure claims are accurately categorized and processed more efficiently for both CMS and providers.

One commenter expressed concern about the overuse of the GY modifier and explained that using the same modifier for different scenarios may create confusion procedurally for providers and their teams because it may be unclear on how to proceed with payment. The commenter recommended that CMS consider the use of two or more unique modifiers—one for coordination of benefits issues or third-party responsibility, another when the service is statutorily excluded from coverage (the dental procedure), and one in which the service may not be statutorily excluded but does not meet the conditions for payment. Commenters requested clarification around the specific instances when a claim must be submitted with the GY modifier, for example, whether a dental claim must be submitted with the GY modifier to coordinate dental benefits with a State's Medicaid program, even in cases in which the Medicaid provider knows a dual-eligible patient will be ineligible for dental benefits under the medically necessary payment rules.

Two commenters did not support the use of the KX or the GY modifiers. The commenters stated that the dental industry and dental software are not ready for the requirement of modifiers within the current architecture supporting the industry's operational aspects. In addition, the commenters stated that the modifiers would entail significant costs for new programs and training to dental offices and carriers alike and would add complexity

without a therapeutic benefit. Further, the commenters stated that they do not believe that the use of the GY modifier would be beneficial but did not give an explanation.

Many commenters supported our intent to require a diagnosis code on claims submitted for physicians' services for dental services inextricably linked to covered medical services on both the 837P and 837D formats, beginning on January 1, 2025. Commenters recognized that the inclusion of these codes is intended to improve the accuracy and coordination of care between medical and dental providers, particularly for services that are intrinsically linked to medical procedures.

Overall, the comments received on the use of modifiers and the inclusion of a diagnosis code on claims requested that CMS allow delay of their implementation. Commenters were concerned that time is needed to resolve potential claims processing issues. Regarding the KX and GY modifiers, commenters stated that there is currently no place on dental claim forms to accommodate them. They were particularly concerned with the readiness of healthcare IT infrastructure, stating that there has been minimal testing among software developers, electronic dental record companies, and claims clearinghouses to verify that CDT codes with these modifiers can be processed accurately. They also stated that the ADA 2024 Paper Claim Form cannot accommodate modifiers at the procedure level.

Commenters appreciated our engagement with them to learn more about the challenges associated with including ICD–10 codes in Medicare dental claim submissions. One commenter explained that using diagnosis codes may create operational difficulties for dental providers since dental practices, especially small dental practices, do not typically have access to patient medical records to include ICD–10 codes on the 837D. A different commenter explained that the dental community does not have a widespread adoption of reporting diagnosis codes and as a result, a delay is necessary to ensure providers can adjust to these new requirements, including updating their practice management systems and training staff on the correct use of ICD–10 codes.

Given these concerns about the potential challenges associated with implementing the reporting of the two modifiers and a diagnosis code, commenters suggested several options for a delay such as, until mid-2025, January 1, 2026, and January 1, 2027. We note that with each suggestion for the duration of a delay, commenters did not provide information that would distinguish a need for one timeframe from another. Commenters explained a delay would allow sufficient time for comprehensive testing, reporting, and educational materials for providers, vendors, and payors. During this transitional period, some commenters recommended CMS allow MACs to adjudicate claims without modifiers, with an approved claim report advising providers that modifiers will be required starting January 1, 2026. Commenters indicated this approach would help alleviate any confusion for providers and ensure the continuation of quality patient care for these new coding requirements. Meanwhile, one commenter strongly urged CMS not to delay the requirement of a diagnosis code, stating that a diagnosis code is critically necessary to understand whether a dental service is covered under Medicare.

Response: We thank commenters for their support of our proposal to require the usage of the KX modifier on the dental claim format 837D and the professional claim format 837P to identify dental services inextricably linked to covered medical services; our intent to require the reporting of a diagnosis code on the 837P and 837D forms for physicians' services for dental services inextricably linked to covered medical services; and our recommendation on the use of the GY modifier on the 837P and 837D forms. We agree with commenters that these claim payment mechanisms would streamline and improve claim submission and generally help to establish a more clear, transparent standard to help ensure coordination between the dental and clinical professional and agree that it will help to identify when dental services may be inextricably linked to other Medicare covered services. We appreciate commenters' concerns regarding the challenges they may encounter in implementing these new aspects of claims submission and found the need for additional time compelling. Therefore, we are finalizing a delay of implementing the requirement for reporting the KX modifier on the professional, dental, and institutional (as discussed in the following comment and response) claim forms to identify dental services inextricably linked to covered medical services. We are also finalizing a delay of implementing the requirement for reporting a diagnosis code on the dental claim form for physicians' services for dental services inextricably linked to covered medical services. That is, both of these billing requirements will be effective July 1, 2025. We agree with commenters that suggested a mid-2025 effective date and believe that this timeframe would allow sufficient time for comprehensive testing, reporting, and educational materials for healthcare providers, vendors, and payors. We are also finalizing that the GY modifier may be used on the professional, dental, and institutional (as discussed in the following comment and response) claim forms in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the dental service does not fit within a Medicare benefit category and is statutorily excluded from coverage.

Comment: Commenters stated that the scope of the proposed billing policies only included the dental claim format 837D and the professional claim format 837P. These commenters requested CMS to clarify if reporting the KX and GY modifiers would apply to the institutional claim format 837I. Commenters explained that this clarification is needed because of the discussion in section III.B.8 of the CY 2025 PFS proposed rule (89 FR 61805 through 61806) wherein CMS establishes that the modifier KX billing requirement applies to rural health clinics (RHC) and federally qualified health center (FQHC) claims, which are submitted using the 837I claim format. This commenter also stated that the 837I claim format is used by Method II critical access hospitals (CAHs) to submit professional charges.

Response: We agree with commenters that the discussion in the CY 2025 PFS proposed rule only referenced the dental claim format 837D and the professional claim format 837P and that we need to be clear regarding whether these proposed billing policies are applicable to the institutional claim format 837I. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3)(i) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We recognize that when dental services are furnished in either the inpatient or outpatient setting, depending on the provider or supplier, they may be billed using the 837I, 837P, or the 837D claim forms. As the commenter stated, FQHC services are paid under Medicare Part B and are billed to Medicare on the 837I claim

form. Therefore, we are finalizing that in addition to the 837D and 837P claim forms, the KX modifier will be required for claims submission for dental services inextricably linked to covered medical services on the institutional claim format 837I. We are also finalizing that the GY modifier may be used on the institutional claim format 837I in instances where a Medicare claim denial is sought for purposes of submission to third party payers or when the dental service does not fit within a Medicare benefit category and is statutorily excluded from coverage. Regarding the requirement to report a diagnosis code, we note that this is already a requirement for the institutional claim format. Please see section III.B.8. of this final rule for the policy discussion of dental services inextricably linked to other covered services when furnished in an RHC or FQHC.

Comment: Several commenters provided feedback regarding operational issues for our dental policies. Many commenters supported CMS adoption of the dental claim format and stated this is a great step to streamline communication between providers and payors alike. A few commenters emphasized there is currently no standard to define what qualifies as an exchange of information or care coordination between a physician and dentist. Commenters mentioned this lack of clarity creates a lot of challenges and recommended CMS establish clear guidance to the MACs to avoid any inconsistences or ambiguity. One commenter requested that CMS ensure that MACs are duly evaluating claims and not automatically denying payment on the basis that they do not squarely match up with a listed clinical example in the regulation. This commenter also asked that CMS issue guidance directing MACs to carefully evaluate—and not simply pass on—claims in which there is indication that a patient needed dental clearance in order to qualify for a Medicare-covered procedure or treatment. A different commenter suggested adopting the ''ADA Medicare Referral Form'' as a standard template to verify coordination of care.

Response: We thank commenters for their suggestions and for raising concerns regarding the MACs' evaluation of claims. CMS continues to provide guidance to the MACs on processing claims for dental services and encourages interested parties to share similar feedback with the MACs to better streamline communication between health care providers and MACs.

Comment: Additionally, the majority of commenters urged CMS to educate providers on billing practices and how dental policies applies to different programs. For example, commenters wanted more information on how dually eligible beneficiaries are affected and a few commenters recommended CMS update the Medicare Managed Care Manual to discuss how it interacts with any supplemental dental coverage. Also, a few commenters offered suggestions on how best to educate providers on billing practices such as through the usage of MLNs, NCDs, as well as establishing a list of services of relevant conditions for which dental care is inextricably linked for providers to utilize. By doing so, commenters highlighted this will encourage more dental providers to enroll in Medicare, including those dental providers that are already contracted with Medicaid.

Response: We thank commenters for their suggestions and will continue to seek ways to better educate healthcare providers on our dental policies related to billing practices and supplemental dental coverage. We would like to highlight that many common questions posed by the commenters regarding billing, claims, or inextricably linked-covered services can be found on our website at: *https://www.cms.gov/medicare/coverage/dental.*

In the CY 2023 PFS final rule, we stated that we believed that MACs are appropriately situated to establish contractor prices for dental services inextricably linked to covered services until we have additional pricing data that could enable national pricing (87 FR 69680). Therefore, as we acknowledged in the CY 2025 PFS proposed rule, dental services inextricably linked to covered services are currently contractor priced. However, we stated in the proposed rule that we have received feedback from the MACs regarding pricing information for dental services inextricably linked to covered services, and the MACs have requested information that would support their efforts to assign payment amounts for such dental services. We stated that the MACs retain broad flexibility with respect to assigning payment amounts to claims for dental services inextricably linked to covered services; however, we seek to facilitate the sharing of available pricing information with the MACs for these purposes. Thus, in the CY 2025 PFS proposed rule, we sought comment from the public on potential sources of payment information for the pricing of dental services inextricably linked to covered services. We noted, for example, that publicly available data (such as Fair Health cost data) are available for purchase; however, we understand that this information may not directly inform payment amounts in a manner useful for the payment of Medicare claims for dental services. We noted that according to Fair Health's website, cost estimate information is based on claims for medical and dental services paid for by private insurance plans, including the country's largest insurers.[268] We also noted that we are aware of other fee schedules, such as those used by State governments for State employees, or discount fee schedules, such as discount dental programs (for example, *https://www.dentalbenefitprogram.com/groupfees.php?id=NEV.*) We aimed to support the ongoing efforts by the MACs to price these services and sought any information from the public that may serve to support and inform the MAC development of payment amounts for dental services inextricably linked to covered services. (89 FR 61763 through 61764)

We received 7 public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated the best source of data available for pricing dental services is by utilizing national benchmark prices, such as those in the FAIR Health database, to help support and inform interim contractor pricing for dental claim reimbursement. A few commenters also mentioned CMS should require MACs to update payment rates annually using the Medicare Economic Index. Additionally, one commenter suggested CMS should establish national rates for CDT codes in the PFS RVU files to ensure consistent reimbursement of these services.

Response: We thank commenters for these suggestions and will take them into consideration in our future development of payment policies for dental services.

We remind readers once again that, to be considered for purposes of the CY 2026 PFS rulemaking, submissions through our public process for recommending additional clinical scenarios where dental services may be inextricably linked to covered services under § 411.15(i)(3)(i) should be received by February 10, 2025, via email at *MedicarePhysicianFeeSchedule@cms.hhs.gov.* Interested parties should include the words ''dental recommendations for CY 2026 review'' in the subject line of their email

[268] *https://www.fairhealthconsumer.org/#answer2*; Accessed May 22, 2024.

submission to facilitate processing. We continue to stress to submitters that recommendations must include at least one of the types of evidence listed in section II.J.1.c. of this final rule when submitting documentation to support the inextricable link between specified dental services and other covered services. We further note that we may also consider recommendations that are submitted as public comments during the comment period following the publication of the PFS proposed rule.

6. Miscellaneous Comments

We also received the following miscellaneous comments concerning our proposals.

Comment: We received many comments generally supporting the ongoing public submission process and our use of the annual rulemaking process to evaluate whether evidence submitted by interested parties meets the standard to permit Medicare payment for dental services. Commenters supported what they described as CMS's efforts to ensure that the ''medically necessary'' standard keeps up with growing clinical evidence and evolving standards of care.

One commenter stated that our rigorous review process for determining whether dental services are inextricably linked to other covered services is essential to ensuring that Medicare beneficiaries receive comprehensive care that addresses both their medical and dental needs. The commenter suggested a collaboration with us and offered their scientific and clinical insights.

One commenter requested that we allow payment for dental services when a beneficiary is pregnant. The commenter explained patients should be routinely counseled about the maintenance of good oral health habits throughout their lives as well as the safety and importance of oral health care during pregnancy.

One commenter requested that we consider payment for dental services following organ and stem cell transplants due to the development of oral chronic graft versus host disease, which damages mucosa and salivary glands and causes sclerotic changes in the oral cavity. The commenter also requested that we consider payment for dental services for a period of time following treatment for head and neck cancer and other cancer types, including blood cancers, as well as following antiresorptive therapy for non-cancer conditions, such as osteoporosis.

One commenter recommended that we clarify the regulatory language to provide that dental and oral care extends to medically necessary diagnostic and treatment services to ensure that the patient is in acceptable oral health prior to any surgical procedure. The commenter stated that dental services and interventions to remove plaque and biofilm from the teeth and gums prior to surgery aid in the prevention of infection.

One commenter requested that we permit payment for dental services for beneficiaries with intellectual and/or developmental disabilities (IDD). The commenter stated that beneficiaries with IDD experience higher rates of complications of poorer oral health such as aspiration pneumonia, cardiovascular disease, diabetes, respiratory disease and stroke,[269] therefore, improving dental coverage for people with IDD will provide better overall health outcomes for these individuals and substantial savings in Medicare spending by preventing and reducing complications that arise from poor oral health. Further, the commenter stated while the importance of improving access and payment for dental services for people with IDD is robustly clear, they understand the need to gain further understanding of any potential relationship between dental services and specific covered medical services for patients with IDD. They suggested that we partner with AHRQ to conduct a rapid response report focused on people with IDD.

One commenter suggested that we explore ways to integrate dentists in the coordination of care for cancer and other illnesses and stated that The National Cancer Institute recommends that dental professionals be considered part of the cancer care team in individuals undergoing cancer treatment and that people see their dentist 4 weeks prior to initiating cancer treatment (if possible) to allow for healing if any dental work is required.

Response: We thank commenters for their support and suggestions. Regarding the specific clinical scenarios identified by these commenters, we did not find that the information they provided indicated an inextricable link between dental services and a covered medical service such that dental services would not be in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth. As we have previously stated, because the Medicare statute generally prohibits payment for dental services, payment may be made in limited situations such as when the dental services are inextricably linked to, and substantially related and integral to the clinical success of certain other covered services as provided by our regulations at § 411.15(i)(3), or under the exceptions provided by section 1862(a)(12) of the Act and codified at § 411.15(i)(2).

7. Request for Information: Services Associated With Furnishing Oral Appliances Used for the Treatment of Obstructive Sleep Apnea

In the CY 2025 PFS proposed rule (89 FR 61764 through 61765) we included a Request for Information (RFI) to help us determine if oral appliances used to treat obstructive sleep apnea can withstand repeated use (furnished as rental equipment for use by successive patients) and thus could be classified as durable medical equipment (DME). We also requested information regarding the types of services furnished by a dentist or other practitioner related to oral sleep apnea appliances. Specifically, we sought information regarding details that may inform or support a future proposal regarding a code assignment for services related to oral sleep apnea appliances under the Medicare physician fee schedule.

We received 400 comments in response to this RFI. We received comments responding to some or all of the RFI questions from approximately 209 stakeholders, with an additional 191 comments that indirectly addressed the RFI questions. While we are not responding to the comments here, we thank the commenters for their detailed and thoughtful input and will consider these comments for future rulemaking.

K. Payment for Skin Substitutes

In the CY 2023 PFS proposed rule (87 FR 46027 through 46029), we outlined several objectives related to refining skin substitute policies under Medicare, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal-based material, to incorporate more consistent payment methodologies; and (4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures. When considering potential changes to policies involving skin substitutes, we noted that we believe it would be appropriate to take a phased

[269] Wilson NJ, Lin Z, Villarosa A, George A. Oral health status and reported oral health problems in people with intellectual disability: a literature review. J Intellect Develop Disabil. 2019:44(3):292–304.

approach over multiple rulemaking cycles to examine how we could appropriately incorporate skin substitutes as supplies under the PFS ratesetting methodology. After receiving feedback from commenters requesting more information on how CMS intends to achieve a consistent payment approach for skin substitute products, we did not finalize any policies in the CY 2023 PFS final rule.

In alignment with our objectives, in the CY 2024 PFS final rule, we solicited comments on different approaches CMS could use to identify appropriate practice expense (PE) direct costs for skin substitute products, such as reviewing various sources for price information, including performing market research, reviewing invoices submitted by interested parties, or cost information on Medicare claims. Discussing these approaches in the CY 2024 PFS final rule provided interested parties with more details about payment mechanisms CMS is considering under our PFS ratesetting methodology.

The CY 2024 PFS proposed rule did not contain a specific proposal for changing how skin substitute products are paid under the PFS; however, we continue to pursue our objectives for refining skin substitute payment policies under Medicare, as mentioned above. More specifically, we continue examining ways to treat skin substitute products as incident-to supplies under the PFS ratesetting methodology. Additionally, we believe continuing this dialogue with interested parties on payment for skin substitute products will help inform potential policy changes for future rulemaking.

We recognize that skin substitute products may vary in composition, size, and applicability and will continue to consider these distinct characteristics in proposing a consistent payment approach and policy. We also note an increase in HCPCS Level II coding request applications for newly developed skin substitute products and are considering broadly all of our relevant payment policies. Such policies, for example, include the discarded drug refund policy and the Part B drug inflation rebate policy and how these policies may align with the usage and payment for skin substitute products. In the CY 2024 PFS final rule (88 FR 79060 through 79061), we finalized that billing and payment codes that describe products currently referred to as skin substitutes are not counted for identifying refundable drugs for calendar quarters during 2023 and 2024. While we continue to consider making changes to the Medicare Part B payment policies for such products, similar to last year, for CY 2025, we proposed that billing and payment codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying refundable drugs for calendar quarters in 2025. We plan to revisit discarded drug refund obligations for skin substitutes in future rulemaking. In section III.I. of this final rule, CMS is finalizing codification of existing policy by including products currently referred to as skin substitutes on the list of product categories that are not considered Part B rebatable drugs in § 427.101(b)(5).

CMS did not make any proposals for payment for skin substitute products for CY 2025; however, we did receive public comments on our intention to move forward with a future proposal to achieve a consistent payment mechanism for all skin substitute products. The following is a summary of comments received and our responses.

Comment: Several commenters raised similar objections to paying for all skin substitute products as supplies, including: (1) commenters suggested skin substitute products should not be treated as supplies since they are affixed into the wound; (2) commenters stated that assessing the costs of skin substitute products within the PE RVU methodology is challenging due to the variability in usage of these products (size, intended use, composition); and (3) commenters suggested bundling payment for skin substitute products would significantly reduce payment for providers, which they state would negatively affect innovation and access to care for Medicare beneficiaries.

Response: We thank commenters for their feedback as we continue to work through ways in which to achieve consistent payment for skin substitute products under the PFS. We refer readers to a similar discussion in the CY 2024 PFS final rule (88 FR 78987 through 78990) where CMS discussed numerous factors we could consider in establishing a consistent payment approach. As also mentioned in the CY 2024 PFS final rule (88 FR 78989), our goal is to achieve a consistent payment approach for skin substitute products that does not negatively impact beneficiary access.

Comment: Many commenters also mentioned alternative options to achieving consistent payment for all skin substitute products under the PFS, such as applying the ASP+6% payment methodology to all skin substitute products and enforcing ASP reporting for skin substitute products. Another commenter recommended an alternative option of applying a maximum fee-for-service price of $150 per cm squared that would be applicable to all skin substitute product, for both Q and A codes. Additionally, one commenter recommended that CMS replace application CPT codes 15271–15278 with newer, temporary codes to describe the more complex wound procedures and offer revisions to the sizing increments.

Response: We thank these commenters for their suggestions and may consider these alternative policies for future rulemaking.

Comment: Several commenters applauded CMS for delaying a proposal for payment of skin substitute products and appreciated our efforts to continue to engage with interested parties. These same commenters also acknowledged the urgency to finalize a proposal to change the way skin substitute products are treated and paid for under the PFS.

Response: We thank these commenters for their feedback and reiterate CMS' commitment to achieving a consistent payment mechanism for all skin substitute products under the PFS. CMS also acknowledges the desire for a proposal on this issue and intends to bridge the gap in variation of pricing for these products through establishing a consistent framework for payment of skin substitutes under the PFS in future rulemaking.

Comment: One commenter recommended reverting to the pre-2014 policy where each skin substitute with its own HCPCS code was paid separately to ensure consistency, given the ASP reporting requirements that became effective on January 1, 2022. The commenter recommended against bundling skin substitute products under the PFS, emphasizing the need for specific PE RVUs and careful consideration of the diverse uses and types of skin substitutes. The commenter also recommended that all skin substitute manufacturers be required to report ASP data, consistent with the approach of treating skin substitutes as drugs and biologicals.

Response: We thank the commenter for their feedback. As discussed in the CY 2024 PFS final rule (88 FR 78987 through 78990), we are working to develop a consistent payment approach for skin substitute products that maintains beneficiary access by evaluating various payment policy aspects, including the diverse uses and types of skin substitutes, in alignment with our goals of consistency and fairness.

Additionally, we acknowledge the recommendation for requiring all skin substitute manufacturers to report ASP data and the concerns regarding bundling under the PFS. These

considerations will be factored into our ongoing efforts as we continue to develop future payment policies for skin substitutes and may consider these suggestions for future rulemaking.

Comment: One commenter urged CMS to acknowledge that skin substitutes should not be classified as refundable drugs under the discarded drug refund program, as this exclusion is mandated by law, irrespective of the year. The commenter highlighted that skin substitutes do not fall within the definition of ''single source drug or biological'' as outlined in section 1847A(c)(6)(D). This is because they are neither approved by the FDA as a biological under section 351 of the Public Health Service Act nor produced or distributed under an FDA-approved new drug application.

Response: We thank the commenter for the feedback and are continuing to consider this issue. As noted, we are finalizing our proposal to continue our policy that billing and payment codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying refundable drugs for calendar quarters in 2025.

Comment: We received one comment requesting that CMS acknowledge skin substitutes as exempt from the discarded drug refund program in all future years.

Response: We are not establishing skin substitutes as exempt from the discarded drug refund policy for all future years, as we plan to revisit the refund obligations for skin substitutes in future rulemaking. However, while we continue to consider making changes to the Medicare Part B payment policies for such products, we are finalizing that billing and payment codes that describe products currently referred to as skin substitutes will not be counted for purposes of identifying refundable drugs for calendar quarters in 2025.

L. Strategies for Improving Global Surgery Payment Accuracy

1. Background

Currently, there are approximately 4,100 physicians' services that are coded and valued under the PFS as global surgical packages (herein ''global packages''). Global packages are single codes that are valued to include a specific surgical procedure and all related services provided during a specified period of days (0-day, 10-day, or 90-day global packages) by a physician (or another practitioner in the same group practice). The PFS Look-up Tool provides information on each procedure code, including the global surgery indicator. This tool is available at *https://www.cms.gov/medicare/physician-fee-schedule/search/overview.*

The global packages include:

- The surgical procedure itself, including day-of pre-service activities and day-of recovery care;
- Related post-operative evaluation and management (E/M) visits and discharge services provided during specified post-operative periods (10-day or 90-day periods for most minor and major procedures, respectively; 0-day global packages do not include post-operative visits);
- Related pre-operative visits on the day of the procedure (for services with 10-day and 90-day periods) and pre-operative visits on the day prior to the procedure (for major procedures with 90-day periods only);
- Services provided during the post-operative period (for services with 10-day and 90-day periods) related to the procedure (for example, treatment of complications, pain management).

Any medical care that requires a return to the operating room during the global period is paid separately and starts a new global period. Like other services paid under the PFS, post-operative visits that are part of the global packages can vary by level and site of service. Global packages are valued using our annual PFS rulemaking process.

As we described and discussed beginning in the CY 2015 PFS final rule (79 FR 67582 through 67591), both CMS and other interested parties have concerns with the accuracy of global package valuation and payment under the PFS. Foremost, we have longstanding concerns regarding whether the number and level of post-operative visits assumed to occur within global packages are consistent with the number and kind of post-operative services actually being furnished. Findings from multiple OIG reports suggest that practitioners perform fewer post-operative visits than are expected and accounted for in the valuation of the global packages. We also described concerns that global packages as currently defined and valued may cause potential distortions in valuation among other PFS services. Furthermore, we noted that the structure of the current packages assumes a single model of care delivery (a single practitioner or other practitioners in the same group practice furnishing the surgical procedure and all associated care) and does not directly address scenarios where the surgical procedure and follow-up care are provided by different practitioners or in different group practices.

Taking these findings and concerns into account, we finalized a policy to transition all 10-day and 90-day global packages to 0-day global packages, which would allow any post-operative visits furnished after the day of the procedure to be billed separately as standalone visits by any practitioner who furnishes them. However, in 2015, through amendments made by section 523 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; Pub. L. 114–10, enacted April 16, 2015), we were prohibited under section 1848(c)(8)(A) of the Act from implementing this finalized policy. Further, under section 1848(c)(8)(B), we were required to collect data beginning in 2017 on the number and level of post-operative visits typically provided to patients during 10-day and 90-day global periods and to use this newly collected data and other data beginning in 2019 to improve the accuracy of global package valuation.

In response to these requirements, over the past 9 years, we have:

- Initiated research contracts and implemented a data-collection process to analyze data to understand the extent to which post-operative visits are furnished to patients and improve the accuracy of payment rates for the global surgical packages. This research contract was funded by CMS (HHSM–500–2014–00036I) and carried out within the Payment, Cost, and Coverage Program in RAND Health Care (''RAND'').
- Released three RAND reports (located at *https://www.cms.gov/medicare/payment/fee-schedules/physician/global-surgery-data-collection*) on the number of post-operative visits furnished during post-operative periods, with the most recent published finding that only 4 percent of expected post-operative visits in 10-day global packages and 38 percent of expected post-operative visits following 90-day global packages were furnished to patients.
- Fielded and released a RAND report on a survey of selected global packages, collecting information related to the level and complexity of medical visits furnished during post-operative periods which found post-operative visits following common procedures were of similar length and intensity as corresponding separately billed E/M visits.
- Released two RAND reports on potential approaches for revaluing the global packages based on these findings.
- Internally, we analyzed the prevalence of transfer of care modifiers (-54 for surgical care only; -55 for post-operative management only; and -56 for

pre-operative management only) applied to global packages.

More recently, in the CY 2023 PFS proposed and final rules, we reviewed the prior work and conversations around the accuracy of global package valuations and solicited comments from the public on (1) suggested strategies for revaluing these services, (2) information on how changes to healthcare delivery and payment may be impacting the relevance or accuracy of global package payments, and (3) possible impact of changes to global packages on health care access for beneficiaries (see 87 FR 69432 through 69437). In response to the comment solicitation in the CY 2023 PFS proposed rule, some commenters generally disagreed with our findings that the post-operative visits in the global packages are not performed as frequently as assumed in our valuation of global surgical packages. However, opposition from commenters was based on anecdotal assertions rather than alternative data. Many of these commenters' specific points restated earlier comments submitted in response to our request for feedback in the CY 2020 PFS proposed rule on claims-based reporting of post-operative visits, survey findings on the level of visits, and potential revaluation approaches. Some commenters supported eliminating 10-day global package periods and requested that the AMA RUC review these services. However, these commenters also acknowledged that the AMA RUC review process could take years. In addition to the comments we received in response to the CY 2023 PFS proposed rule, we have received feedback over several years from many interested parties regarding the findings from claims-based reporting of post-operative visits and considered revaluation methodologies presented in our prior reports.

Overall, we have continued exploring ways to improve the accuracy of valuation and payment for global packages to ensure appropriate payments to the practitioners providing pre-operative, surgery, and post-operative care to Medicare beneficiaries while considering feedback from interested parties. In addition, commenters have not proposed specific alternative strategies to revalue global surgical packages beyond what CMS has previously proposed.

Separately, we continue to review approaches to better describe physicians' services in the context of the evolving care delivery landscape and to allow practitioners to furnish patient-centered care. Our review work includes considering care delivery models discussed with interested parties (and developed though our CMS Innovation Center work), reviewing our policies and billing requirements, identifying care elements that could serve as the building blocks for describing newer, impactful services, and seeking opportunities to reduce administrative burdens for practitioners while ensuring accurate payment. Through this lens, we have also recently reviewed our billing requirements and payment policies for the global packages, concurrent with continued analysis of the Medicare claims data.

While ongoing, our review highlights opportunities for us to clarify or revise longstanding policy and billing instructions for global packages, using data and experience gathered over the last several years, consistent with our overall objectives to pay more accurately for services and to right-size the valuation of PFS services based on how practitioners currently furnish these services. In this final rule, we discuss proposals (1) to revise our transfer of care policy for global packages to address instances where one practitioner furnishes the surgical procedure and another practitioner furnishes related post-operative E/M visits during the global period, and (2) to develop a new add-on code that would account for resources involved in post-operative care provided by a practitioner who did not furnish the surgical procedure. In the proposed rule, we stated that we believe that clarifying the scope of global surgical packages, addressing the use of transfer of care modifiers, and documenting the time and resources involved when practitioners who do not furnish the surgical procedure provide post-operative care, are essential steps in aligning payment with the way in which surgical procedures are currently furnished as evidenced in our data, and would make meaningful progress toward more accurate payment for these services in particular and improve relative valuation for PFS services overall.

2. Clarifying the Scope of Global Surgical Packages

We have valued global packages to include the surgical procedure and services furnished during the specified global period related to the surgical procedure when furnished by the practitioner who performs the surgery (hereafter in this section, the proceduralist) or by another practitioner in the same group practice as the proceduralist.

Under current Medicare payment policy, certain services furnished during the global period by the proceduralist or by another practitioner in the same group practice may be separately billed with an appropriate modifier:

- Initial decision for surgery: E/M service billed with modifier -57 (Decision for Surgery).
- E/M services unrelated to the procedure: billed with modifier -24 (Unrelated E/M Service During a Global Period).
- Other services unrelated to the procedure (including underlying condition treatment, diagnostic tests, distinct procedures) not including care for complications/returns to the operating room: no modifier required.
- Failure of a less extensive procedure requiring a more extensive procedure: no modifier required.
- Organ transplant immunosuppressive therapy: no modifier required.
- Critical care services unrelated to surgery: billed with modifier -FT if in the post-operative period.

Under our current policy, the scope of the global package extends to services furnished by the entire group practice of the proceduralist, including services furnished by practitioners in the group practice who are a different specialty from the proceduralist. In other words, the PFS payment for post-operative visits and other services furnished during the global period that are related to the surgical procedure and provided by the proceduralist or a practitioner in the same group practice as the proceduralist is bundled into the global package, and those services are not separately billable. If the proceduralist or a practitioner in the same group practice as the proceduralist wants to bill during the global period for a service furnished to the surgical patient, but unrelated to the global package, the correct modifier must be used to indicate that the service is not related to the global package. Without a modifier to indicate otherwise, during the global period for a global package, all E/M services furnished to the patient by the proceduralist or another practitioner in the same group practice as the proceduralist are presumed to be related to, and included in the payment for, the global package. Modifiers for separate payment (such as modifier -24) are required when services unrelated to the global package are billed by the proceduralist or a practitioner in the same group practice as the proceduralist during the global period.

In general, except where a formal transfer of care modifier applies, a practitioner other than the proceduralist or a practitioner in the same group practice as the proceduralist can bill separately for an E/M visit for services

they furnish during the global period for a global package, including post-operative E/M visits related to the procedure. We established formal transfer of care modifiers to apply in cases where the work, time, and resources involved in furnishing services included in the global packages are split between the proceduralist (or another practitioner in the same group practice) and other practitioners providing related post-operative visits during the global period. Under our current transfer of care policy, transfer of care modifiers must be reported when a formal transfer of care arrangement is documented by both the proceduralist and a practitioner (or group practice) providing the related post-operative visits. Based on our analysis of Medicare fee-for-service claims data, these formal transfer of care modifiers are rarely used and, when they are, it is often with respect to certain ophthalmologic procedures (for example, cataract surgery).

3. Strategies To Address Global Package Valuation

We recognize that we are precluded under section 1848(c)(8)(A) of the Act from revisiting the policy we established in the CY 2015 PFS final rule to revalue all 10-day and 90-day global packages to 0-day global packages (79 FR 67582 through 67591). Further, we note that transitioning all global packages to 0-day global periods could take several years and require substantial CMS resources (see CY 2014 PFS final rule (77 FR 44737 through 44738) for previous discussion). We have also considered revaluing 10-day and 90-day global packages to reflect the observed number of post-operative visits furnished to patients based on data we have collected over nearly a decade and note that this approach would be quicker to implement, assuming there would be straightforward ways to revalue the services with the data. However, interested parties have continued to express uncertainty about the validity of claims-based counts of post-operative visits. This uncertainty stems in part from CMS not having complete information surrounding the use of the transfer of care modifiers since they are not currently routinely used. The same interested parties also object conceptually to revaluing the 10-day and 90-day global packages using the ''building block'' framework, where each component of a service, including bundled post-operative visits, contributes to total valuation to align valuation with the number of post-operative visits typically provided to patients. Some interested parties have expressed larger concerns about the redistributive impacts across the PFS among specialties if we were to implement and revalue all global packages.

We acknowledge the practical challenges involved in revaluing 10-day and 90-day global packages, whether they remain as 10-day and 90-day periods with fewer post-operative visits or are transitioned to 0-day global packages, and continue to carefully consider how to best improve global package valuation given access to administrative claims data and other inputs that help us understand the scope of services provided to patients within global packages. Ultimately, we want to ensure payments to practitioners and the relative values assigned to global surgical packages are accurate and, to the extent possible, driven by real-world objective and updatable information regarding the relative resources involved in furnishing the services.

For CY 2025, we focused on different aspects of our policy objectives for global packages and proposed policies (as discussed in greater detail later in this section), which are not mutually exclusive, to obtain information and allow for more accurate payment to reflect time and resources spent on post-operative care associated with the current global packages. We will continue to assess and monitor for potential future opportunities to improve our payment approach for the global packages more broadly.

Additionally, in developing our proposed policies to pay more accurately for the global packages, we also considered whether, when, or how our policies may be affected when services are provided by the proceduralist, versus another practitioner who did not perform the procedure but is providing follow up care. We also recognized that there may be multiple practitioners in the same or different specialties in the same group practice and considered how our policies should apply to practitioners in a range of specialties within the same group practice. We sought comment on these considerations in the context of our proposed policies and welcomed feedback that may further inform our valuation of global surgical services and payment policy for global packages. Additionally, as we continue to better understand what services are being furnished in the global period, by whom, and how the global surgical packages are valued and billed, we sought comment on how remote monitoring and other types of new technologies represent new resource costs and/or produce efficiencies and effectiveness of post-operative care. This information could be useful both for purposes of valuation for surgical and post-operative care, as well as for policies regarding when specific PFS codes should be reported during global periods for global packages.

We sought public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of our ongoing efforts to pay more accurately for global surgical services. Some commenters stated that finalizing these policies is an essential step in aligning payment with how surgical procedures are currently furnished and that these proposed policies would make meaningful progress toward more accurate payment for these services and improve relative valuation for PFS services overall.

Many commenters requested that CMS update the values of the global surgical packages to reflect the revalued E/M visits with the full increase of work and physician time for the inpatient hospital and observation care visits (CPT codes 99231–99233, 99238, and 99239), and office visits (CPT codes 99202–99215) for each CPT code with a global period of 10 days and 90 days, in addition to updating the practice expense inputs. Several commenters suggested referring the 90-day global packages to the RUC for revaluation.

A few commenters objected to the policy of global surgical packages entirely, or provided suggestions on how they could be revalued by CMS, for example, by shifting 10-day and 90-day global periods to 0-day global periods or aligning work RVUs with the amount of post-operative care typically provided to patients. Commenters also expressed concerns about unbundling post-operative visits from the global packages and the effect this could have on beneficiary cost-sharing and stated that the financial burden may cause patients to not seek follow up care.

We received some specific feedback from commenters in response to our solicitation for comments specific to the provision of RPM and RTM during the global period. These commenters supported allowing separate billing and payment for RPM and RTM during the global period by the physician who performed the procedure. Commenters expressed that there is a shift to value-based care and these services do not replace an alternate form of care, rather they enhance care with additional capabilities that improve patient outcomes and ultimately lower Medicare costs. Other commenters

stated that good patient care should not be impeded by coding or billing restrictions. One commenter cautioned that the current coding and billing restrictions related to Medicare global payments for surgical services prevent the providers of these services from using remote monitoring technology.

Another commenter suggested that CMS provide clarification related to post-operative visits that are furnished via telehealth or telecommunications and stated that follow up care can be done remotely and alleviates travel burden.

Response: We appreciate the recommendation to consider a broader revaluation of global surgical packages as a critical next step to improving the accuracy of global surgical valuation and payment. As we note above, we consider improving the accuracy of global surgical package valuation and payment as a crucial, ongoing process. We view our proposals for the CY 2025 PFS rulemaking cycle as steps in this direction.

While not directly related to our proposals, in public comments on the CY 2025 PFS proposed rule, many commenters stated that CMS should increase the valuation of the global surgical packages based on the previously revalued E/M visits. We have discussed these concerns in previous rules and consider this topic out of scope with respect to our proposals. We refer the commenters to our most recent discussion in the CY 2020 PFS final rule (84 FR 62858).

We understand commenters' concerns about unbundling post-operative visits from the global packages and the effect this could have on beneficiary cost-sharing and potential financial burden that may cause patients to not seek follow up care. While we do not have the authority under section 1848 of the Act to waive beneficiary cost-sharing for services furnished under the PFS, we understand the potential for financial implications and will take this into consideration in our process for improving global payment accuracy in possible future rulemaking.

We appreciate the commenters' support and insight describing the use of RPM and RTM in the post-operative global period and may consider these comments for future rulemaking. CMS considers improving the accuracy of global surgical package valuation and payment as a crucial, ongoing process. With regard to the provision of follow up visits via Medicare telehealth, we wish to clarify that when a separately billable E/M visit is furnished via Medicare telehealth during the global period, that visit is subject to the requirements of section 1834(m) and should be reported with the applicable Medicare telehealth place of service codes. For global surgeries, the applicable place of service (POS) code would be the one associated with where the procedure is performed.

4. Expand Applicability of Transfer of Care Modifiers

We created transfer of care payment modifiers at the inception of the PFS. Under our current policy, these modifiers are required to be appended to the relevant global package code when billing for services that are within the scope of the global package (within the global period and related to the surgical procedure) only when the proceduralist and one or more other practitioners who are not in the same group practice as the proceduralist formally document their agreement to provide distinct portions of the global package.

The following transfer of care modifiers describe the different portions of the global surgical package that could be provided by different practitioners:

- Modifier-54 Surgical Care Only: this modifier is appended to the relevant global package code to indicate that the proceduralist performed only the surgical procedure portion of the global package.
- Modifier-55 Post-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the post-operative management portion of the global package.
- Modifier-56 Pre-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the pre-operative portion of the global package.

For each of these modifiers, the payment for the global package is adjusted based on the applicable percentage noted in the PFS Relative Value files *https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files.*

As previously noted, we currently require the transfer of care modifiers (-56 for pre-operative care, -54 for procedures, and -55 for post-operative care) to be appended in cases where there is a formal documented transfer of care agreement, that is, ''in the form of a letter or an annotation in the discharge summary, hospital record, or Ambulatory Surgical Center (ASC) record'' (CMS Manual System, Pub 100–04 Medicare Claims Processing, Transmittal 11287). In our recent analyses of 2022 Medicare claims data, we identified that these modifiers were rarely used other than for certain ophthalmology global packages. We found over 99 percent of claim lines for 90-day surgical procedures billed with modifier -54 were ophthalmology services (primarily cataract-related procedures). We also identified a difference in the number of claim lines annually for a given 90-day global package with modifier -54 and with modifier -55. In other words, there are sometimes more claim lines billed with modifier -54 than there are corresponding lines with modifier -55 and vice versa during a year. We note that modifier -56 (pre-operative management only) is only very rarely used in practice. These recent observations suggest (1) the overwhelming concentration of reported transfer of care modifiers is in ophthalmology procedures, and (2) a potential mismatch in billing for formal transfer of care cases between proceduralists and other practitioners providing post-operative care.

While we recognize the benefits to continuity of care when the proceduralist also provides pre-operative and follow-up care for the procedure, we also recognize that it is not always feasible, or even perhaps typical practice for the same practitioner to furnish all portions of the global package; for example, in instances when the practitioner furnishing the procedure does not schedule a post-operative visit(s) on the day of the procedure or plans for the patient to follow up with their primary care provider, or when the practitioner performing the surgery arranges alternative follow-up care because it would be difficult for the beneficiary to travel to return for follow-up care. Because our current policies require use of the transfer of care modifiers only where there is a formal documented agreement between practitioners to provide specific portions of the global package, we believe there are many practical and potentially common circumstances under which the transfer of care modifiers would not be required or used.

Beginning for services furnished in 2025, we proposed to broaden the applicability of the transfer of care modifiers for the 90-day global packages. We proposed to require the use of the appropriate transfer of care modifier (modifier -54, -55, or -56) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a global package (including but not limited to when there is a formal, documented transfer of care as under current policy,

or an informal, non-documented but expected, transfer of care). Practitioners billing for a global package procedure code with modifier -54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. To do so, the practitioner would append modifier -24 to the claim line for the E/M service.

We stated in the proposed rule that this proposed policy, which would be a first step toward improved valuation and payment would provide us with more accurate information on the resources involved in furnishing components of global surgical packages. This proposal would prevent duplicative Medicare payment for post-operative care because the global surgical package payment would be adjusted based on the appended modifier, and payment for post-operative care would not be made both as part of a global surgical package and through separately billed E/M visits. We also stated that we anticipate that the proposed policy would provide us with insight into changes in standards of practice and post-operative patient care for services that are not billed with transfer of care modifiers pursuant to our current policy (that is, services other than certain ophthalmology procedures).

We acknowledge the potential challenge associated with anticipating whether other practitioners (or their group practices) will furnish post-operative care and, accordingly, appending the appropriate modifier when billing global package services.

We are interested in understanding and sought comment on the circumstances under which practitioners in separate group practices furnish different portions of the care included in global packages, and what that means for reporting the transfer of care modifiers. While we made proposals related to the 90-day global periods beginning for services furnished in 2025, we also sought comment on whether we should consider proposing these changes for the 10-day global packages in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal regarding the use of transfer of care modifiers. Several commenters stated that broadening the cases where transfer of care modifiers must be reported is an important step in improving the accuracy of payment for global surgical services. One commenter stated that broader use of transfer of care modifiers provides an important opportunity for CMS to emphasize the expectation that billing practitioners accurately indicate when a portion of care is shared with another provider to inform CMS on how the post-operative care is being furnished and to avoid inaccurate or fraudulent billing. Other commenters said this clarification of the transfer of care modifiers will align with CMS's objective of reducing administrative burden and ensuring accurate payments. Another commenter stated that CMS should collaborate with HHS leadership and the Office of the Inspector General to assess the use of the transfer of care modifiers and the impact of this policy change to ensure it has the intended effect on reducing duplicative Medicare payment for post-operative care.

Some commenters expressed concerns regarding our proposed policy and intent for expanding the scope for transfer of care modifier reporting, while others requested clarification regarding how CMS plans to identify an informal transfer of care.

Commenters also expressed concern regarding the oversight and monitoring of modifier use through several aspects; namely the Recovery Audit Contractor (RAC), Medicare Administrative Contractors (MACs), and in consideration of the False Claims Act. Commenters stated that the modifiers were not well defined and are unnecessary, and thus their use would give rise to more frequent auditing and therefore not decrease costs overall. Commenters stated that the modifiers would require significant monitoring for accuracy and processes for appeal when inaccuracies are recognized, and their use would require extensive work and likely be ineffective.

Response: We appreciate the commenters' support for our proposal to broaden the required use of the transfer of care modifiers. We agree that our proposal is a first step in an iterative process towards improving the accuracy of global surgical service valuation and payment.

We acknowledge the concerns raised by commenters regarding the applicability of the transfer of care modifiers. We are finalizing the requirement that in instances when a practitioner only intends to perform the procedure and does not intend to provide the post-operative care, that the appropriate modifier (modifier-54) be applied.

We appreciate commenters' concerns surrounding potential increased risk for audit and general oversight of these modifiers. We will continue to monitor these concerns by monitoring claims data and may address them in future rulemaking if needed. Additionally, we will continue to engage with interested parties for education and feedback as needed.

Comment: Some commenters expressed concerns with the proposal to require that transfer of care modifiers be reported for both formal (per our current policy) and other transfers of care. Commenters suggested that CMS should maintain current policy and only require transfer of care modifiers for formal transfers of care, while others stated that these transfers do not occur often. Several commenters asked CMS to clarify between formal and other transfers of care, what it means when the transfer of care is 'expected', and what steps the practitioner furnishing the follow up care would need to take to ''accept'' transfer of care from the proceduralist. One commenter stated they were unclear on the application of the transfer of care modifiers when the transfer occurs in an emergent situation or in instances where practitioners may not have the tools to provide the post-operative care appropriately.

Some commenters stated concerns regarding administrative burden associated with modifier use while others stated that the responsibility for the patient's post-operative care rests primarily with the operating surgeon and transferring may compromise care. Some commenters broadly criticized our rationale for expanding the application of the transfer of care modifiers, stating that in modern medical practice it is common for a surgeon to direct a patient's overall post-operative care while the patient also sees other practitioners, for example, a primary care practitioner. Commenters expressed concerns about the assignment of liability to either the surgeon or the practitioner assuming post-operative care under the proposed transfer of care modifier expansion and stated that CMS needs to clarify which clinician would assume liability for post-operative care.

Response: We acknowledge that the commenter expressed uncertainty surrounding the application of the transfer of care modifiers in an emergent situation or in instances where practitioners may not have the tools to provide the post-operative care appropriately. As we stated previously, we acknowledge the potential challenge associated with anticipating whether other practitioners will furnish portions of the global package and, accordingly, appending the appropriate modifier

when billing global package services. We are finalizing that in instances when a practitioner only intends to perform the procedure and does not intend to provide the post-operative care, that the appropriate modifier (modifier–54) be applied. We note that when practitioners intend to bill a significant service that is medically reasonable and necessary separately outside a global package, standard Medicare billing rules continue to apply.

Comment: One commenter stated that if the surgeon did not report modifier -54, the claim from a different physician or practice during the 90-day global period is denied as ''bundled'' unless it is an unrelated E/M service. Should the post-operative visit be correctly billed with modifier-55, they stated that allowing the physicians to communicate directly about surgical package component billing is a reasonable and far better solution than our proposed policy.

Commenters expressed confusion about how modifier-55 should be appropriately used and documented under our proposal, as well as concern about the need for extensive education for operating and non-operating practitioners to ensure appropriate use. Many commenters further questioned the applicability of the transfer of care modifiers to services that may be subject to the multiple procedure payment reduction (MPPR) and identified by modifier-51. Commenters asked CMS to only apply payment adjustments to the primary procedure when multiple procedures are performed and billed on the same day and not to adjust payment on the second and subsequent services reported with modifier-51. Commenters stated that the MPPR already reduces payment for the second and subsequent service(s) and therefore, a reduction for the service to which a transfer of care modifier applies would be redundant.

Several commenters stated that this proposal would add administrative burden and layers of complexity and also stated that the data received from the modifier usage could be misinterpreted or not actionable and possibly skewed with a high number of modifier-55. Commenters also expressed concerns about potential inaccuracies in claims data when utilization of procedure codes are reported by both the performing surgical specialty and the non-proceduralist managing the post-operative care. One commenter stated utilization may remain low due to a lack of clinician education. One commenter did not object to the use of the transfer of care modifiers but questioned how much the utilization of the modifiers would change based on the proposal. They stated that surgeons and hospitalists, for example, would not be discussing and adjudicating which party should get credit for which clinical services and urged CMS to continue to evaluate the gaps that exist between the goals of global periods and the results they achieve, and ensure that clinicians are accurately and appropriately credited for the services they provide. One commenter asked that we clarify how our proposed policy would affect the use of modifier-24 (Unrelated E/M Service During a Global Period) for services provided during the post-operative period.

Another commenter suggested that CMS should also take into consideration that even when an in-person post-operative visit does not take place, significant time is still spent on phone calls from the patient/caregiver and discussions with the patient's primary and referring health care providers and stated that the time spent should count towards the cumulative global period or be separately reimbursed.

Several commenters recommended CMS delay implementation of the transfer of care modifier proposal until CY 2026. Commenters suggested that CMS implement the proposed transfer of care modifier changes in the CY 2025 PFS final rule for tracking purposes only and delay payment changes associated with these modifiers until CY 2026. Commenters stated a delay until CY 2026 would allow CMS more time to refine the policy so it does not create inadvertent burden for all clinicians involved in the billing of these modifiers and would allow for time to adjust to new workflows.

Response: We appreciate and acknowledge these comments related to the implementation of the transfer of care modifiers proposal. However, broadly, we emphasize the need to balance any potential administrative burden on practitioners and billers with accurate valuation and payment for global surgical services. Without separate billing by the practitioners furnishing procedures and post-operative visits, when appropriate, Medicare may be making duplicative payment for some of the services included in global surgical package valuations (for example, by making an unmodified global surgery payment to the proceduralist in addition to separate payment for follow-up E/M services to other practitioners). Ultimately, the solution to both global surgical package valuation and practitioner burden may be to update the valuations to reflect the number of post-operative visits typically provided by the proceduralist or by another practitioner in the same group practice. Then, services outside the scope of global surgical packages (for example, those furnished by a practitioner who is not in the same group practice as the proceduralist) could be separately billed without the need to refer to the initial global surgical procedure.

We clarify the purpose of our proposal and emphasize that our main focus was on scenarios where the proceduralist does not anticipate seeing the patient for any follow-up visits. In those instances, under our proposal, the proceduralist would append the transfer of care modifier, modifier-54. We acknowledge the concerns from commenters regarding the lack of clarity around the actions a practitioner may have to take to accept the transfer of the patient's care; however, this was not intended to be the primary focus of our proposed policy. For the reasons we discussed in the proposed rule, we believe the transfer of care modifier-54 is important to append even if the proceduralist does not formally transfer the patient's care, and we are finalizing our policy as proposed with regard to modifier-54.

With regard to commenters' concerns about the liability of the surgeon performing the procedure or practitioner assuming post-operative care, our proposal was not intended to affect the scope of services that a physician or other practitioner would otherwise furnish. Rather, we believe that the proposed policy would serve as a mechanism to reflect practice patterns that are already occurring. As we stated previously, we view this as a first step in ensuring global surgical package payment accuracy, and we are putting other tools in place (such as the add-on code, as discussed later) to appropriately account for time and resources and recognize practice patterns that are already occurring.

We acknowledge the substantial confusion from commenters regarding the applicability of the other transfer of care modifiers, particularly modifier-55. After consideration of the comments received, we are not finalizing any changes to our current policy with regard to the use of modifier-55 or modifier-56. Because our policy for CY 2025 remains unchanged for formal transfers of care, we do not expect the practitioner 'receiving' the patient through an informal transfer of care to use modifier-55. Practitioners other than the proceduralist and, if applicable, those outside the proceduralist's group practice, can continue to separately bill for post-operative services without the need to report a modifier.

We thank the commenters for their suggestions regarding the MPPR modifier (modifier-51). Modifier-51 is the most commonly applied modifier under the PFS, and it typically reduces the payment of a second (and any subsequent) procedure if conducted on the same patient on the same day, most often with the most expensive procedure getting paid in full and additional procedures having their payment cut in half. It is a very common modifier for surgical services of all types, and we continue to believe that modifier-51 should continue to apply and payment for any subsequent surgeries should be reduced regardless of whether the proceduralist performed only the surgery and not the pre- or post-operative visits or performed the entire global surgery package.

Comment: One commenter suggested CMS consult with ophthalmologists about how they have integrated the transfer of care modifiers into their clinical practice to see if there is guidance that could be developed to apply across specialties based on their practice of using these modifiers more frequently than other physicians.

Response: We appreciate the commenter's suggestion.

After consideration of the public comments, we are finalizing the proposal to broaden the applicability of transfer of care modifier-54 for 90-day global packages as proposed. Beginning with services furnished in CY 2025, modifier-54 is required for all 90-day global surgical packages in any case when a practitioner plans to furnish only the surgical procedure portion of the global package (including both formal and other transfers of care). We are not finalizing any changes regarding the use of modifier-55 and modifier-56 for CY 2025. Modifiers-55 and -56 will continue to be billed exclusively in cases where there is a documented formal transfer of care.

We will continue to assess the full range of modifiers for future consideration.

5. Payment for Global Packages

In the proposed rule, we stated that under our current policy for global packages where the transfer of care modifiers are used (required only where there is a formal transfer of care arrangement), the total combined PFS payment made for the global package during the global period does not exceed the total global surgical package payment established for the procedure when billed without any transfer of care modifier. In general, we continue to believe this is the appropriate result when more than one practitioner furnishes portions of a global package. Under our proposal (which we are finalizing, as discussed previously), we would require that practitioners performing the surgical procedure but not intending to furnish the post-operative portions of a 90-day global service would appropriately append modifier-54, which would adjust the portion of the payment received to reflect that the proceduralist did not provide post-operative care.

More specifically, as noted in the discussion earlier, the transfer of care modifiers correspond to three distinct portions of the global package (pre-operative services, the surgical procedure itself, and post-operative care). We have assigned a proportion of the global package payment to each portion of the service based on longstanding assumptions. We stated in the proposed rule that under our current policy, the payment for the entire global package is made to the billing practitioner unless a transfer of care modifier is included on the claim. Payment is only adjusted if a transfer of care modifier is included on the claim. We requested comments, as we further develop our payment policies for global packages, on how best to determine the appropriate payment proportions for the three portions of the global package, which impact payment to the different practitioners who may furnish different portions of the global surgical service.

We noted in the proposed rule that we are continuing to consider approaches to establishing the payment allocations for portions of the global package when the transfer of care modifiers are used, and anticipate revising the allocations through future rulemaking. We sought comment on potential approaches to revise these payment allocations and how they could be established to better reflect current medical practice and conventions for post-operative follow-up care. We sought to identify a procedure-specific, data-driven method for assigning shares to portions of the global package payment to more appropriately reflect the resources involved in each portion. We stated in the proposed rule that we would appreciate and carefully consider recommendations from interested parties, including the AMA RUC, on what those allocation percentages should be, based on how the global package codes are valued and any other relevant information. We also stated in the proposed rule that CMS could use data collected over nearly a decade on the observed number of post-operative visits furnished to patients as the basis for calculating new data-driven payment allocations.

We received public comments in response to our comment solicitations. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that the current component percentages published in the PFS were developed using magnitude estimation and cross-specialty scaling. These commenters stated they did not believe that any reverse engineering of work and time can be performed to develop a better percentage of pre-, intra- and post-operative work than what is currently published in the PFS.

Response: We appreciate the information received on the origins of allocation percentages. However, we note the development of the component percentages occurred three decades ago and that both PFS global surgical procedures and relative valuations have since changed.

We also note that a series of analytic reports from RAND have found (located at *https://www.cms.gov/medicare/payment/fee-schedules/physician/global-surgery-data-collection*) that fewer post-operative visits are provided to patients compared to the number of visits reflected in the valuation of global packages, with variation across procedure services in the share of visits assumed to occur during global periods (as noted in the Physician Time File) versus the number of visits actually furnished. Both the RAND reports (located at *https://www.cms.gov/medicare/payment/fee-schedules/physician/global-surgery-data-collection*) and, in prior PFS rules, CY 2015 PFS final rule (79 FR 67582 through 67591), and CY 2023 PFS final rule (see 87 FR 69432 through 69437), CMS, note data from claims-based reporting of post-operative visits could be used to exclude post-operative visit RVUs from total global package valuation on a code-by-code level.

If our allocation of the global package payment based on the presence of transfer of care modifiers were to undervalue the surgical procedure portion or the post-operative care portion of the global package, we are concerned that we could unintentionally introduce incentives that influence current medical practice for transfers of care. This points to RAND's prior recommendation that we revalue global packages to reflect the actual number of post-operative visits provided to patients. After revaluation, separating the procedure and post-operative payments would reflect observed data and mitigate any possible inappropriate incentives in place for practitioners to initiate transfers of care

and support use of transfer of care modifiers as medically appropriate. This approach has the advantage of anchoring the valuation of separate modifier-54 and -55 components using real-world information on post-operative visits reported to CMS rather than on historical assumptions or current survey data reflecting estimates of the typical number and level of visits.

In our internal review of the percentages assigned for the pre-operative, surgical care, and post-operative portions of the global package, we found that there are a small number of codes that do not have any assigned percentages in our files even though these codes are identified as global packages. HCPCS codes 77750 (Infusion or instillation of radioelement solution (includes 3-month follow-up care)), HCPCS code 77761 (*Intracavitary radiation source applic simple*), HCPCS code 77762 (*Intracavitary radiation source applic intermed*), and HCPCS code 77763 (*Intracavitary radiation source applic complex*) do not have assigned percentages in our RVU files. It is our understanding, however, that the MACs have local edits in place to ensure appropriate payment for these services when billed with the transfer of care modifiers. We sought comment on whether we should consider, first, whether these codes are appropriately categorized as 90-day global package codes. If these are appropriately considered to be 90-day global package codes, we sought comment on what the assigned percentages should be for the pre-operative, surgical care, and post-operative portions of the service.

We did not receive public comments in response to this comment solicitation.

6. Post-Operative Care Services Add-on Code

We recognize the importance of continuity in surgical and post-operative care. However, we recognize that there are instances where post-operative care is not furnished by the proceduralist or another practitioner in the same group practice, or even by a practitioner who is in the same specialty as the proceduralist, despite there being no formal transfer of care. We also recognize that there is an extra level of complexity involved when a practitioner sees a patient post-operatively after a surgical procedure performed by another practitioner in those circumstances. The practitioner providing the post-operative care may not be involved in creating the surgical plan and may not have access to the operative notes to know how the surgery went or be abreast of any particular considerations related to the procedure that may factor in medical care decisions for the post-operative care. As such, we recognize that there are comparatively more resource costs incurred when a practitioner who did not furnish the surgical procedure in a global package provides the follow-up care. We proposed to address these scenarios, which can occur in a few different ways, by establishing a new add-on code that would account for resources involved in post-operative care for a global package provided by a practitioner who did not furnish the surgical procedure and does not have the benefit of a formal transfer of care. However, we noted in the proposed rule that when a patient is seen by practitioners in the same group practice or specialty as the surgeon, the same resources are not incurred during follow-up and therefore, the add-on code should not be billed by another practitioner in the same group practice as the practitioner who performed the surgical procedure, or in the same specialty as the practitioner who performed the surgical procedure. In the case of a practitioner providing follow up care who is of a different specialty and not within the same group practice as the proceduralist, researching the procedure to determine expected post-operative course and potential complications may be needed, which would warrant using the add-on code. We also acknowledged that sometimes the proceduralist does not schedule the patient to follow up with them post-operatively and directs the patient to follow up with other practitioners as needed, such as with the patient's primary care provider. The patient may independently choose to follow up with their primary care provider or another practitioner based on other considerations such as convenience of the practice location or ease of scheduling. We stated that we understand and acknowledge that the patient can choose to see another practitioner without the knowledge of the practitioner who performed the procedure.

To more appropriately reflect the time and resources involved in these kinds of visits, we proposed to make payment using a new add-on code to be billed with an office/outpatient E/M visit for post-operative follow-up care during the global period of a global package to capture additional resources associated with practitioners who were not involved in furnishing the surgical procedure. This follow-up care may include, but is not limited to, obtaining and reviewing the surgical notes and surgical history, monitoring for signs and symptoms of infection, taking into account any considerations from the surgical procedure that may affect the medical care, and monitoring for any potential post-operative complications that may arise. It is often difficult in these circumstances for the practitioner who did not perform the surgical procedure to know how the wound looked after the procedure, and so it is more challenging to recognize possible changes that may have occurred since the time of the procedure (when this is something the operating surgeon would have been able to know). This new code would be billed by the practitioner who furnishes the post-operative office/outpatient E/M visits when that practitioner is not the proceduralist and is not in the same specialty or group practice as the proceduralist. Documentation in the medical record must justify use of the add-on code and that the E/M visit was, as clinically understood by the reporting practitioner, related to a post-operative visit furnished during the 90-day post-operative period. As noted earlier, we proposed and are finalizing an expansion of our current policy for reporting the transfer of care modifiers-54 and -55 as a first step toward improving payment accuracy for the global packages to promote improved valuation and payment for these services. Instituting an add-on code to capture the time and intensity of post-operative work absent a formal transfer of care would be an essential step in recognizing how the services are currently furnished and make meaningful progress toward 'right-sizing' the structure of the global packages.

Given the history of the global packages since data collection began, as specified in section 1848(c)(8) of the Act, and in consideration of our policies for post-operative care and our proposal requiring the use of the transfer of care modifiers in a broader set of circumstances, we stated in the proposed rule that we believe that the timing is appropriate to establish an add-on code and payment for post-operative care provided in the office/outpatient setting by a practitioner other than the proceduralist (or another practitioner in the same specialty) to account for the additional time, intensity, and resources that are involved in post-operative care. We proposed a new HCPCS code, G0559, to capture the additional time and resources spent in providing follow up post-operative care by a practitioner who did not perform the surgical

procedure and who has not been involved in a formal transfer of care agreement.

We proposed the following code and descriptor for the add-on code:

G0559 (Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice), and is of a different specialty than the practitioner who performed the procedure, within the 90-day global period of the procedure(s), once per 90-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:

- Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.
- Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).
- Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.
- Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established)).

We proposed that HCPCS code G0559 would be reported by a physician or other practitioner who did not perform the surgical procedure for a global package and provides related post-operative visits during the global period despite the absence of a formal transfer of care. We proposed that the add-on code (HCPCS code G0559) would only be reported with an office or other outpatient E/M visit for the evaluation and management of a new or established patient. We would expect the documentation in the medical record to indicate the relevant surgical procedure, to the extent the billing practitioner can readily identify it, in order to aid in our understanding of the post-operative care being furnished and when there is no transfer of care modifier appended on the claim.

We proposed that this code could be billed only once during the 90-day global period for the global package because we believe the practitioner will only have additional resource costs upon the first visit following the procedure. We proposed to assign a ZZZ global period payment indicator for HCPCS code G0559, as this allows the add-on code to be billed during the post-operative time frame that applies to payment for each surgical procedure and, under our proposed policy, this code would be reportable with an E/M visit. The ZZZ global period payment indicator would identify this code as a service that is related to another service paid under the PFS and is always included in the global period of the other service.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS's proposal to establish a new add-on code to capture the time and resources spent by a practitioner who is assuming post-operative care for a patient. Some of these commenters stated that the add-on code would support patient flexibility to seek follow up care from practices other than those that performed the surgery, such as when patients have had to travel long distances for their surgery. Several commenters stated that the policy would help address inadequate payment for post-operative care delivered by clinicians and primary care physicians. Another commenter stated that the add-on code would improve access to post-operative care. One commenter supported the introduction of an add-on code, but was concerned about the impact it would have on overall PFS budget neutrality.

Response: We appreciate commenters' support of the proposed new add-on code. We agree our proposals in the CY 2025 PFS proposed rule would result in more accurate payment by helping to ensure that practitioners of other specialties, who do not have a formal transfer of care agreement with the surgeon, providing post-operative care are paid for the time and work involved in furnishing post-operative care. We also agree with commenters that patients' ability to choose their practitioner for post-operative follow up care would be positively impacted thus improving patients' access to care. We continue to believe that it is important to accurately value the relative resource costs involved in furnishing services that pertain to a procedure that are not explicitly described in the E/M code set.

Comment: Several commenters voiced strong general opposition to the add-on code viewing our rationale as ignoring the expertise, training and continuity necessary to perform appropriate follow-up care for some procedures and skeptical that non-specialists could adequately learn the necessary information to provide appropriate follow-up care within minutes. Other commenters suggested that the proposed time was not sufficient to learn and address everything surrounding the post-operative visits including complications. Some commenters supported the add-on code although some stated that the proposed code descriptor was ambiguous, poorly defined, and requested clarification regarding when it could be billed and that it should not be limited to the office/outpatient E/M visits. Some commenters stated that the current E/M visit codes are sufficient to account for additional time and resources and that the revised E/M guidelines is robust and designed to capture the varying intensity of services while also reducing administrative reporting burdens. Commenters requested clarification as to which specialty can bill the new add-on code for post-operative work, whether multiple practitioners are able to bill, and, if so, how payment would be impacted. Commenters questioned whether patient consent is required, whether coordination between the surgeon and the non-surgeon practitioner billing G0559 is required, and some commenters questioned the regulatory oversight of the code being billed. Other commenters questioned whether use of HCPCS code G0559 would result in reliable data on the number of visits furnished by the operating surgeon or if it would confirm the care was related to the surgery.

A few commenters pointed to CPT code 99024 and how it is currently available to report unpaid post-operative visits that are normally included in the surgical package and this could provide data that CMS can consider.

Response: We appreciate commenters' concerns regarding the proposed add-on HCPCS code G0559 and lack of clarity surrounding when and by whom it can be billed. Under our proposal, HCPCS code G0559 would be reported by a physician or other practitioner who did not perform the surgical procedure within a global package but provided a related post-operative visit during the global period despite the absence of a formal transfer of care agreement. We understand that there may be instances where there is no formal coordination (*i.e.,* to require billing of the transfer of care modifier -55) or no coordination at all between the proceduralist and the practitioner who provides post-operative care and expect that HCPCS code G0559 would be used in those instances. We are finalizing HCPCS code G0559 with modification such that

it may be billed by a practitioner of the same specialty as the proceduralist who is not in the same group practice as the proceduralist. We recognize that in some clinical scenarios, it is possible that post-operative care would be furnished only by a particular specialty. We believe it is plausible for a patient to follow up with another practitioner in the same specialty as the proceduralist in cases where a patient may travel for the procedure or in instances where a patient may opt to follow up with another practitioner of their choosing. Additionally, there may be instances when a surgeon may refer a patient to another practitioner specifically for post-operative care and they may be of the same specialty as the proceduralist. We continue to believe that when a patient is seen by practitioners in the same group practice regardless of their specialty, the same resources are not incurred during post-operative care as compared to when a patient is seen by a practitioner who is not in the same group practice. For this reason, the add-on code should not be billed by another practitioner in the same group practice as the practitioner who performed the surgical procedure. In cases where the practitioner furnishing the post-operative care is of the same specialty as the surgeon but not within the same group practice, they would be able to bill for HCPCS code G0559 given the time and resources that could be incurred by a practitioner who is providing post-operative care when they themselves did not perform the actual procedure.

As discussed above regarding the expanded policy for reporting transfer of care modifier -54, the new G-code, HCPCS code G0559, is a mechanism to account for practice patterns that are already happening where practitioners are spending time and resources with patients who are seen for a post-operative visit and to ensure those practice patterns are accurately reflected in coding and payment policy.

We expect the add-on code will be reported with an office or other outpatient E/M visit for the evaluation and management of a new or established patient. We understand commenters' concerns surrounding not knowing which global surgical package was billed and how one may not know whether there was a transfer of care modifier appended on the claim. Practitioners can bill the G-code when applicable, regardless of whether the proceduralist billed for the procedure with or without transfer of care modifier -54. We specifically proposed the G-code to capture the work involved when a practitioner may not know the surgical history. We expect that this code would be billed only once per practitioner during the 90-day global period for the global package because we expect the patient to typically see one practitioner, either a specialist or their primary care physician for post-operative care.

We appreciate the commenters pointing to CPT code 99024 and its applicability during the global surgical period. We note that CPT code 99024 is billed by the proceduralist, or another practitioner in the same group, to indicate that a post-operative visit was performed during the global period and that CPT code 99024 is not separately payable. We clarify that CPT code 99024 should not be reported by practitioners in a different group practice than the proceduralist when billing for post-operative care.

Regarding concerns surrounding program integrity and audit, as with implementation of any new billing code, we will be monitoring its use going forward, not just for data and other purposes, but also for program integrity reasons.

After consideration of public comments, we are finalizing the proposed code descriptor with modification, as follows:

- G0559 (*Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice) and is of the same or of a different specialty than the practitioner who performed the procedure, within the 90-day global period of the procedure(s), once per 90-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:*

++ Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.

++ Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).

++ Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.

++ Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/outpatient evaluation and management visit, new or established)).

7. Valuation for G0559 Add-On Code

We noted in the proposed rule that the proposed valuation of HCPCS code G0559 is meant to capture the additional resource costs, including for visit complexity inherent to office/outpatient care associated with a post-operative visit that is not accounted for in the appropriate office/outpatient E/M base code billed by the physician or practitioner. Therefore, we stated that we believe that CPT code 90785 (Interactive complexity (List separately in addition to the code for primary procedure)) serves as an appropriate reference for the purposes of valuing HCPCS code G0559. CPT code 90785 was created to capture additional work that occurs during diagnostic psychiatric evaluation, psychotherapy, psychotherapy performed with an E/M service and group psychotherapy sessions, and the service refers to specific communication factors that complicate the delivery of a psychiatric/psychotherapy procedure. However, we also stated that we believe there may be relatively less work involved for G0559 when compared to the work of CPT code 90785, considering the amount of time needed to gather the operative history and conduct the elements discussed above. Therefore, we proposed a work RVU of 0.16, which represents approximately half of the assigned work for minutes of CPT code 90785. Additionally, we proposed a work time of 5.5 minutes (or half of the 11 minutes established for CPT code 90785), personally performed by the billing practitioner including the elements discussed above during the post-operative E/M visit furnished during the global period, that is, no later than 90-days following a 90-day global code, respectively. CPT code 90785 has no direct PE inputs, and we proposed the same for HCPCS code G0559.

To help inform whether our proposed valuation reflects the typical service, we sought comment on the typical time and intensity physicians and practitioners spend over and above a separately billed E/M visit when providing post-operative care to a patient when they did not perform the surgical procedure, gathering the surgical history as well as the pre-operative, intra-operative, and post-operative, and on the proposed service elements and the relative intensity compared to similar service elements of other CPT codes. For the individual practitioner, not having an intimate knowledge of the procedure itself and not having a before/after comparison to look at for the wound can all complicate their E/M visit. The proposed work RVUs are intended to

account for the additional relative resource costs in time and intensity in addition to those involved in the E/M visit.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters were generally supportive of the proposed valuation of HCPCS code G0559.

Response: We thank the commenters for their support.

Comment: Several commenters stated that the proposed work RVU and work time for HCPCS code G0559 was not sufficient to accurately reflect assessment of certain post-operative patients. One commenter stated the complexity of post-operative work for patients in some settings, such as tertiary care centers, may often exceed the ''typical'' post-operative work in other settings. One commenter stated the shift to value-based care in the last decade has led to evolution in how many surgical procedures are managed, which requires a new comprehensive consideration.

One commenter acknowledged that other specialists should be involved when a patient has relevant complications and the current procedural RVUs are not valued to include management of such complications, stating that current valuations only include routine post-operative care. One commenter had concerns about whether CPT code 90785, primarily used in diagnostic psychiatric evaluation, is the appropriate reference for post-operative E/M care from a clinician that did not perform the index surgery.

Response: We thank the commenters for sharing their concerns surrounding the valuation of the add-on code. While CMS agrees some providers (such as tertiary care centers) may provide more post-operative care within global periods than typical compared to other settings, we note that the proposed add-on code, HCPCS code G0559, can only be valued to reflect the typical work time and resources for this service. We believe that the proposed work RVU and work time accurately capture the initial time and resources spent by a practitioner when they see the patient for a post-operative visit.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services for which we originally established G-codes and adopted them through the CPT Editorial Panel process. We note that we would consider using any newly available CPT coding to describe services similar to those described here in future rulemaking.

For discussion of our expected utilization assumptions for this service, see the outline in the Regulatory Impact Analysis section of this final rule.

After consideration of public comments, we are finalizing valuation for HCPCS code G0559 as proposed.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (hereinafter referred to as ''the Infrastructure Act'') amended section 1847A of the Act to redesignate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as ''refundable drug'') for calendar quarters beginning January 1, 2023.

In the CY 2023 PFS final rule (87 FR 69710 through 69734), we finalized many policies to implement this provision. First, we finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs and biologicals (hereinafter referred to as ''drugs'') with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023 (87 FR 69719). We also finalized the requirement that billing providers and suppliers report the JZ modifier for all such drugs with no discarded amounts beginning no later than July 1, 2023, and we stated that we would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023 (87 FR 69718 through 69719). After the issuance of the CY 2023 PFS final rule, CMS published a JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document [270] to provide further guidance on the correct use of these modifiers.

Second, we adopted a definition of ''refundable single-dose container or single-use package drug'' at § 414.902, which also specifies exclusions from this definition (87 FR 69724). These three exclusions are: radiopharmaceutical or imaging agents, certain drugs requiring filtration, and drugs approved by FDA on or after November 15, 2021 for which payment has been made under Part B for fewer than 18 months.

Third, regarding reports to manufacturers, we specified that we would send reports (including information described in section 1847A(h)(1) of the Act) for each calendar quarter, on an annual basis, to each manufacturer of a refundable drug (87 FR 69726).

Fourth, we finalized how the refund amount will be calculated, which is specified in regulation at § 414.940 (87 FR 69731). We stated we would issue a preliminary report based on available claims data from the first two quarters of CY 2023 to provide manufacturers information regarding discarded amounts of refundable drugs prior to the initial refund report (87 FR 69725). In these reports, which were sent in December of 2023, we included preliminary information on estimated discarded amounts of refundable drugs for each labeler code based on available claims data from the first 2 quarters of CY 2023 for any refundable drug for which discarded units were billed using the JW modifier. More information about discarded drugs, including the discarded drug refund and the JW and JZ modifier policy, can be found at *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs*.

Fifth, we addressed drugs with unique circumstances for which we can, through notice-and-comment rulemaking, increase the applicable percentage otherwise applicable for determining the refund. Section 1847A(h)(3)(B)(ii) of the Act provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. We adopted an increased applicable percentage of 35 percent for drugs reconstituted with a hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69731). Lastly, we adopted a dispute resolution process through which manufacturers can challenge refund calculations, and we established enforcement provisions, including manufacturer audits, provider audits, and civil money penalties required by statute (87 FR 69732 through 69734).

In the CY 2024 PFS final rule (88 FR 79047 through 79064), we finalized the

[270] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

date of the initial refund report to manufacturers, the date for subsequent reports, method of calculating refunds for discarded amounts in lagged claims data, method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances, and a future application process by which manufacturers may apply for an increased applicable percentage for a drug, which would precede proposals to increase applicable percentages in rulemaking.

We also finalized that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug are required to be billed with the JZ modifier, since we believe it is unreasonable to collect discarded drug data from beneficiaries. We were concerned that claim rejections may occur in the absence of a claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier.

b. Application for increased applicable percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice and comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS–10835, OMB 0938–1435) by which manufacturers could apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. We explained that manufacturers could benefit from a formal process through which they can provide information, including that which may not be publicly available, in order to request an increase in their refundable drug's applicable percentage and provide justification for why the drug has unique circumstances for which such an increase is appropriate, including in the case of a drug with an applicable percentage that has already been increased by virtue of its unique circumstances. We finalized the application deadline of February 1 of each year, adopted a deadline of August 1 for the FDA-approval of the drug and the deadline for notifying and submitting the FDA-approved label to CMS of September 1 of the year before the year in which the increased applicable percentages would apply. We codified this process in regulation at § 414.940(e). The application process requires the applicant to provide a written request comprising FDA-approved labeling for the drug; justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage.

We received one application for increased applicable percentage for CY 2025 from the manufacturer of Leukine® (sargramostim). Leukine® is a leukocyte growth factor that is primarily used in hematological malignancies to increase white blood cell counts. The applicant submitted the information required under § 414.940(e)(1), including its justification for consideration for increased applicable percentage, and justification for the requested applicable percentage of 72 percent. The applicant did not submit FDA-approved labeling for the drug for the adjuvant uses described in the application (further described below in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant states that there are several manufacturers in late-stage (Phase II and Phase III) development using Leukine® as a vaccine adjuvant in oncology indications, specifically in stimulating the immune response of dendritic cells when used alongside these vaccines. Cancer treatment vaccines are different from the vaccines that work against viruses (for example, influenza). Cancer treatment vaccines try to get the immune system to mount an attack against cancer cells in the body. Instead of preventing disease, they are meant to get the immune system to attack a disease that already exists.[271] The applicant stated that it has no ownership stake in the development of these cancer treatment vaccines and does not possess control or influence over the design and execution of the clinical trials. The estimated completion dates for Phase III clinical trials vary, with the earliest expected in March 2025 [272] and the latest in March 2029.[273] The adjuvant use of Leukine® in predetermined dosage is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or body surface area (BSA). The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggested that if use of these small doses were to become more common for an approved indication, the percentage of discarded units could increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. If another manufacturer were to seek FDA approval for adjuvant use of sargramostim, the available single-dose 250-mcg vial presentation of Leukine® would likely not be optimized for the small doses being studied in these trials.

As part of CMS's review of the application, we analyzed existing claims data from the first quarter of 2023 through the first quarter of 2024 and found the percentage of units discarded for the Healthcare Common Procedure Coding System (HCPCS) code for Leukine® (J2820) ranged from 1.2 percent to 3.8 percent, which is below the applicable percentage of 10 percent. Since we did not yet know the impact of a new adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines [274] on the current percentage of units discarded, we did not propose an increased applicable percentage. Because it was not yet known whether sargramostim would be approved for additional indications and dosages, as indicated in the information provided by the applicant, and the available data did not provide enough information for CMS to determine whether Leukine® had unique circumstances that would prompt an increase in the applicable percentage, we did not propose an increase in the applicable percentage for the drug in the CY 2025 PFS proposed rule, and stated the applicant may reapply in a future application cycle when more information becomes available.

The following is a summary of the comments we received and our responses.

Comment: We received one comment related to the single application we received for an increased applicable percentage beginning in CY 2025. The manufacturer of Leukine® agreed with our rationale, noting that we lacked sufficient information to determine whether Leukine® has unique circumstances that would prompt an

[271] *https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.*

[272] *https://clinicaltrials.gov/study/NCT04229979.*

[273] *https://clinicaltrials.gov/study/NCT05100641.*

[274] *https://www.cancerresearch.org/treatment-types/cancer-vaccines.*

increase in the applicable percentage. The commenter indicated they will reapply in a future application cycle when more information becomes available.

Response: We appreciate the commenter's feedback and agreement with why we did not propose an increased applicable percentage at this time for this product. Taking into account the commenter's support for our assessment of the application for increased applicable percentage application beginning in CY 2025 for Leukine®, we are finalizing that we will not increase the applicable percentage for the drug at this time. As discussed above in this section, the application, including reapplication, for an increased applicable percentage is due by February 1 of the calendar year prior preceding the year in which the increased applicable percentage would apply, as described at § 414.940(e).

We received several comments related to categories and products that commenters believe we should consider for increased applicable percentages for unique circumstances, as well as a general comment concerning the finalized applicable percentage for orphan drugs.

Comment: We received comments recommending increases in the applicable percentages in the following scenarios:

(1) an increased applicable percentage above 10 percent when treating pediatric indications with products packaged for adult dosing. The commenter did not suggest a specific applicable percentage increase and stated that some discarded amounts of drug is unavoidable with pediatric patients, as their dosing is typically based on adult requirements;

(2) a 100 percent applicable percentage for all products with vial fill volumes smaller than 1 mL. The commenter stated that the small amount of drug remaining in vials after intravitreal injections is not ''wastage'' and should not be subject to the refund requirement;

(3) a 100 percent or the highest possible applicable percentage for all cell and gene therapies, without requiring manufacturers to submit applications justifying the exemption. The commenter noted that the unique characteristics of these therapies necessitate tailored approaches to drug availability and administration, requiring upfront preparation and sufficient drug supply. They also emphasized the importance of having the personalized medication available to avoid delays and potential complications, particularly in outpatient settings;

(4) a unique circumstances category to exempt orphan drugs with a single indication from drug refund liability; and

(5) a unique circumstances category to increase the applicable percentage for drugs that treat multiple indications across diverse patient types and characteristics (for example, weight-based dosing and dose titration).

Response: As we discussed in prior rulemaking, we continue to believe it would be inappropriate for any product to have an applicable percentage of 100 percent, as stated in the CY 2024 PFS final rule (88 FR 79053), or to expand the list of exclusions described in section 1847A(h)(8)(B) of the Act by proposing an increased applicable percentage of 100 percent to drugs not excluded in such section. Such an applicable percentage would, in effect, exclude drugs from the refund liability altogether, creating a significant loophole that undermines the goal of minimizing discarded amounts. This could jeopardize the integrity of our policy framework. We also recognize that there may be other drug products with unique circumstances, and that an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking, as required by section 1847A(h)(3)(b)(ii) of the Act. In the CY 2023 PFS (88 FR 79060), we finalized the application process for increased applicable percentages, including the application deadline of February 1 of the calendar year preceding the year in which the increased applicable percentage would apply. We direct commenters to § 414.940(e) for further details and urge commenters seeking increased applicable percentages to utilize this request process for CY 2026 and subsequent years.

Comment: We received a comment in support of the increased applicable percentage of 26 percent for certain orphan drugs, which we finalized last year in the CY 2024 PFS final rule.

Response: We thank the commenter for its support.

After reviewing all comments, we are not finalizing any changes to the applicable percentage for any drug, including those used in pediatrics, ophthalmology, cell and gene therapies, or drugs with multiple indications.

c. Clarifications for the definition of refundable single-dose container or single-use package drug

(1) Exclusions for drugs for which payment has been made under Part B for fewer than 18 months

Section 1847A(h)(8)(B)(iii) of the Act excludes from the definition of refundable drug a drug approved or licensed by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months. This is codified in the definition of refundable single-dose container or single-use package drug in § 414.902. In the CY 2023 PFS final rule (87 FR 69720 through 69731), we finalized that the 18-month period begins on the first day of the calendar quarter following the date of first sale as reported to CMS for the first National Drug Code (NDC) assigned to the HCPCS code. We expected that the first date of sale would approximate the date of payment of the first Part B claim, and we finalized that we would use the first date of sale because it is more operationally feasible than identifying the date when the first Part B claim was paid for a new drug. We did not receive any opposing comments to this approach when the policy was proposed (87 FR 69719 through 69724). Since then, however, we found one instance where the date of first sale for a drug, as reported to CMS, did not adequately approximate the first date for which payment was made under Part B.

As such, we proposed that, while we would continue to use the first date of sale reported to CMS for most refundable drugs, we would use the date on which the drug is first paid under Part B if the date of first sale as reported to CMS does not adequately approximate the first date of payment under Part B due to an applicable National Coverage Determination (NCD). Under the proposed exception, the first date for which the drug was actually paid under Part B (not the date of first sale) would be used to determine the beginning of the 18-month exclusion period.

As an example, we described in the case of Leqembi® (lecanemab-irmb), a drug targeting cerebral amyloid-beta plaques in Alzheimer's disease to receive FDA approval, the first date of sale reported to CMS via the Average Sales Price (ASP) portal was in January 2023, as it was marketed and sold under accelerated approval granted on January 6, 2023. However, because Leqembi® was subject to the NCD for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease under coverage with evidence

development (CED),[275] and because Leqembi® was initially marketed and sold under accelerated approval, Leqembi® coverage under Part B required the product to be furnished in a randomized controlled trial (RCT) conducted under an investigational new drug (IND) application.[276] In public comments on the CY 2024 proposed rule, the manufacturer of Leqembi® explained that Leqembi®'s Phase III confirmatory trial was already fully enrolled and complete prior to FDA granting accelerated approval, and as such, there was no RCT in which to enroll Medicare beneficiaries. Leqembi® received traditional approval on July 6, 2023. The first Part B payments for Leqembi® did not occur until after traditional FDA approval of the drug on July 6, 2023, and Medicare paid for the drug beginning that month in CED studies using a registry.[277] Under policies finalized in the CY 2023 PFS final rule, the 18-month exclusion period for Leqembi® would begin on April 1, 2023, which marks the first day of the calendar quarter after the drug's first date of sale as reported to CMS in January 2023. Based on this example, we believed that, in this situation, our current policy of using the date of first sale as reported in ASP data does not adequately approximate the beginning of the 18-month period for which payment has been made for the drug under Part B.

As stated in the CY 2025 PFS proposed rule (89 FR 61768), we proposed that the 18-month exclusion for Leqembi® would be October 1, 2023, through March 31, 2025 (that is, 6 full calendar quarters following the date that the drug was first paid under Medicare Part B).

Therefore, to maintain operational feasibility of this provision and better align the policy with statutory language when the date of first sale reported to CMS does not adequately approximate the date of first payment under Medicare Part B, we proposed to amend the exclusions in the definition of refundable single-dose container or single-use package drug at § 414.902. We noted that we also proposed to revise the structure of the definition of *Refundable single-dose container or single-use package drug* and as part of that restructuring, we proposed that exclusions would be defined at paragraph (2) of the definition. Moreover, we proposed to add a fourth exclusion to paragraph (2) to address drugs for which the date of first sale does not adequately approximate the first date of payment under Part B due to an applicable NCD. We stated that we anticipate that instances of inadequately approximating the date of first payment under Medicare Part B based on the date of first sale due to an applicable NCD will be rare, as coverage of a drug under Part B is not often restricted by an NCD.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal regarding the 18-month exclusion period, which uses the date a drug is first paid under Part B when the date of first sale reported to CMS does not adequately approximate the first date of payment under Part B due to an applicable NCD. Three commenters recommended creating a new unique circumstance category to extend the exclusionary period up to 36 months for manufacturers actively conducting post-marketing product formulation optimization efforts. They stated that an additional 18 months would accommodate the typical development, testing, and production of new drug delivery systems or vial sizes.

Response: We appreciate the support from the commenters regarding the clarification of the 18-month exclusion period. Section 1847A(h)(8)(B)(iii) of the Act excludes from the definition of refundable single-dose container or single-use package drug those drugs or biologicals approved by FDA on or after November 15, 2021 for which payment has been made under Part B for fewer than 18 months. The 18-month period is therefore prescribed in the statutory text, and as such, we do not have flexibility to extend it to 36 months to accommodate post-marketing product formulation optimization efforts.

Comment: One commenter requested that CMS notify manufacturers when the first Part B payments are made as this would allow manufacturers to be aware of the starting point for any potential 18-month exclusion period.

Response: Although drugs described in section 1847A(h)(8)(B)(iii) of the Act are excluded from the definition of refundable single-dose container or single-use package drugs, we agree that providing information regarding discarded amounts from such drugs would be beneficial to the manufacturers during the 18-month exclusion period. In the CY 2023 PFS final rule (87 FR 69726), we finalized that an annual refund report would provide information on the total number of units of the billing and payment code of drugs meeting this exclusion (and not meeting any other exclusion in section 1847A(h)(8)(B) of the Act) that were discarded during the 18-month exclusion period. We reiterate that, in most cases, the first date of sale indicated in the annual refund report would approximate the date of payment for the first Part B claim (87 FR 69719 through 69724). However, for refundable drugs where the date of first sale does not approximate the first date of payment under Part B, the annual refund report will include them after the first Part B claim for those drugs is paid.

Comment: One commenter recommended the use of consistent language, noting that the regulatory text describing the standard 18-month exclusion period uses the term ''has been marketed (as reported to CMS),'' while the proposed new paragraph for drugs subject to an NCD uses ''date of first sale.''

Response: We thank the commenter for the feedback. We agree with the commenter that the regulation text should use consistent terminology. Therefore, we are finalizing a modification to the regulatory text at § 414.902 describing the 18-month exclusion for drugs subject to an NCD from ''date of first sale as reported to CMS'' to ''date the drug was first marketed (as reported to CMS)'' to use consistent terminology throughout the definition of refundable drug.

After considering public comments, we are finalizing that we will amend the exclusions in the definition of refundable single-dose container or single-use package drug at § 414.902 as proposed.

(2) Clarification for identifying single-dose containers

In the CY 2023 PFS final rule (87 FR 69719), we finalized that the definition of refundable drug would apply to drugs paid under Medicare Part B (that is, under any payment methodology) that are described in FDA-approved labeling as being supplied in a ''single-dose'' container or ''single-use'' package. This definition also includes drugs described in FDA-approved labeling as a part of a ''kit'' that is intended for a single dose or single use. We also finalized that for a drug to meet the definition of refundable drug, all NDCs assigned to the drug's billing and payment code must be single-dose containers, as described in each product's labeling.

During our analysis in identifying refundable drugs for the preliminary

[275] Section 200.3 of the Medicare National Coverage Determinations Manual.

[276] *https://www.cms.gov/medicare/coverage/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad.*

[277] *https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval.*

reports (which are based on available JW modifier data from the first and second quarters of 2023), we learned that some product labeling [278] did not specify the package type terms (for example, whether the product was supplied in a single-dose or single-use package or a multiple-dose preparation). This might occur in drugs that were approved prior to October 2018 when FDA issued guidance [279] regarding the selection of the appropriate package terms to address bacterial and viral infections among patients resulting from improper use of single-dose containers such as vials, ampules, and prefilled syringes. The guidance defines a single-dose container as a container of a sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements. The guidance further states a single-dose container is designed for use with a single patient as a single injection/infusion and, when space permits, the label should include the correct package type term and appropriate discard statements. Discard statements include instruction for discarding or, if appropriate, storage guidance for drugs remaining after preparation. The guidance defines a multiple-dose container as a container of sterile medication for parenteral administration that has met antimicrobial effectiveness testing requirements or is excluded from such testing requirements. In addition, the guidance defines the term ''single-patient-use'' container, which describes a package that contains multiple doses of an injectable medical product that is intended to be used in a single patient.

Some drugs approved prior to the release of this guidance (that is, those prior to October 2018) and certain orphan drugs did not include the package type terms and explicit discard statements. Examples of drugs without the package type terms and discard statements included certain manufacturers of digoxin injection (approved in 1954), oxytocin injection (approved in 1980), diphenhydramine hydrochloride injection (approved in 1982), phenobarbital sodium injection (orphan drug without FDA approval). Several of these drugs were available in small containers with only a few mL of labeled drug in the containers.

Based on these reasons, we proposed to include injectable drugs with a labeled volume of 2 mL or less and that lack the package type terms and explicit discard statements in their product labeling to be single-dose containers in the definition of refundable single-dose container or single-use package drugs. We identified 2 mL as a threshold for this proposal for several reasons. For intramuscular administration, the maximum volume administered at one time for diphenhydramine hydrochloride and digoxin is less than or equal to 2 mL. We also noted that for adults, the maximum volume [280] for intramuscular administration is typically limited to 3 mL. For drugs administered intravenously and supplied in containers containing 2 mL or less, like digoxin and phenobarbital sodium, dosages are calculated based on body weight, potentially leading to discarded amounts. We believe that preparation of these drugs would likely be used for a single dose based on the range of dose sizes for these drugs and the amount of drug in the container. In other words, it is unlikely that more than one dose could be prepared from the amount of drug in the container.

Another category of drugs approved before 2018 that lack discard statements is drugs contained in ampules (also spelled as ampoules or ampuls, hereinafter referred to as ''ampules''). The term ampule is an airtight vial made of glass, plastic, metal, or any combination of these materials.[281] Examples of drugs currently contained in ampules include epinephrine injection (approved in 1939), lidocaine hydrochloride injection (1948), dicyclomine hydrochloride injection (1950), digoxin injection (1954), chlorpromazine hydrochloride injection (1957), fentanyl citrate injection (1968), promethazine hydrochloride injection (1973), alprostadil injection (1981), nalbuphine hydrochloride injection (1993), and tacrolimus injection (1994). Drugs contained in ampules are accessed by breaking the concaved part (''the neck''), and the content should be passed through a sterile filter to remove any residual glass particles.[282]

Therefore, we also proposed to amend the definition of refundable single-dose container or single-use package drug to include drugs contained in ampules and for which there is no discard statement. We proposed to classify drugs supplied in ampules to be drugs in single-dose containers for purposes of this discarded drug policy because this approach will be consistent with the description of single-dose container in the October 2018 FDA guidance. We noted that some drugs contained in ampules may be excluded from the definition of refundable drug under section 1847A(h)(8)(B)(ii) of the Act because dosage and administration instructions included in the product labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. This exclusion will still be applicable for ampules that can demonstrate that they meet that exclusion. However, this is not the case for the product labeling of all drugs contained in ampules.

In summary, we proposed to amend the definition of *Refundable single-dose container or single-use package drug* at § 414.902 by including ''single-patient-use container'' as a package type term and adding three types of products that may be considered refundable single-dose container or single-use package drugs under paragraph (1). These are:

(1) Product furnished from a single-dose container or single-use package based on FDA-approved labeling or product information.

(2) Product furnished from an ampule for which product labeling does not have a discard statement or language indicating the package type term, like ''single-dose container,'' ''single-use package,'' ''multiple-dose container,'' or ''single-patient-use container''.

(3) Product furnished from a container with a total labeled volume 2 mL or less for which product labeling does not have language indicating the package type term, like ''single-dose container,'' ''single-use package,'' ''multiple-dose container,'' or ''single-patient-use container''. As noted above, we also proposed to revise the organization of this definition in the regulatory text.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing general support for our proposals to include injectable drugs with a labeled volume of 2 mL or less that lack package type terms and explicit discard statements in their product labeling, as well as drugs contained in ampules without discard statements, in the definition of refundable single-dose container or single-use package drugs.

[278] ''Product labeling'' in this document means the container label, carton labeling, or prescribing information.

[279] *https://www.fda.gov/media/117883/download.*

[280] Open Resources for Nursing (Open RN); Ernstmeyer K, Christman E, editors. Nursing Skills [internet]. 2nd edition. Eau Claire (WI): Chippewa Valley Technical College; 2023. Chapter 18 Administration of Parenteral Medications. Available from *https://www.ncbi.nlm.nih.gov/books/NBK596739/.*

[281] 40 CFR 273.9.

[282] Pharmaceutical Compounding—Sterile Preparations. *USP–NF* 2023. November 1, 2023.

Response: We thank the commenters for their support.

Comment: One commenter stated that ''many'' drugs with a labeled volume of 2 mL or less do not specify whether they are single-dose container or single-use package. The commenter added that these drugs often require administrative equipment from different suppliers, which contribute to the discarding of a portion of the drug during administration. The commenter expressed concern that the proposal may incentivize manufacturers to produce formulations requiring in-office dilution to avoid potential rebate [sic] for discarded amounts.

Response: We disagree with the commenter's claim that there are ''many'' drugs with a labeled volume of less than 2 mL that lack package type terms and explicit discard statements in their labeling. The commenter did not specifically name ''many'' drugs but cited one study utilizing botulinum exotoxin A (that is, botulinum toxin type A). All four commercially available botulinum toxin type A products mentioned in the study cited by the commenter are supplied in single-dose vials and instruct users to discard any unused remaining solution.[283] Additionally, these four products require dilution without filtration to achieve the various final concentrations, which range from 1.25 units per 0.1 mL to 50 units per 0.1 mL.

While we acknowledge that additional administrative equipment may be required to achieve a final product volume of less than 2 mL, this dilution process does not exempt these products from discarded drug refund requirements. We reiterate that drugs or biologicals that require filtration prior to dilution and administration are exempt from discarded drug refund requirements, as described in section 1847A(h)(8)(B)(ii) of the Act. Furthermore, we have not seen evidence that the equipment used during drug preparation results in discarded amounts exceeding 10 percent.

Comment: One commenter raised concern about the proposed change to classify injectable drugs with a label of 2 mL or less as single-dose containers, noting that this would impose an administrative burden to retinal care specialists who commonly administer such drugs.

Response: We disagree with the commenter regarding the administrative burden on retinal care specialists who frequently administer drugs with a labeled volume of 2 mL or less. We note that the clarification we are making in this final rule as to injectable drugs with a labeled volume of 2 mL or less as single-dose containers applies only to those without package type terms or explicit discard statements in their product labeling. While many ophthalmic drugs have a labeled volume of 2 mL or less, many of these ophthalmic drugs include package type terms and explicit discard statements in their labeling; therefore, this proposal does not apply to them.

Comment: A few commenters requested CMS publish NDC codes for drugs identified as meeting the definitions of single-dose containers or single-use packages, as well as multiple-dose containers, on at least a quarterly basis. They noted that regular publication of NDC codes would help providers in verifying and reporting discarded amounts accurately.

Response: Drugs and biologicals payable under Medicare Part B are billed using billing and payment codes (that is, HCPCS codes) rather than the NDC of each individual product. CMS has published a non-exhaustive list of specific billing and payment codes assigned exclusively to single-dose containers or single-use packages on the Discarded Drug Refund website,[22] having manually identified each code. An analysis to definitively identify an exhaustive list of all NDCs that would be accurate in real time is not operationally feasible at this time. Because new drugs, including therapeutically equivalent drugs and those with new formulations are continuously introduced, we intend to update this list periodically as they become available and as is feasible.

Comment: One commenter objected to the proposal to include injectable drugs with a labeled volume of 2 mL or less, which lack package type terms and explicit discard statements, in the definition of refundable single-dose containers or single-use package drugs. The commenter argued that the 2 mL threshold is arbitrary and would result in the misclassification of numerous drugs. The commenter recommended a comprehensive review of a broader range of injectable drugs, in consultation with physicians who administer these drugs, to determine if 2 mL is an appropriate threshold.

Response: We disagree with the commenter that the 2 mL threshold is arbitrary. According to FAQs [284] published by the Joint Commission in response to the question, ''What are the Joint Commission's expectations for managing multi-dose vials of sterile, injectable medication?'', multiple-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. If a multiple dose vial has been opened or accessed (for example, needle-punctured), the vial should be dated with the last date that the product should be used (expiration date) and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. An exception to this guidance on the presence of preservative applies to certain vaccines and allergenic product described in 21 CFR 610.15(a).[285] In contrast, single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative. As a result, once the necessary amount is withdrawn, any remaining contents in the single-dose or single-use vials must be discarded.

When a drug lacks explicit package terms or discard statement, we proposed to treat it as a single-dose container. If a drug does not contain a preservative or include labeling about stability and sterility after being opened, it is reasonable to infer that it is not intended to be used as a multiple-dose container. In the absence of such critical information, treating the product as single-dose container minimizes the risk of contamination from multiple entries, which could compromise patient safety. This conservative approach aligns with the principle of *first, do no harm,*[286] ensuring that safety is prioritized in the face of uncertainty.

Initially, we considered injectable drugs that lacked the package type terms and explicit discard statements, regardless of their labeled volume, to be packaged in single-dose containers. However, given that many of these drugs have a labeled volume of 2 mL or less and typically yield no more than one dose from the container, we intentionally proposed to narrow the scope of our policy to only drugs with a labeled volume of 2 mL or less. We proposed this narrowing in an effort to mitigate any unintended consequences from this policy change. We note that this clarification would apply to very few drugs, most likely those approved by the FDA before 2018, as most drugs approved since the publication of FDA

[283] *https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=485d9b71-6881-42c5-a620-a4360c7192ab.*

[284] *https://www.jointcommission.org/standards/standard-faqs/behavioral-health/medication-management-mm/000001529/#:~:text=If%20a%20multi%2Ddose%20has,date%20for%20that%20opened%20vial.*

[285] *https://www.ecfr.gov/current/title-21/part-610/section-610.15#p-610.15(a).*

[286] *https://www.cms.gov/blog/first-do-no-harm.*

guidance include package type terms and discard statements.

Comment: One commenter inquired how refunds will be calculated when a drug subject to the discarded drug refund policy no longer meets the definition of refundable drug mid-way through a quarter. Specifically, the commenter asked on which date CMS would consider a single source drug to become a multiple source drug, thereby no longer meeting the definition of refundable drug.

Response: CMS internally evaluates drugs each quarter to determine whether each is a single-source drug or biological (as defined in section 1847A(c)(6)(D) of the Act) or multiple source drug (as defined in section 1847A(c)(6)(C) of the Act). That is, for a given calendar quarter, a drug cannot be considered both a single source drug and a multiple source drug. When a drug that is rated as therapeutically equivalent in FDA's Orange Book [287] to a previously single source drug is newly marketed and sold, and partial quarter data is reported to CMS for the therapeutically equivalent product in a quarter, then that data is included in the calculation of the volume-weighted ASP-based payment limit for the quarter. The therapeutically equivalent product is crosswalked to the same billing and payment code as the previously single source drug. Therefore, both drugs become multiple source drugs for that entire quarter. It follows that, if a refundable drug becomes multiple source drug mid-way through a quarter, it would be a multiple source drug for the entire quarter and would not meet the definition of refundable drug for the quarter, provided that both the original product (likely the reference listed drug) and one or more therapeutically equivalent products are marketed and sold in the same quarter.

For example, if a therapeutically equivalent product to a single source drug is first marketed and sold in May 2024, the original product (that is, the single source drug) would be reclassified as a multiple source drug starting in the second quarter of 2024. Even though the therapeutically equivalent product was introduced mid-way through the quarter, both drugs would be treated as multiple source drugs for the entire second quarter. As a result, starting in the second quarter of 2024 and continuing thereafter, the original drug would no longer be classified as a single source drug or meet the definition of a refundable single-dose container or single-use package drug. This change exempts the drug from the discarded drug refund policy for that quarter and beyond.

In contrast, if all therapeutically equivalent products are no longer sold or marketed and only the reference listed drug remains, which was previously classified as a multiple source drug, the reference listed drug would be reclassified as a single source drug. However, if the reference listed drug is no longer sold or marketed and only one therapeutically equivalent product remains, the therapeutically equivalent product would continue to be classified as a multiple source drug because it was approved by the FDA under an *abbreviated* new drug application (ANDA). According to section 1847A(c)(6)(D)(ii) of the Act, a single source drug is defined as a drug approved by the FDA under a new drug application.

After consideration of public comments, we are finalizing the amendment of the definition of *Refundable single-dose container or single-use package drug* at § 414.902 as proposed.

(3) Skin substitutes

As discussed in the CY 2023 PFS final rule (87 FR 69650 through 69655), CMS aims to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes. In the CY 2024 PFS final rule (88 FR 79060 through 79061), we finalized that billing and payment codes that describe products currently referred to as skin substitutes were not counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024.

While we continue to consider changes to the Medicare Part B payment policies for these products, we are finalizing, similar to last year, that billing and payment codes that describe products currently referred to as skin substitutes will not be counted for the purposes of identifying refundable drugs for calendar quarters in 2025. A more detailed discussion of potential future billing approaches for skin substitute products, including comments and responses, is provided in section II.K of this final rule.

d. Discarded amounts

Effective January 1, 2017, providers and suppliers were required to report the JW modifier on all claims that bill for drugs separately payable under Medicare Part B with unused and discarded amounts (that is, discarded amounts) from single-dose containers or single-use packages. In the CY 2023 PFS, we finalized the requirement to use the JW modifier for single-dose container drugs that are separately payable under Part B, and we finalized the use of the JW modifier (or any successor modifier that includes the same data) to identify discarded billing units of a billing and payment code for the purpose of calculating the refund amount as described in section 1847A(h)(3) of the Act. In that final rule, to align with the JW modifier policy, we also finalized the requirement that, beginning July 1, 2023, the JZ modifier is required when there are no discarded amounts of a single-dose container drug for which the JW modifier would be required if there were discarded amounts.

In the CY 2023 PFS final rule (87 FR 69723), we discussed the applicability of the JW and JZ modifiers to drugs that are not administered by the billing supplier, including drugs furnished through a covered item of DME that may be administered by the beneficiary. In such cases, we stated that the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the patient's home. In the JW Modifier and JZ Modifier Policy FAQ document [288] released on January 5, 2023, we reiterated that suppliers who dispense but do not actually administer a separately payable drug are not expected to report the JW or JZ modifier.

Then, in the CY 2024 PFS final rule (88 FR 79062), we finalized a change to this policy, such that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier. This meant that the JW modifier would not be used on these claims. As we stated in that rule, in the absence of a claims modifier to designate that a drug was dispensed, but not administered, by the billing supplier (as finalized in the CY 2023 PFS), we were concerned that claims rejections may occur. Therefore, this change in policy required the JZ modifier on all such claims to ensure claims rejections did not occur unnecessarily. On October 16, 2023, we updated the JW Modifier and JZ Modifier Policy FAQ document to include the requirement of the JZ modifier by the supplier. However, after this policy was finalized, interested parties have requested further clarification on how to appropriately bill for discarded amounts from single-dose containers when there are amounts

[287] *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.*

[288] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.*

discarded during preparation by the billing supplier who is not administering the drug. To provide additional clarity, we proposed to require the JW modifier if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. Such a supplier would report the JZ modifier if no amounts were discarded during the preparation process before supplying the drug to the patient.

We believe this proposal is appropriate because drug preparation occurs before supplying a drug to the beneficiary and the billing supplier can determine the discarded amount at the site of drug preparation. These discarded units should be billed using the JW modifier in the same way as a drug that is administered incident-to physician service. In addition, suppliers and other interested parties have expressed that suppliers are accustomed to using the JW modifier in this context already. Therefore, we proposed to require the JW modifier if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. For example, if a billing supplier prepares a dose from a single-dose vial labeled as containing a total of 50 billing units such that 45 billing units of the drug are used in the prepared dose and 5 billing units are discarded during preparation, and then the drug is supplied to the patient (but not administered by the supplier), the claim should be submitted on two lines: 45 units (without a modifier) and 5 units with the JW modifier. We reiterate that suppliers who dispense a drug, but do not actually administer the drug, are not expected to monitor or bill for discarded amounts that are discarded after the drug is supplied because they are not at the site of administration to measure discarded amounts. For example, if the patient who was supplied the above dose with 45 billing units subsequently only receives 35 of those billing units, the above billing supplier would not be expected to account for the 10 subsequently discarded billing units on the claim. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Four commenters expressed general support for the proposal to require the JW modifier for reporting discarded amounts during drug preparation by a billing supplier.

Response: We thank the commenters for their support.

Comment: One commenter requested clarification on the definitions of ''supplier'' and ''provider'' as they relate to the JW modifier to prevent ambiguity about who this proposed policy applies to.

Response: In § 400.202,[289] ''supplier'' is defined as a physician, or other practitioner, or an entity other than a provider that furnishes health care services under Medicare. In contrast, ''provider'' is defined in § 400.202 as a hospital, critical access hospital (CAH), skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice, or a clinic, rehabilitation agency, or public health agency that furnishes outpatient physical therapy or speech pathology services, all of which must have an agreement to participate in Medicare. The definition of ''provider'' also includes community mental health centers with a similar agreement to provide partial hospitalization services. For the purposes of the JW and JZ modifier requirements, a billing supplier or billing provider who prepares but does not administer the drug would be subject to the JW and JZ modifier requirements.

We received several comments regarding the JW and JZ modifier requirements more generally. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern about the administrative burden associated with the use of modifiers. One commenter, without providing further details, stated that the use of any modifiers for billing drugs creates an administrative burden. Another commenter specified that the burden stems from the added complexity involved in preparing and administering chemotherapy drugs. Specifically, one commenter noted that drugs used for cancer treatments are disproportionately subject to discarded drug refund requirements, citing 2020 CMS drug pricing dashboard data that showed 22 of the 39 drugs with over 10 percent discarded amount were cancer drugs. The commenters suggested CMS conduct outreach to impacted providers for modifier training and collect data to evaluate whether the JW modifier imposes an excessive burden on suppliers.

Response: We thank the commenters for their feedback. For a complete discussion on potential burden as to JW and JZ modifiers, we refer readers to our discussion in the CY 2023 PFS final rule (87 FR 69711 through 69720), in which we codified the JW modifier policy that had been in place since 2017.

In that rule, we explained that the most practicable method for improving our data quality for amounts of discarded drug is by requiring providers filing claims for drugs from single-dose containers to report either a JW modifier when there are discarded amounts, or JZ modifier when no amount is discarded. We continue to believe providers are the only party that can obtain complete and accurate information on used and discarded amounts of variably dosed drugs. We acknowledge that, in some situations, it may be difficult to quantify discarded quantities of drugs and associate the specific amount with a single beneficiary, but we believe that, in most situations, there are no practical impediments that would prevent billing providers or other staff, such as nurses or pharmacists, from incorporating the measurement of discarded amounts into the process of preparing and administering the drug.

Further, we stated in the CY 2024 PFS final rule (88 FR 79062) that we believe that in most cases the JW and JZ modifier requirements impose no new burdens on providers beyond the requirement of measuring and reporting discarded amounts by use of the JW modifier that predates the enactment of the discarded drug refund policy under section 1847A(h) of the Act. Providers and suppliers who have been complying with the JW modifier requirement effective January 1, 2017 have already been assessing and documenting what is needed for the JZ modifier, and the new requirement of reporting the JZ modifier is minimal and justifiable for the purposes of obtaining more complete discarded amount data.

According to the HHS Assistant Secretary for Planning and Evaluation (ASPE),[290] biologicals contributed to 89 percent of the growth in Part B drug spending from 2008 to 2021. The report also highlighted that 12 of the 20 top drugs and biologicals by expenditure carried oncology indication(s). As the utilization and expenditure of drugs and biologicals continue to rise, the implementation of the discarded drug refund policy will help reduce waste and control spending within the Medicare Part B program.

As noted in the 2024 PFS final rule (88 FR 79059), most drugs in single-dose containers are manufactured in package sizes efficient enough to keep discarded amounts below 10 percent. We believe that drugs with more than 10 percent

[289] *https://www.ecfr.gov/current/title-42/section-400.202.*

[290] *https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.*

discarded amounts could reflect an inefficiency related to vial sizes and high utilization. Since JZ and JW modifiers apply equally to all drugs packaged in single-dose containers, CMS does not target any particular subset of drugs, including therapeutic classes. A high discarded amount is likely due to mismatch between vial sizes and patient needs, leading to excess drug being discarded after each use.

CMS has created Discarded Drug Refund website [22] for additional information, and following the publication of this final rule, the Medicare Claims Processing Manual will be updated with the finalized policies regarding the JW and JZ modifiers. These updates will be accompanied by other CMS communications, such as an MLN Matters® article, directed to the provider community.

Comment: One commenter expressed concern about the administrative burden on ophthalmic practices due to the drug modifier requirement, particularly for intravitreal drug injections. The commenter requested a 100 percent increase in the applicable percentage to exempt ophthalmic drugs with labeled volume of less than 1mL.

Response: As discussed in the previous response, we stated in the CY 2023 PFS final rule (87 FR 69711 through 69720) that the burden of the JW and JZ modifier requirements is not a recent occurrence, as the JW modifier policy has been in place since 2017 and was codified in the CY 2023 final rule without change. Providers should currently be reporting the JW modifier on their claims, as well as documenting the discarded amounts in the beneficiary's medical records. We further explained that the most practicable method for improving our data quality for amounts of discarded drug is by requiring providers filing claims for drugs from single-dose containers to report either a JW modifier when there are discarded amounts, or JZ modifier when no amount is discarded. We also stated (87 FR 69724) that increasing the applicable percentage to 100 percent does not relieve the burden complying with the JW and JZ modifier requirements.

Section 1847A(h) of the Act establishes that CMS provide information on the total number of units of the billing and payment code, if any, that were discarded during a quarter, as determined by the JW modifier (or any such successor modifier that includes such data). Section 1847A(h)(8)(B) of the Act delineates three exclusions from the definition of refundable drug, one of which includes a specific class of drugs—radiopharmaceuticals and imaging agents—and does not include ophthalmic drugs. CMS has compiled a list of drugs with an increased applicable percentage, emphasizing that many injectable ophthalmic drugs are already included in this category on the Discarded Drug Refund website.[291]

Comment: One commenter noted the use of the JW modifier might lead to unintended consequences with Medicare's Medically Unlikely Edits (MUEs), potentially resulting in unnecessary claim denials. MUEs set the maximum number of units of a drug or service that can be reported on a claim. The current MUE policy includes both administered and discarded units in this calculation. The commenter explained that the MUE limit for Tecvayli® (teclistamab-cqyv, HCPCS code J9380) is 480 billing units, which could lead to claims denials if two vials of Tecvayli®, each containing 153 mg (that is, 306 billing units per vial), are used. The commenter recommended that the MUE policy be amended to exclude discarded units identified by the JW modifier from the unit of service calculations to prevent these unnecessary denials.

Response: The MUE files [292] for both facility outpatient hospital services and practitioner services, effective July 1, 2024, listed the MUE limit for Tecvayli® as 480 units, as the commenter noted. However, we clarify that effective October 1, 2024, the limit in the MUE file is 612 units to accommodate claims for two vials.

After consideration of public comments, we are finalizing the proposal that the JW modifier is required when a billing supplier is not administering a drug but discards drug amounts during the preparation process before supplying it to the patient. We are finalizing that JZ modifier is required if no drug amounts are discarded during preparation.

We received a few general comments about the discarded drug refund provisions. Below is a summary of comments and our responses.

Comment: One commenter cited *Loper Bright Enterprises* v. *Raimondo,* stating that ''courts [must] use every tool at their disposal to determine the best reading of the statute.'' [293] The commenter argued that CMS failed to adopt the ''best reading'' of the statutory requirement for the discarded drug refund, contending that its interpretation unfairly penalizes manufacturers with ''refundable drugs'' available on the market when the regulations took effect, despite regulatory decisions being made in compliance with laws prior to the enactment of section 90004 of the Infrastructure Act.

Response: As stated in the CY 2023 PFS final rule (87 FR 69713), we do not have discretion on whether to implement the Infrastructure Act, which was signed into law on November 15, 2021. As these policies affect refunds that will be paid in the future after the promulgation of the rule, there are no retroactive effects on payments that have already been made.

Specifically, manufacturers were informed that drugs in vial sizes specified in FDA labeling, with discarded amounts exceeding the 10 percent applicable percentage, would trigger the refund policy beginning on January 1, 2023, such that no retroactive penalties are imposed. While some vial sizes optimized for manufacturing prior to the Infrastructure Act may no longer be considered efficient due to resulting discarded amounts, our policy reflects the standards set by Congress. Therefore, we maintain that our interpretation of the statutory requirement for the discarded drug refund is appropriate and does not unfairly penalize manufacturers.

Comment: One commenter expressed the requirement in the CY 2024 PFS final rule raises due process concern, stating that ''the requirement attaches new legal consequences to events completed prior to enactment of the law, and this retroactive effect of the law is in conflict with the well-established due process principle of fair notice.''

Response: We disagree with the view that implementation violated the principle of fair notice. As these policies affect refunds that will be paid in the future after the promulgation of the rule, we disagree that our proposed implementation of section 1847A(h) of the Act violates the due process principle of fair notice. There are no retroactive effects on payments that have already been made. Additionally, we have finalized the requirement to provide ample notice that the refund amounts specified in the initial refund report must be paid no later than February 28, 2025. This includes provisions for the application process related to increased applicable percentages and dispute resolution. Furthermore, we have made every effort to keep interested parties informed

[291] *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs.*

[292] *https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-medically-unlikely-edits.*

[293] *Loper Bright Enters. v. Raimondo, No. 22–1219, 2024 WL 3208360, at *16 (2024).*

about the new requirements by providing as much advance notice as possible, including information on the decision to revisit the process and timeline for manufacturers' provisions of refunds (87 FR 69727) to align with the Medicare Prescription Drug Inflation Rebate Program.

The rule aligns with fair notice standards by clearly setting forth explicit criteria, timelines, and thresholds, allowing manufacturers to adjust their practices accordingly. While we recognize that adjusting vial sizes may require time and resources, the regulation applies prospectively and is intended to promote efficiency and minimize drug waste in a fair and transparent manner.

Comment: One commenter recommended evaluating whether CMS's proposals regarding the 18-month exclusion period, the clarification for identifying single-dose containers, and use of JW and JZ modifiers when a billing supplier is not administering a drug effectively reduce wastage and inappropriate overpayment for unused medication. The commenter recommended that CMS conduct this evaluation by measuring payment timeliness, administrative burden, and product adjustments by provider.

Response: We recognize the importance of assessing whether these measures effectively reduce wastage and prevent inappropriate payment for unused medications. We began applying claims edits for both the JW and JZ modifiers on October 1, 2023 (87 FR 69718 through 69719). As we monitor reporting information for refundable drugs with multiple manufacturers, we plan to analyze the following: (1) the frequency of claims with JW versus JZ modifiers, which will help identify drugs with non-optimized package sizes and prescribing patterns by providers; (2) trends in refund amount, which may reveal insights, such as decreasing refund amounts suggesting lower drug utilization or optimized package sizes, while increasing refund amounts may indicate higher drug utilization or new indications requiring different dosing; (3) the frequency of disputes and the timeliness of their resolution, which may highlight issues that we cannot directly measure, such as administrative burden. We also regularly update the list of specific billing and payment codes that we identified as being assigned exclusively to single-dose containers. We believe that analyzing the variability in the percentage of discarded drugs from quarter to quarter can inform future policy development.

2. Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales Price (ASP) Data (§ 414.904)

a. Background

Drugs payable under Medicare Part B fall into three general categories: those furnished incident to a physician's service (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those furnished via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and other drugs for which coverage is specified by statute (for example, certain vaccines described in sections 1861(s)(10)(A) and (B) of the Act). Payment limits for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. If CMS determines a payment limit for a drug, it is published in the ASP pricing file or Not Otherwise Classified (NOC) pricing file,[294] which are both updated quarterly.

We generally calculate the payment limits for drugs payable under Part B on a quarterly basis using the manufacturer's ASP (as defined in § 414.902). Manufacturers are required to report ASP to CMS under sections 1847A(f)(2) and 1927(b)(3) of the Act. Manufacturers are instructed to calculate ASP in accordance with section 1847A(c) of the Act and § 414.804(a).

For each NDC, in most cases, the manufacturer's ASP is a positive dollar value, along with a positive number of units sold (hereinafter referred to as ''positive manufacturer's ASP data''). However, sometimes the reported data is not positive manufacturer's ASP data. Specifically, a manufacturer could report that an NDC has a negative or zero-dollar value for the manufacturer's ASP with a positive, negative, or zero number of units sold, or a positive dollar value for the manufacturer's ASP with a negative or zero number of units sold (each of these scenarios is hereinafter referred to as ''negative or zero manufacturer's ASP data''). Such negative or zero manufacturer's ASP data could occur because of lagged discounts, units returned to the manufacturer, drug shortages, discontinuation of a drug, or other reasons that are not known to CMS. Negative or zero manufacturer's ASP data can occur when a manufacturer calculates its ASP in accordance with section 1847A of the Act.

First, section 1847A(c)(3) of the Act requires that the manufacturer's calculation of its ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program or the Medicare Prescription Drug Inflation Rebate Program) (hereinafter referred to as ''price concessions''). Second, section 1847A(c)(5)(A) of the Act requires each manufacturer to apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to price concessions if there is a lag in the reporting of the information on rebates and chargebacks under section 1847A(c)(3) of the Act. These provisions may result in the inclusion of large price concessions from a quarter or quarters with a higher sales price prior to price concessions in the ASP calculation for a subsequent quarter with a much lower sales price, which can result in negative dollar value ASP. The same situation could happen in a quarter if more units were returned to the manufacturer than are sold, which can result in a negative dollar value ASP as well as a negative number of units sold. The requirement to use a rolling average for lagged price concessions is codified at § 414.804(a)(3), which states that, to the extent data on price concessions are available on a lagged basis, the manufacturer must estimate its ASP in accordance with the described methodology in that paragraph. In certain instances, as stated above, lagged price concessions can lead to negative or zero manufacturer's ASP data.

In 2022, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a report assessing potential inaccuracies in manufacturer reporting of ASP and noted that manufacturers believe additional guidance may be needed to reduce distortions and inconsistencies in the calculation of payment limits.[295] The report found that several manufacturers would like additional guidance regarding reporting of negative ASP data and how CMS uses negative ASP data in payment limit calculations. CMS concurred with the OIG's recommendation to actively review current guidance and determine whether additional guidance would

[294] *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[295] OEI–BL–21–00330. *https://oig.hhs.gov/oei/reports/OEI-BL-21-00330.asp.*

ensure more accurate and consistent ASP calculations.

Accordingly, we reviewed our current guidance and determined that it is appropriate for us to provide additional guidance regarding how CMS will handle payment for drugs separately payable under Part B when the manufacturer's ASP for at least one NDC within the billing and payment code (that is, HCPCS code) of the drug is negative or zero. Currently, when all NDCs assigned to a HCPCS code have negative or zero manufacturer's ASP data, CMS establishes the payment limit in other ways. As appropriate given the data available for a drug, we will either calculate a payment limit for a billing and payment code based on other applicable and available pricing data or not include a payment limit for the billing and payment code on the ASP pricing file. When a payment limit for a drug separately payable under Part B is not included in the ASP pricing file, the payment limit is based on either the published Wholesale Acquisition Cost (WAC) or invoice pricing, as described in section 20.1.3, Chapter 17 of the Medicare Claims Processing Manual.[296]

We previously contemplated how to set a payment limit in certain situations in which ASP data is ''not available'' for multiple source drugs. In the CY 2011 PFS final rule (75 FR 73461 through 73465), we addressed situations in which ASP data for some, but not all, NDCs in a multiple source drug billing and payment code are not available for the calculation of an ASP payment limit (for example, if a manufacturer's entire submission of data was not received or manufacturer's ASP data for specific NDCs was not reported).[297] In that rule, we finalized a process, consistent with authority in section 1847A(c)(5)(B) of the Act, to update payment limits based on the manufacturer's ASP reported for the most recent quarter for which data are available. We specified that if manufacturer's ASP data is not available for some but not all NDCs in a multiple source drug billing and payment code prior to the publication deadline for quarterly payment limits and such unavailability of manufacturer's ASP data significantly changes the quarterly payment limit for the billing and payment code when compared to the prior quarter's payment limit, CMS will calculate the payment limit by carrying over the most recently available manufacturer's ASP from a previous quarter for an NDC, adjusted by the weighted average of the change in the manufacturer's ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter, and codified this policy in § 414.904(i).[298] In that final rule, we explained that such circumstances are limited to when a manufacturer's data for a multiple source drug product with sales during a quarter is missing, and efforts to obtain manufacturer reported ASP data before Medicare ASP payment limits publication deadlines have not been successful. We continue to believe that this process, which we apply in cases ASP data is ''not available'' for some but not all NDCs associated with a multiple source billing and payment code, is appropriate.

b. Approach to Payment Limit Calculations When Manufacturer's ASP Data is not Available

As described in the previous section, we determined that it is appropriate for CMS to provide additional guidance regarding how we will handle payment for drugs separately payable under Part B when the reported manufacturer's ASP for at least one NDC within the billing and payment code (that is, HCPCS code) of the drug is negative or zero (that is, has negative or zero manufacturer's ASP data). As detailed below, we proposed to consider ASP data to be not ''available'' for the purposes of calculating a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported, consistent with section 1847A(c)(5)(B) of the Act. We also proposed how CMS would calculate a payment limit in these circumstances, consistent with section 1847A(c)(5)(B) of the Act.

Our existing policy, before the regulatory changes finalized in this final rule as discussed below, did not address how payment limits are calculated for several situations in which a drug separately payable under Part B does not have available ASP data. The set of situations in which this might occur include circumstances in which either some or all NDCs for a billing and payment code have a negative or zero manufacturer's ASP data; in which negative or zero manufacturer's ASP data is reported for a drug which has been discontinued; and vary further depending on whether a drug is multiple source or single source (both as defined in § 414.902). In each of these circumstances, there are various other pricing data available that we believe can appropriately be used to calculate a payment limit.

Therefore, we proposed, consistent with section 1847A(c)(5)(B) of the Act, a methodology for calculating payment limits in certain circumstances based on manufacturer's ASP for the most recent quarter for which data are available. Specifically, we proposed to specify that positive manufacturer's ASP data are considered ''available'' and that negative or zero manufacturer's ASP data are considered ''not available'' for purpose of CMS calculating a payment limit under the statute. We believe it is appropriate to consider negative or zero manufacturer's ASP data to be not available because if used to calculate a payment limit, this data can result in a negative or zero payment limit, which would require CMS to collect payment from providers and suppliers for a drug, rather than make payment for a drug. Negative or zero payment limits for a drug are not reasonable because Medicare does not expect to collect payment from providers and suppliers for their provision of separately payable drugs. Therefore, we proposed to specify the methodology we will use for calculating the payment limit in such circumstances to ensure reasonable payment amounts based on the best available data for separately payable drugs. In the following sections, we proposed how payment limits would be determined using available ASP data for each scenario.

We received comments regarding this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for our proposal to consider positive manufacturer's ASP data ''available'' and to consider negative or zero manufacturer's ASP data ''not available'' for the purpose of calculating payment limits under the section 1847A of the Act. The commenter stated they believe this would provide predictability for manufacturers and mutual accountability between CMS and manufacturers when ASP data isn't available. Another commenter shared their support for using available pricing data as a basis for payment limits when manufacturers report negative or zero manufacturer's ASP data. The commenter stated that they support a pricing metric that accounts for price concessions, citing program cost savings, and oppose those that do not account for price concessions, such as WAC and average wholesale price (AWP).

Response: We thank the commenter for their support. We generally agree

[296] *https://www.cms.gov/%E2%80%8BRegulations-and-Guidance/%E2%80%8BGuidance/%E2%80%8BManuals/%E2%80%8BDownloads/%E2%80%8Bclm104c17.pdf.*

[297] *https://www.govinfo.gov/content/pkg/FR-2010-11-29/pdf/2010-27969.pdf.*

[298] *https://www.ecfr.gov/current/title-42/part-414/section-414.904#p-414.904(i).*

with the commenter that a pricing metric that accounts for price concessions is preferable as the basis of payment limits when manufacturer's ASP data from the most recent quarter is unavailable; in general, we also believe use of the most recent positive ASP data available for a billing and payment code for a drug is most consistent with the payment limit calculations described in section 1847A(b) and (c) of the Act, including section 1847A(c)(5)(B) of the Act.

After consideration of public comments, we are finalizing our policy as proposed that for the purposes of calculating a payment limit for Part B drugs, we will consider positive manufacturer's ASP data ''available'' and negative or zero manufacturer's ASP data ''not available.''

c. Single and Multiple Source Drugs When Negative or Zero Manufacturer's ASP Data is Reported for some, but not all NDCs

In the case that a drug separately payable under Part B has negative or zero manufacturer's ASP data reported for some, but not all, NDCs associated with a billing and payment code for that drug, we proposed to calculate a payment limit using only NDCs with positive manufacturer's ASP data (and omitting NDCs with negative or zero manufacturer's ASP data) for that drug and proposed to codify this at § 414.904(i). We proposed this policy to apply to both single source drugs and biologicals, including biosimilar biological products (defined at § 414.902) (hereinafter referred to as a ''biosimilars'') and multiple source drugs. We believed this was appropriate because it would result in payment limits based on the most recent positive manufacturer's ASP data reported by manufacturers with NDCs associated with a billing and payment code.

However, we noted that, as discussed in section III.A.2.a of this final rule, CMS already has a policy in place for multiple source drugs for which the absence of ASP data would result in a significant change (that is, a 10 percent or greater change) in the ASP payment limit compared to the payment limit of the previous quarter, as finalized in the CY 2011 PFS final rule (75 FR 73461 through 73465). In that discussion (75 FR 73462), we noted several examples of situations in which data is not available to be included in the calculation of a payment limit, such as when a manufacturer's entire submission was not received or when the manufacturer's ASP data for specific NDCs has not been reported. We did not intend for our proposed policy to override that existing policy; rather, we intend for the proposed policy described above to address circumstances not addressed in that rulemaking (that is, we intend to address circumstances of single source drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs, and of multiple source drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs and the absence of such data from the calculation of the payment limit does not result in a significant change in the payment limit compared to the payment limit of the previous quarter) and thus fill a policy gap. In addition, the circumstances we provided as examples in which ASP data is not available in the CY 2011 PFS final rule continue to be circumstances we consider manufacturer's ASP data not available under current § 414.904(i) (which we proposed to move within § 414.904(i) to fit within the structure of the proposed new set of payment limit methodologies); but, as noted in section III.A.2.b of the rule, we are expanding what we consider to be not available to include circumstances in which negative or zero manufacturer's ASP data is reported.

We received several public comments on the proposed payment limit calculation for single and multiple source drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for the proposal for calculation of the payment limit for drugs when negative or zero manufacturer's ASP data is reported for some, but not all NDCs, specifically as it would apply to biosimilars.

Response: We thank the commenter for their support.

Comment: One commenter opposed the approach of using available positive ASP data when some but not all NDCs are reported with positive ASP data for single source drugs and biologicals, including biosimilars. The commenter recommended an alternative approach that calculates the volume-weighted ASP for a drug in this circumstance using the most recent positive manufacturer's ASP for each NDC in the billing and payment code, while using the current quarter's reported units sold for each NDC. The commenter suggested this would result in a payment limit that more accurately reflects market conditions than simply relying on only the NDCs that have positive ASP data in a given quarter, as we proposed in this section.

Response: We thank the commenter for their thoughtful response. Subsection 1847A(c)(5)(B) of the Act directs the Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent calendar quarter for which such data are available. We believe our proposal for single source drugs and biologicals is consistent with subsection (c)(5)(B) of section 1847A of the Act, which directs the Secretary to use available ASP data from a singular quarter, that being the most recent one with positive manufacturer's ASP data for a given drug.

Further, we believe the proposed policy would base payment limits on data most closely related to the current market conditions because it would rely on the most recently available data required to be reported under section 1847A(c) of the Act from a full calendar quarter associated with a billing and payment code. We disagree with the commenter that calculating the payment limit for a drug using positive manufacturer's ASP data from multiple quarters would result in a payment limit that is more reflective of current market conditions because more time would have passed since the sales reflected in the additional quarters for which inclusion is sought by the commenters. The manufacturer's positive ASP data in a given quarter represent the full set of most recently available data for the statutory calculation of an ASP-based payment limit, as discussed in section III.A.2.a of this final rule; the data set is not made more complete or accurate by the inclusion of older data.

Comment: Two commenters recommended that in lieu of our proposal for calculating a payment limit for a drug with negative or zero manufacturer's ASP data reported for some, but not all, associated NDCs, the ASP payment limit should be calculated using a volume-weighted average of available positive manufacturer's ASP data from the previous four quarters for which data are available. The commenters recommended this approach to smooth payment limit fluctuations caused by changes in the market. One commenter described this recommendation as consistent with the policy we finalized in the CY 2011 PFS final rule (75 FR 73461 through 73465), described above.

Response: We thank the commenters for their feedback. As noted above, section 1847A(c)(5)(B) of the Act directs the Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent single calendar quarter for which such data are available, rather than

several quarters. For this reason, we believe using a single quarter of data, as proposed, is most appropriate.

We disagree with the commenters who described carrying over four quarters of ASP data as consistent with the existing carryover policy finalized in the CY 2011 PFS final rule. Under this policy, in circumstances in which the unavailability of manufacturer's ASP data for an NDC causes a significant change in the ASP payment limit when compared to that of the previous quarter, CMS carries over only a single previous quarter's available ASP data for the NDC. In addition, as the commenter suggested a need for smoothing, we note that a smoothing function is already incorporated in the calculation of ASP payment limits by section 1847A(c)(5)(A) of the Act and codified at § 414.804(a)(3), which requires manufacturers to factor a 12-month rolling average to estimate the costs attributable to rebates and chargebacks. We disagree with the commenters that an additional smoothing function using older data would lead to payment limits more representative of current market prices.

After consideration of these comments, and for the reasons stated above and in the proposed rule, we are finalizing as proposed the calculation of the payment limit for a drug separately payable under Part B with negative or zero manufacturer's ASP data reported for some, but not all, NDCs associated with a billing and payment code for that drug at § 414.904(i). We will calculate the payment limit for such a drug using only NDCs with positive manufacturer's ASP data (and omitting NDCs with negative or zero manufacturer's ASP data). This policy applies to single source drugs and biologicals, including biosimilars, and multiple source drugs.

d. Multiple Source Drugs With Only Negative or Zero Manufacturer's ASP Data

In the case of a multiple source drug (as defined in § 414.902) separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug (and at least one NDC for the drug is actively being marketed (that is, not discontinued)), we proposed to carry over all positive manufacturer's ASP data from the most recently available previous quarter with positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter. Specifically, we proposed to calculate the payment limit for the applicable quarter using data from the most recent calendar quarter for which ASP data are available, that is, for which there is positive manufacturer's ASP data. We believe this is appropriate because, similar to the methodology described in section III.A.2.c of this rule, it would result in payment limits based on the most recent positive manufacturer's ASP data reported by manufacturers with NDCs associated with a billing and payment code. Similarly, we believe the most recently available positive manufacturer's ASP data from NDCs associated with a billing and payment code are more likely to be reflective of providers' acquisition costs for drugs associated with that billing and payment code in a given quarter than other pricing data, and unlikely to result in challenges to access for these drugs for providers and beneficiaries.

We note that because section 1847A of the Act provides for payment limit calculations that differ between single-source drugs (as defined in section 1847A(c)(6)(D) of the Act and § 414.902) and multiple source drugs (as defined in section 1847A(c)(6)(C) of the Act and § 414.902), we proposed different ways to determine payment limits for each, in cases in which only negative or zero manufacturer's ASP data is reported, to reflect these differences. Specifically, the payment limit for single source drugs is described in section 1847A(b)(4) of the Act; for multiple source drugs, the payment limit is described in section 1847A(b)(3) of the Act. The payment limit for single source drugs is determined using the lesser of ASP or WAC; but WAC is not used for multiple source drugs whose ASP exceeds WAC. Nonetheless, our proposals for the calculation of the payment limit for single source and multiple source drugs with only negative or zero manufacturer's ASP data are consistent in that, where ASP is used, we proposed to use the most recently available positive manufacturer's ASP data from at least one NDC for the drug. We believe using similar input data in our calculation of the payment limit is consistent with our goal to ensure reasonable payment amounts based on the best available data for separately payable drugs.

We proposed to amend § 414.904(i) to include the above proposal regarding how CMS would calculate the payment limit in circumstances in which only negative or zero manufacturer's ASP data is reported for a multiple source drug.

We received two comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Both commenters recommended that for multiple source drugs with only negative or zero manufacturer's ASP data, CMS calculate the ASP payment limit using a volume-weighted average of available positive manufacturer's ASP data from the previous four quarters for which data are available.

Response: We thank the commenters for their feedback. Our proposed approach to use a single calendar quarter of data is most consistent with the Secretary's requirement under section 1847A(c)(5)(B) of the Act because the statute directs that Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent single calendar quarter for which such data are available, rather than several quarters. For this reason, we believe using a single quarter of data is most appropriate. We also note a smoothing function for lagged price concessions is already incorporated into the ASP payment limit calculation by section 1847A(c)(5)(A) of the Act. We disagree with the commenters that an additional smoothing function using older data would lead to payment limits more representative of current market prices. We refer readers to the response to the same approach recommended for single and multiple source drugs when zero or negative manufacturer's ASP data are reported for some, but not all NDCs in section III.A.2.c of this rule.

After consideration of these comments, and for the reasons stated above and in the proposed rule, we are finalizing as proposed the methodology for calculating the payment limit for a multiple source drug separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug at § 414.904(i). We will calculate the payment limit for such a drug using all positive manufacturer's ASP data from the most recently available previous quarter for which ASP data are available for at least one NDC.

e. Single Source Drugs With Only Negative or Zero Manufacturer's ASP Data, Excluding Biosimilar Biological Products

In the case of a single source drug, excluding biosimilars (both as defined in § 414.902), separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug (and at least one NDC for the drug is actively being marketed (that is, not discontinued)), we proposed to set the payment limit for

the given quarter for the single source drug at the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

- 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for a quarter. If the payment limit from the quarter with the most recently available positive manufacturer's ASP data was based on 106 percent of the WAC because of the application of § 414.904(d)(1), that payment limit would be carried over; or
- 106 percent of the WAC for the given quarter. If there is more than one WAC per billing unit for the drug, the payment limit would be set using the lowest WAC per billing unit.

We proposed to only use the lesser of the positive manufacturer's ASP or WAC data from that previous quarter or the WAC data from the given quarter until positive manufacturer's ASP data are available for a future quarter. We proposed that once positive manufacturer's ASP data for a drug is available again in a future quarter, we would have data available to input into the routinely used methodologies described in section 1847A(b) of the Act and § 414.904.

As discussed above, we continue to believe it is appropriate to apply different policies for determining payment limits for single and multiple source drugs when negative or zero manufacturer's ASP data is reported because of statutory differences in the payment limit calculations.

We received several public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal for single source drugs, excluding biosimilars, when all NDCs have negative ASP data.

Response: We thank the commenter for their support.

Comment: One commenter recommended that for single source drugs with only negative or zero manufacturer's ASP data, excluding biosimilars, CMS set the payment limit by calculating the volume-weighted ASP for a drug in this circumstance using the most recent positive manufacturer's ASP for each NDC in the billing and payment code, while using the current quarter's reported units sold for each NDC.

Response: We thank the commenter for their feedback. Our proposed approach is most consistent with section 1847A(c)(5)(B) of the Act, which directs the Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent calendar quarter for which such data are available. In addition, we believe the proposed policy would base payment limits on data most closely related to the current market conditions because it would rely on the most recently available data required to be reported under section 1847A(c) of the Act from a full calendar quarter associated with a billing and payment code. We disagree with the commenter that calculating the payment limit for a drug using positive manufacturer's ASP data from multiple quarters would result in a payment limit that is more reflective of current market conditions because more time has passed since the sales reflected in the additional quarters for which inclusion is sought by the commenter. We refer readers to the response to the same approach recommended for single and multiple source drugs when zero or negative manufacturer's ASP data are reported for some, but not all NDCs in section III.A.2.c of this rule.

Comment: Two commenters recommended that for single source drugs with only negative or zero manufacturer's ASP data, excluding biosimilars, CMS calculate the ASP payment limit using a volume-weighted average of available positive manufacturer's ASP data from the previous four quarters for which data are available.

Response: We thank the commenters for their feedback. Our proposed approach to use a single calendar quarter of data is most consistent with the Secretary's requirement under section 1847A(c)(5)(B) of the Act because the statute directs that Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent single calendar quarter for which such data are available, rather than several quarters. For this reason, we believe using a single quarter of data is most appropriate. We also note a smoothing function for lagged price concessions is already incorporated into the ASP payment limit calculation by section 1847A(c)(5)(A) of the Act. We refer readers to the response to the same approach recommended for single and multiple source drugs when zero or negative manufacturer's ASP data are reported for some, but not all NDCs in section III.A.2.c of this rule.

After consideration of the comments we received, and for the reasons stated above and in the proposed rule, we are finalizing as proposed the methodology for calculating the payment limit for a single source drug, excluding biosimilars, separately payable under Part B that has negative or zero manufacturer's ASP data reported for all NDCs associated with a billing and payment code for that drug at § 414.904(i). We will set the payment limit for such a drug at the lesser of 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for a quarter and 106 percent of the WAC for the given quarter. In the former case, if the payment limit from the quarter with the most recently available positive manufacturer's ASP data was based on 106 percent of the WAC because of the application of § 414.904(d)(1), that payment limit will be carried over. In the latter case, if there is more than one WAC per billing unit for the drug, the payment limit would be set using the lowest WAC per billing unit.

f. Biosimilars With Only Negative or Zero Manufacturer's ASP Data

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter (and at least one NDC for the biosimilar is actively being marketed (that is, not discontinued)), and positive manufacturer's ASP data are available for another biosimilar(s) with the same reference biological product (hereinafter referred to as a ''reference product'') for the given quarter, we proposed to set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the particular biosimilar for which negative or zero manufacturer's ASP data is reported for all NDCs has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals as defined in § 414.902, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

We believe this proposal was appropriate because section 351(i)(2) of the Public Health Service Act defines the terms biosimilar and biosimilarity to mean that a biosimilar is highly similar to its reference product, notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of the

safety, purity, and potency of the product. In addition, biosimilars with the same reference product likely compete in the marketplace since they all rely on FDA's previous determination of safety, purity, and potency for the reference product for approval. For these reasons, we believe that when a biosimilar has only negative or zero manufacturer's ASP data, the volume-weighted average of positive manufacturer's ASP data of biosimilars with the same reference product would be an appropriate payment limit for a biosimilar that, under this proposal, would be considered to have ASP data that is not available. As such, we proposed to calculate the payment limit for a biosimilar with only negative or zero manufacturer's ASP data based on the positive manufacturer's ASP data of other biosimilars with the same reference product.

We noted that in the CY 2016 PFS final rule (80 FR 71096 through 71101), we finalized that we would group all biosimilars with a common reference product in a single billing and payment code with a single payment rate, in a manner similar to how we price multiple source or generic drugs because of the significant similarities between each biosimilar and its reference product. In the CY 2018 PFS final rule (82 FR 53182 through 53187), we changed the initial policy and finalized separate coding and payment for biosimilars. In that final rule, we stated that that there is a program need for assigning Part B biosimilars into separate billing and payment codes; specifically, that this policy change addressed concerns about the public interest in a stronger marketplace, access to these drugs in the United States marketplace, and provider and patient choice and competition. Our proposal for biosimilars with negative or zero manufacturer's ASP data reported for all NDCs is consistent with the CY 2018 PFS rulemaking, as it would not result in grouping biosimilars with a shared reference product in a single billing and payment code. Rather, it would allow CMS to calculate an operationally reasonable payment limit using positive manufacturer's ASP data for products that are biosimilar to a shared reference product in limited instances.

This proposal would also provide payment limit stability that could help avoid potential access issues for providers and beneficiaries that could otherwise occur if we were to calculate a payment limit for a drug with negative or zero manufacturer's ASP data that is far below the provider's cost for acquiring the drug. If a biosimilar's ASP falls below zero only after several quarters of declining but still positive manufacturer's ASP data, the most recent positive manufacturer's ASP data from a previous quarter for a drug may be significantly lower than the volume-weighted average of the biosimilars with the same reference product as the biosimilar with negative ASP data. In such a case, the payment limit based on the ASPs of competitor biosimilars would be higher than if we were constrained to use ASP data only from the biosimilar that has most recently reported negative or zero manufacturer's ASP data. We noted that under the methodology proposed in section III.A.2.c of this rule, in circumstances in which some, but not all NDCs of a single or multiple source drug are negative or zero, we would similarly calculate the payment limit using only NDCs with positive manufacturer's ASP data from the given quarter and omitting those that had declined to zero or a negative value in ASP or sales. Likewise, we believe that such an approach would likely result in a payment limit reflective of providers' acquisition costs of biosimilars and be helpful in avoiding access issues for providers and beneficiaries.

In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a biosimilar for a given quarter and either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, we proposed that we would set the payment limit for the given quarter equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference product (as defined in § 414.902) for the given quarter.

In situations in which CMS would use the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter, we proposed we would only use positive manufacturer's ASP data from that previous quarter until positive manufacturer's ASP data are available for a future quarter. This proposed methodology is similar to the proposed methodology for multiple source drugs and single source drugs that are not biosimilars when manufacturers report negative or zero manufacturer's ASP for all NDCs.

In addition to the payment approaches we proposed for biosimilars with only negative or zero manufacturer's ASP data, we considered two alternatives for which we solicited public comment. Under the first alternative, the volume-weighted ASP calculation would include the ASP data and billing units sold of its reference product for a given quarter along with those of the other biosimilars that reference the same reference product in the volume-weighted average calculation. We believe including the reference product's data in the blended calculation for a biosimilar's payment limit in the limited circumstance described could be appropriate in determining an operationally reasonable payment limit because the FDA approval for the biosimilar relies in part on FDA's previous determination of safety, purity, and potency for the reference product, and the biosimilar is necessarily approved for at least one condition of use that has been previously approved for its reference product, as required under the 351(k) approval pathway;[299] therefore, the case that the two are comparable is at least as strong as that for any two biosimilars with the same reference product. If it is preferable, as we proposed, to base the payment limit on the available positive manufacturer's ASP data submitted by manufacturers of market competitor biosimilars (in this context, biosimilars that reference the same reference product), then including the ASP data and billing units sold of the reference product would also increase the likelihood that positive data in such a group is available, particularly in the case that a reference product only has one biosimilar. Under this alternative, the payment limit would be set equal to the sum of the volume-weighted average of the positive manufacturer's ASP data from all other biosimilars with the same reference product and the reference product plus 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference product for the given quarter. We solicited public comments about whether including ASP data from the reference product in a variant of the proposed calculation would produce a more appropriate payment limit for a biosimilar with only negative or zero manufacturer's ASP data.

Under the second alternative, we would calculate payment limits for all

[299] *Section 351(k)(2)(A)(i)(III) of the Public Health Service Act (42 U.S.C. 262).*

biosimilars with only negative or zero manufacturer's ASP data in the manner described above for biosimilars when either no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter. That is, under this alternative we would not consider the manufacturer's ASP data of other biosimilars with the same reference product; rather, we would base the payment limit of the biosimilar on the volume-weighted average of the its own most recently available positive manufacturer's ASP data from a previous quarter and either 6 or 8 percent, as appropriate, of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter. We solicited comments from interested parties about whether, and if so, why, it is preferable for the payment limit to be calculated only using manufacturer's ASP data from the biosimilar that reports negative or zero manufacturer's ASP data in a given quarter.

We received many public comments on our proposed payment limit calculations for biosimilars with only negative or zero manufacturer's ASP data and alternatives considered in this section. The following is a summary of the comments we received and our responses.

Comment: Regarding our proposal to calculate the payment limit for a biosimilar with all negative or zero manufacturer's ASP data for a given quarter when positive manufacturer's ASP data are available for another biosimilar(s) with the same reference product for the given quarter, multiple commenters opposed the proposed use of ASP data from drugs with other billing and payment codes to calculate a payment limit. Commenters stated that they believe this may create competitive asymmetries between biosimilars and reference products.

Two commenters stated that they believe treating payment for biosimilars in a manner similar to that of multiple source drugs, even in the limited circumstances described in the proposal, would distort the ASP-based payment system as a whole for biosimilars. Multiple commenters argued the biosimilar proposal would undermine profitability in the biosimilar marketplace and result in less participation by manufacturers and fewer treatment options for patients.

Several commenters opposed the proposal on the grounds that they believe it would undermine the policy we established in the CY 2018 PFS final rule (82 FR 53182 through 53187) to allocate separate billing and payment codes for each biosimilar product and urged that we extend that policy to circumstances in which no manufacturer ASP data is available in a given quarter. Commenters stated that the interests we articulated in the CY 2018 rulemaking, namely, to advance patient access, improve marketplace dynamics, and long-term program savings, continue to be served by the assignment of unique payment limits for each biosimilar and would be undercut by either the proposed methodology for biosimilars with all negative or zero manufacturer's ASP data when positive manufacturer's ASP data are available for another biosimilar(s) with the same reference product or the first alternative. Two commenters stated that they believe payment limits for single source drugs and biosimilars reporting zero or negative manufacturer's ASP data must reflect the unique market dynamics that an individual product faces and be based on the product's own sales data. One commenter stated that they believe we should avoid implicating interchangeability where it hasn't been established.

In general, commenters who opposed the proposal favored the second alternative. Several commenters explained their support for the second alternative due to its consistency with the requirement in section 1847A(b)(8) of the Act that a biosimilar's payment limits be based on its own ASP data when ASP data is available. Commenters also expressed approval of its consistency with other drug pricing methodologies that employ a carryover approach when manufacturer data is negative or zero.

Response: We appreciate the commenters' thoughtful responses to our proposal and alternatives and recognize the variety of different policy preferences expressed in the comments. In response to feedback expressed by the majority of interested parties, we are finalizing the second alternative policy as described in the proposed rule (89 FR 61774). That is, we will set the payment limit for a biosimilar for which negative or zero ASP data are reported for all NDCs equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

We will not consider the manufacturer's ASP data of other biosimilars with the same reference product.

After considering the comments, we are persuaded by feedback provided by interested parties that the second alternative also supports our stated goal in the proposed rule: to codify a clear payment methodology for situations in which manufacturer ASP data is zero or negative, while accurately and fairly paying for these drugs and biosimilars. While we continue to believe our proposal would be suitable to achieve these program objectives and is consistent with the other calculations we are finalizing in sections III.A.d and e of this final rule, the second alternative also offers the advantages of methodologic simplicity and has broad support from interested parties.

However, we continue to believe that there are advantages to our original proposed policy relative to the alternative method that we are finalizing. As stated in the proposed rule, we believe the proposed policy is consistent with policies finalized in the CY 2018 PFS rulemaking, as the proposal would allow CMS to calculate an operationally reasonable payment limit using positive manufacturer's ASP data for highly similar products in limited instances, but also not group biosimilars with a shared reference product in a single billing and payment code.

We also disagree with commenters that our original proposed policy would cause general disruptions in the biosimilar market, provide competitive advantages to certain products relative to a reference biological product, or lead to the withdrawal of treatment options for patients, given the very narrow range of circumstances in which it would have applied. Furthermore, both the proposal and the second alternative would result in positive payment limits increased by the use of alternative data when price concessions for the given quarter would otherwise reduce the manufacturer's ASP to or below zero and neither would affect the payment limits of competitor products. The argument that one calculation would undermine the market or introduces harmful competitive asymmetries solely due to the source of the data and the other would not is unpersuasive.

Our priority, however, is to establish a transparent and predictable payment approach and avoid unnecessary inconsistency in the overall payment policy structure. Therefore, we are

finalizing the second alternative as described in the proposed rule, meaning we are finalizing that we will calculate payment limits for all biosimilars for which negative or zero manufacturer's ASP data is reported for all NDCs regardless of whether other biosimilars have been approved for the same reference product or whether other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter, as set forth in the language we are finalizing at § 414.904(i)(3)(ii), by setting the payment limit equal to the sum of the following until at least one NDC for the biosimilar has positive manufacturer's ASP data for a quarter:

- The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter, and
- 6 percent (or 8 percent for qualifying biosimilar biologicals, as appropriate) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

Comment: One commenter opposed the proposal and recommended that for biosimilars with only negative or zero manufacturer's ASP data, CMS set the payment limit by calculating the volume-weighted ASP using the most recent positive manufacturer's ASP for each NDC in the billing and payment code, while using the current quarter's reported units sold for each NDC. The commenter noted that if we do not incorporate this recommendation into our final policy, they would support the second alternative.

Response: We thank the commenter for their feedback. The approach we are finalizing, basing the payment limit of the biosimilar on the volume-weighted average of the its own most recently available positive manufacturer's ASP data from a previous quarter and an add-on payment amount determined under section 1847A(b)(4) of the Act for the reference biological product, is most consistent with section 1847A(c)(5)(B) of the Act, which directs the Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent calendar quarter for which such data are available. In addition, we believe the policy we are finalizing will base payment limits on data most closely related to the current market conditions because it would rely on the most recently available data required to be reported under section 1847A(c) of the Act from a full calendar quarter associated with a billing and payment code. We disagree with the commenter that calculating the payment limit for a drug using positive manufacturer's ASP data from multiple quarters would result in a payment limit that is more reflective of current market conditions because more time has passed since the sales reflected in the additional quarters for which inclusion is sought by the commenter. We refer readers to the response to the same approach recommended for single and multiple source drugs when zero or negative manufacturer's ASP data are reported for some, but not all NDCs in section III.A.2.c of this rule.

Comment: Two commenters expressed support for the second alternative discussed in the proposed rule, but requested that it be modified by calculating the first component of the payment limit with the volume-weighted average of the positive ASP data from the previous four quarters for which positive data are available for the biosimilar, rather than only the most recent calendar quarter for which data are available.

Response: We thank the commenters for their feedback. The calculation we are finalizing for biosimilars for which negative or zero ASP data is reported for all NDCs, using a single calendar quarter of data, is most consistent with the Secretary's requirement under section 1847A(c)(5)(B) of the Act because the statute directs that Secretary to update quarterly a drug's ASP payment limit using manufacturer's ASP data from the most recent single calendar quarter for which such data are available, rather than several quarters. For this reason, we believe using a single quarter of data is most appropriate. We also note a smoothing function for lagged price concessions is already incorporated into the ASP payment limit calculation by section 1847A(c)(5)(A) of the Act. We refer readers to the response to the same approach recommended for single and multiple source drugs when zero or negative manufacturer's ASP data are reported for some, but not all NDCs in section III.A.2.c of this rule.

Comment: Several commenters stated that they believe CMS does not have the statutory authority to set payments limit for biosimilars for which ASP data is not available using pricing data associated with other biosimilar products. Some of those commenters stated that they believe section 1847A(b)(8) of the Act, which provides the methodology for calculating the payment limit of biosimilars when manufacturer's ASP data is available, requires the calculation of ASP-based payment for biosimilars to be particular to each biosimilar product even when ASP data is not available for a given quarter and prohibits the proposed blending of manufacturer ASP data. Two commenters stated that they believe section 1847A(b)(8)(A) of the Act similarly prohibits basing a payment limit on a reference product's ASP data, and therefore they believe the first alternative is similarly impermissible.

One commenter stated its view that the Social Security Act does not expressly provide for how CMS should calculate payment amounts for separately payable Part B drugs when manufacturers report negative or zero ASP data, but urged CMS to apply a policy in these circumstances that adheres as closely as possible to the statutory payment limit requirements that apply when ASP data is available. The commenter stated that the main proposal and the first alternative considered are inconsistent with statutory requirements when positive manufacturer's ASP data is available, which require payment limit calculations, other than the add-on payment, to be specific to each biosimilar.

Response: We disagree with commenters regarding our statutory authority to implement the proposed policy (which we note we are not finalizing).. The methodology described in section 1847A(b)(8)(A) of the Act applies to circumstances in which manufacturer's ASP data is available for the calculation of a biosimilar's payment limit for a given quarter, which is not the circumstance we are addressing in this policy.

We agree with the commenter who expressed the view that the section provides no statutory methodology for the calculation of a drug's payment limit when manufacturers report negative or zero ASP data. We also agree with the commenter that the proposal for calculating the payment limit for a biosimilar for which negative or zero ASP data are reported for all NDCs is dissimilar from the methodology provided in statute for circumstances when positive manufacturer's ASP data is available. While such inconsistency does not preclude the from establishing a payment limit calculation for circumstances not described in section 1847A of the Act, the calculation are finalizing earlier in this section aligns more closely with the methodology described in section 1847A(b)(8)(A) of the Act and other calculations finalized in this final rule for payment limits for drugs for which negative or zero ASP data are reported for all NDCs.

Comment: One commenter noted that our proposal and the second alternative do not address situations in which price

concessions significantly reduce the ASP-based payment limit but the payment limit is still positive, and urged that we pursue either a legislative proposal to exclude certain rebates from payment limit calculations, discussed further below in section III.A.2.h of this rule, or the first alternative considered. The commenter stated that the first alternative would provide the greatest assurance that the payment limit for a biosimilar does not fall below provider acquisition costs and recommended finalizing that methodology.

Response: We appreciate the commenter's response. However, circumstances in which price concessions significantly reduce the ASP payment limit but the limit is still positive are outside the scope of the proposed rule. We appreciate the commenter's support for the first alternative, but for the reasons discussed above, we are finalizing the second alternative. We note that section 1847A(c)(3) of the Act expressly requires that in calculating the manufacturer's ASP, such price shall be calculated net of discounts as described in that paragraph.

Comment: One commenter, while generally supporting the proposal and the first alternative, expressed concern that in biosimilar markets with few participants, the proposal and first alternative would provide manufacturers a perverse incentive to employ aggressive rebate strategies or otherwise manipulate pricing data in order that competitor products' ASP data be used as the basis for a more favorable payment limit.

Response: We thank the commenter for their feedback. As we are finalizing neither the proposal nor the first alternative, we are not considering refinements to these approaches that may stem any pricing data manipulation resulting from these approaches.

Comment: Two commenters recommended that in lieu of our proposal, we propose measures that address the underlying causes of negative or zero ASP data or biosimilar market dynamics that may cause manufacturers to exit the market.

Response: We thank the commenters for their feedback and note that we may consider this input for potential policy proposals through future rulemaking.

g. Discontinued Drugs

Generally, for single source drugs and multiple source drugs for which negative or zero manufacturer's ASP data is reported for all NDCs and for which all relevant applications (for example, new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs)) have a marketing status of ''discontinued'' on the FDA website,[300] [301] we proposed that the drug be priced by MACs consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual for developing payment limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file.[302]

Once a drug is discontinued, as indicated by the marketing status on the FDA website (either at *Drugs@FDA* [303] for drugs or the Purple Book [304] for biologicals), the manufacturer might not have sales to calculate an ASP and, therefore, the manufacturer often reports zero sales for the drug or a negative number for its calculated ASP or number of sales. However, even if a drug has a marketing status of discontinued on the FDA website, there may theoretically be available product that could be billed by the provider until the expiration date of the last lot sold for the drug. Relatedly, we have observed that very few claims are paid for drugs following their discontinuation. For these reasons, setting a payment limit for drugs with a marketing status of discontinued on the FDA website is not expected to be practically useful for claims processing and is not a prudent use of CMS resources.

We did not receive any public comments on our proposal to have single source drugs and multiple source drugs for which negative or zero manufacturer's ASP data is reported for all NDCs and all NDCs have a marketing status of ''discontinued'' priced by the MACs consistent with section 20.1.3 in Chapter 17 of the Medicare Claims Processing Manual and are finalizing it as proposed.

h. General Comments

Comment: One commenter expressed general support for the proposed changes under each of the circumstances, and expressed the view that these changes, if finalized, will simplify the process of establishing a payment limit when a drug is under circumstances that would otherwise make doing so difficult. Another commenter expressed support for the principle of using positive ASP data from the most recent quarter with at least one NDC with positive ASP to calculate a drug's payment limit when the manufacturer reports negative or zero ASP data. One commenter expressed general support of the use of ASP as the basis of payment whenever possible and appropriate, and added that ASP is the most transparent, predictable, and consistent pricing metric available.

Response: We thank the commenters for their support.

Comment: One commenter requested clarification on several technical aspects regarding when manufacturers report negative or zero ASP, including: whether negative values are to be noted by putting a number in parentheses or by including an initial minus sign; and how ''false positive'' ASPs (that is, ASPs calculated with negative values for both total sales and total units sold) are to be reported.

Response: We thank the commenter for their request. Manufacturers should report negative values with a minus sign. In instances of false positives, manufacturers should report zero for the drug's ASP and provide clarification in their reasonable assumptions. We will update the Medicare Part B ASP Module Submitter User Guide and ASP Quarterly Publication Process Frequently Asked Questions documents to reflect these instructions.

Comment: A couple commenters supported the proposed policies, but expressed concern that they do not go far enough to address the challenges posed by drugs for which the provider acquisition costs exceed their payment limits. Several commenters urged CMS to work with Congress to modify the payment limit calculations described in section 1847A of the Act to ensure payment limits are greater than acquisition costs. Specifically, commenters requested legislative proposals including an add-on payment for drugs based on 8 percent of acquisition costs and the exclusion of certain price concessions from the payment limit calculation, such as rebates paid to pharmacy benefit managers (PBMs). One commenter requested that CMS clarify that PBMs, group purchasing organizations (GPOs), and payers are not purchasers referenced in section 1847A(c) of the Act and that sales to such entities are excluded from ASP payment limit calculations.

Response: We thank the commenters for their feedback on the gaps between provider acquisition costs and payment

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[300] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[301] *https://purplebooksearch.fda.gov/.*

[302] Medicare Claims Processing Manual Chapter 17, section 20.1.3: *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[303] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.*

[304] *https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.*

limits. As the commenters noted, in previous rules (that is, the Manufacturer Submission of Manufacturer's ASP Data for Medicare Part B Drugs and Biologicals interim final rule with comment (69 FR 17936) and the Manufacturer Submission of Manufacturer's ASP Data for Medicare Part B Drugs and Biologicals final rule (69 FR 55763 through 55765) on what price concessions described in section 1847A(c)(3) of the Act must be included in manufacturer's ASP calculations, we did not distinguish between whether the recipient of the concession is a purchaser or not. Further information is available in the ASP Quarterly Publication Process Frequently Asked Questions document,[305] which specifies that manufacturers must report each drug's sales volume including the manufacturer's sales to all purchasers in the United States and ASP reflecting all price concessions as specified in 42 CFR 414.804(a)(2) and (a)(3). We note, however, that both the legislative proposals and the recommended interpretation of a purchaser as it relates to manufacturer ASP calculations under section 1847A(c) of the Act are out of scope for this final rule.

i. Summary

We are finalizing amendments to § 414.904(i) to reflect CMS's approach to setting a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported by a manufacturer for a drug, beginning with the payment limits included in the January 2025 ASP Drug Pricing file. Specifically, we are finalizing our proposal to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a multiple source drug, we will calculate the payment limit using the positive manufacturer's ASP data reported for the drug, except for the existing carryover policy for multiple source drugs that we will apply when unavailable data results in a significant change in the ASP payment limit. We are finalizing our proposal to move this carryover policy for multiple source drugs within § 414.904(i) to fit within the structure of the proposed new set of payment limit methodologies. We also finalizing our proposal to codify that in the case of a multiple source drug for which negative or zero manufacturer's ASP data is reported for all NDCs, we will set the payment limit using the most recently available positive manufacturer's ASP data from a previous quarter until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

We are finalizing our proposal to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a single source drug that is not a biosimilar, we will calculate the payment limit using the positive manufacturer's ASP data reported for the drug. We finalizing our proposal to codify that for single source drugs that are not biosimilars with all negative or zero manufacturer's ASP data for a given quarter, the payment limit will be, until at least one NDC for the drug has positive manufacturer's ASP data for a quarter, the lesser of 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data for at least one NDC from a previous quarter and 106 percent of the WAC, and we will use 106 percent of the lowest WAC per billing unit if there is more than one WAC per billing unit available.

We are also finalizing our proposal to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a biosimilar, we will calculate the payment limit using the positive manufacturer's ASP data reported for the biosimilar. Lastly, we are finalizing a modification to our proposal to codify a methodology for calculating payment limits when the manufacturer reports negative or zero manufacturer's ASP for all NDCs for a biosimilar for a given quarter. We are adopting the approach proposed for circumstances when no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter for all circumstances, regardless of whether positive ASP data is reported for other biosimilars that reference the same reference product. In other words, we are finalizing for all biosimilars with all negative or zero manufacturer's ASP data that we will set the payment limit equal to the sum of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

3. Payment of Radiopharmaceuticals in the Physician Office

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs by adding section 1847A to the Act, which established a new ASP drug payment methodology for separately payable Medicare Part B drugs, beginning January 1, 2005. Specifically, section 303(h) of the MMA states, ''Nothing in the amendments made by this section [303 of the MMA] shall be construed as changing the payment methodology under [Medicare] Part B . . . for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.''

In accordance with the law, radiopharmaceuticals are not required to be paid using payment methodology under section 1847A of the Act, as currently described in the Medicare Claims Processing Manual (MCPM) Chapter 17, section 20.1.3. The manual instructs MACs to determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003, before the passage of the MMA, in the case of radiopharmaceuticals furnished in settings other than the hospital outpatient department. Currently, payment can vary by MAC. For example, payment can be based on 95 percent of Average Wholesale Price (AWP), invoices, or other reasonable payment methods/data made available when the product is contractor priced.[306] [307] [308] [309] [310] [311]

We have heard from MACs and other interested parties that there is confusion about which exact methodologies are available to MACs for pricing of radiopharmaceuticals in the physician office setting, as different MACs had different methodologies in place as of

[305] *https://www.cms.gov/files/document/frequently-asked-questions-faqs-asp-data-collection.pdf.*

[306] How Does Palmetto GBA Price Drugs and Biologics?, Palmetto GBA. *https://www.palmettogba.com/palmetto/jjb.nsf/DIDC/8EELKH2211~Specialties~Drugs%20and%20Biologicals.*

[307] Radiopharmaceutical Fee Schedule 2024 Update, Noridian. *https://med.noridianmedicare.com/web/jeb/fees-news/fee-schedules/radiopharmaceutical-fees.*

[308] Radiopharmaceutical Drugs—Billing Instructions, A Celerian Group Company. *https://www.cgsmedicare.com/partb/pubs/news/2013/0313/cope21543.html.*

[309] Reimbursement Guidelines for Radiopharmaceuticals HCPCS Level II Codes, Novitas Solutions. *https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00231502.*

[310] Reimbursement Guidelines for Radiopharmaceuticals Procedure Codes (Prior to January 2023), First Coast Service Options, Inc. *https://medicare.fcso.com/Coverage_News/0494780.asp.*

[311] Radiopharmaceutical Reimbursement, National Government Services. *https://www.ngsmedicare.com/web/ngs/fee-schedule-lookup-details?lob=93617&state=97256&rgion=93623&selectedArticleId=4920515.*

November 2003. MACs are uncertain whether they can use *any* of these payment policies that were in place, or only the policy that was in place for their jurisdiction as of November 2003.

Accordingly, while we evaluate our broader policies in this space for future rulemaking, we proposed to clarify that *any* payment methodology that was being used by *any* MAC prior to the enactment of the MMA can continue to be used by any MAC, including the use of invoice pricing. That is, we proposed to clarify that any methodology that was in place to set pricing of radiopharmaceuticals in the physician office setting prior to November 2003 can be used by any MAC, regardless of whether that specific MAC used the methodology prior to November 2003.

Thus, we proposed to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing general support for the proposal to clarify that any MAC may use any radiopharmaceutical payment methodology available on or prior to November 2003. One commenter expressed strong support for separate Medicare payment for radiopharmaceuticals.

Response: We thank the commenters for their support.

Comment: Several commenters recommended various approaches to improve transparency around how MACs make payment for radiopharmaceuticals, including for CMS to closely monitor and evaluate how MACs make payment for radiopharmaceuticals and to direct MACs to publish the prices of these radiopharmaceuticals and publicly state the specific payment methodology that they use. Specifically, one commenter recommended CMS require that MACs routinely update (for example, quarterly or semiannually) their invoice and AWP reference files to accurately set payment limits for these therapies. In addition, the commenter requested that CMS publish AWP and WAC pricing information for therapeutic radiopharmaceuticals in the quarterly ASP pricing file on the CMS website. Another commenter encouraged CMS to work with MACs to ensure that appropriate metrics such as WAC, invoice pricing, and ASP are used as the basis to establish payment rates.

Response: We appreciate the many commenters for their feedback. In accordance with our clarification, *any* payment methodology that was being used by *any* MAC prior to the enactment of the MMA can continue to be used by any MAC, including the use of invoice pricing. MACs update their own pricing files, and therefore, we suggest that the commenters share their concerns with the MACs. We note that CMS was able to find public pricing file information for some MACs.[312] [313] We appreciate the other commenters' feedback and may address our broader policies regarding payment of radiopharmaceuticals in the physician office in future rulemaking.

Comment: A few commenters urged CMS to direct MACs to utilize a single payment methodology across all the MACs, and the commenters suggested that they believe uniform payment would alleviate confusion for MACs. They also stated that payment variation across MACs results in difficulty obtaining the payment rate prior to submitting a claim. Other commenters raised concern that there is significant variation in coverage of radiopharmaceuticals across jurisdictions, resulting in some providers not offering certain radiopharmaceuticals. One commenter recommended implementing invoice-based pricing, asserting that that payment methodology would result in savings for Medicare. Another commenter recommended standardizing a single rate across MACs of AWP minus 5%, which they claim would ensure acquisition and administration costs are covered to support access to this treatment in the community-based setting.

Response: We appreciate the commenters feedback. We may consider these comments on the broader policies regarding payment of radiopharmaceuticals in the physician office if addressed in future rulemaking.

Comment: A few commenters recommended CMS issue educational materials on radiopharmaceutical payment as well as to reach out to contractors, providers, and other stakeholders to educate them on this issue. One commenter requested CMS engage with interested parties early in any process that could potentially impact longstanding Medicare payment policies for radiopharmaceuticals.

Response: We appreciate the feedback from commenters. CMS plans to update the Medicare Claims Processing Manual to reflect the finalized policies for payment of radiopharmaceuticals in the physician office. In addition, we welcome engagement on other ways to educate interested parties on our current payment policies, as well as possible payment policies CMS could consider.

Comment: We received one comment that recommends MACs disclose how payment rates will be determined, and for this method to be open for public comment. The commenter also requested MACs work with providers if the resulting payment is below the cost of the radiopharmaceutical.

Response: We appreciate the commenter's feedback. This recommendation as to the way MACs determine appropriate payment rates is outside the scope of this proposal. This proposal clarifies that MACs may use any payment methodology that was being used on or prior to November 2003.

After consideration of public comments, we are finalizing as proposed a revision to § 414.904(e)(6). For radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

4. Immunosuppressive Therapy (§§ 410.30 and 414.1001)

a. Background

Medicare Part B coverage of drugs used in immunosuppressive therapy was established by section 9335(c) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (OBRA '86). OBRA '86 added subparagraph (J) to section 1861(s)(2) of the Act to provide Medicare Part B coverage for immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period not to exceed 1 year after the transplant procedure. Coverage of these drugs under Medicare Part B began January 1, 1987. Section

[312] Radiopharmaceutical Fee Schedule, Noridian Healthcare Solutions. *https://med.noridianmedicare.com/web/jfb/fees-news/fee-schedules/radiopharmaceutical-fees.*

[313] Fee Schedule Lookup Details, National Government Services. *https://www.ngsmedicare.com/web/ngs/fee-schedule-lookup-details?lob=93617&state=97256&rgion=93623&selectedArticleId=4920515.*

4075 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) (OBRA '87) revised section 1861(s)(2)(J) of the Act so that the scope of coverage was expanded from coverage of ''immunosuppressive drugs'' to coverage of ''prescription drugs used in immunosuppressive therapy.'' For the purposes of this proposed rule, we refer to this benefit as the immunosuppressive drug benefit.

In the February 16, 1995 Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy final rule (60 FR 8951 through 8955),[314] we codified policies related to the scope of drugs for which payment may be made under this benefit. We finalized that payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the U.S. Food and Drug Administration (FDA) and meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a Part B carrier, in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

We also finalized the period of coverage eligibility for a transplant patient.[315] Lastly, we established the policy that drugs are covered under this provision irrespective of whether they can be self-administered. We codified these policies at § 410.31 (later redesignated as § 410.30).

We note that we do not maintain a list of drugs covered under this benefit; rather, MACs are expected to maintain a list of these drugs, as stated in section 80.3, Chapter 17 of the *Medicare Claims Processing Manual.* MACs are expected to keep informed of FDA approvals of immunosuppressive drugs and update guidance as applicable.

While the eligibility timeframe has been extended and eligibility has been expanded since the immunosuppressive drug benefit under Medicare Part B was revised by OBRA '87, the scope of drugs payable under this benefit has not changed. Some examples of how the benefit has been extended and expanded include: section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93) (Pub. L. 103–66), amended section 1861(s)(2)(J) of the Act to extend the duration of coverage for the immunosuppressive drug benefit to 36 months from the hospital discharge date following a covered transplant procedure for drugs furnished after CY 1997; section 113 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA) revised section 1861(s)(2)(J) of the Act to eliminate the time limits for coverage of prescription drugs used in immunosuppressive therapy under the Medicare program; and most recently, section 402 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 226A(b)(2) to allow certain individuals whose Medicare entitlement based on ESRD would otherwise end 36 months after a kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

After reviewing our longstanding policies for the immunosuppressive drug benefit and engaging with interested parties about current practices and challenges, we proposed policies aimed to reduce barriers faced by beneficiaries receiving immunosuppressive drugs under this benefit, as described below.

b. Compounded Immunosuppressive Drugs With Oral or Enteral Routes of Administration

As discussed in the previous section, the immunosuppressive drug benefit currently includes immunosuppressive therapies that have been approved for marketing by the FDA (and meet other regulatory requirements at § 410.30). Interested parties have expressed concern that compounded formulations of immunosuppressive drugs (for example, a liquid formulation of an immunosuppressive drug not commercially available from a manufacturer but prepared by a pharmacist) are not included in the immunosuppressive therapy benefit because these formulations are not approved by the FDA (that is, FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients [316]), which is a regulatory requirement under the current benefit. These interested parties communicated that compounded formulations are frequently used in the treatment of transplant recipients who cannot swallow oral capsules or tablets due to age or oral-motor dysfunction. Some examples of drugs compounded for preventing or treating the rejection of a transplanted organ or tissue include, but are not limited to, azathioprine,[317] cyclophosphamide,[318] and tacrolimus.[319]

We recognize certain patient groups, such as those with dysphagia, those with enteral feeding tubes (for example, a nasogastric feeding tube or a percutaneous endoscopic gastrostomy (PEG) tube), and many pediatric patients [320] [321] covered under Medicare rely on compounded immunosuppressive drugs for maintenance therapy and believe that

[314] *https://www.govinfo.gov/content/pkg/FR-1995-02-16/pdf/95-3835.pdf.*

[315] Since the establishment of the benefit by the enactment of OBRA '86, the period of coverage for a transplant patient under section 1861(s)(2)(J) of the Social Security Act has been subsequently amended by section 202 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360), the Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234), section 13565 of the Omnibus Reconciliation Act of 1993 (OBRA '93) (Pub. L. 103–66), section 160 of the Social Security Act Amendments of 1994 (Pub. L. 103–432), section 113 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) (BIPA 2000). The last of these statutory changes eliminates the time limits for coverage of prescription drugs used in immunosuppressive therapy under the Medicare program, effective with immunosuppressive drugs furnished on or after December 21, 2000.

[316] *https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.*

[317] United States Pharmacopeia (2024). USP Monographs, Azathioprine Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[318] United States Pharmacopeia (2024). USP Monographs, Cyclophosphamide Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[319] United States Pharmacopeia (2024). USP Monographs, Tacrolimus Compounded Oral Suspension. USP–NF. Rockville, MD: United States Pharmacopeia.

[320] In the United States, children under 18 years of age comprise only 0.14 percent of the total Medicare ESRD population. Source: CY 2024 End-Stage Renal Disease Prospective Payment System final rule (88 FR 76374).

[321] Lentine, K, Smith, JM, Lyden, GR, Miller, JM, Dolan, TG, Bradbrook, K, Larkin, L, Temple, K, Handarova, DK, Weiss, S, Israni, AK, Snyder, JJ (2024). OPTN/SRTR 2022 Annual Data Report: Kidney. *American Journal of Transplantation,* 24(2), S19–S118. *https://doi.org/10.1016/j.ajt.2024.01.012.*

their inclusion in the immunosuppressive drug benefit will help to ensure that each beneficiary is able to access the most clinically appropriate formulation of an immunosuppressive drug.[322] [323] [324] Nonadherence to lifelong maintenance immunosuppressive therapy contributes to unfavorable post-transplant outcomes, with obstacles to accessing medication being a prominent risk factor for such nonadherence.[325] Therefore, in the CY 2025 PFS proposed rule, we proposed revisions at § 410.30 to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or have been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit. As we intend this proposal to enhance access and address adherence concerns for patients who are not able to swallow capsules or tablets and we do not believe there are access concerns with other types of formulations, we proposed to limit the included compounded formulations to those products with oral and enteral routes of administration (for example, oral suspensions or solutions).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposal to include orally and enterally administered compounded formulations for immunosuppressive drugs covered under the Part B immunosuppressive therapy benefit. Several commenters reiterated that compounded medications may be the only treatment option available for certain patient populations in need of immunosuppressive therapy, such as those with dysphagia, those with enteral feeding tubes, and children who are transplant recipients. These commenters stated that the proposed policy would ensure these patient groups have access to appropriate care.

Response: We thank the comments for their support.

Comment: One commenter requested clarification on whether the proposed revision to the immunosuppressive therapy benefit includes compounds prepared with the same active ingredients contained in the FDA-approved drug or whether the FDA-approved drug must itself be compounded. The commenter also asked whether all active ingredients in the FDA-approved drug must be included in the compounded formulation administered to the beneficiary to be included in the benefit, or whether a subset of active ingredients from the FDA-approved drug may be included in the compounded formulation.

Response: We thank the commenter for the questions. We clarify that for a compounded formulation to be included in the immunosuppressive therapy benefit, it must be compounded from an FDA-approved drug for which the approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or has been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit. A bulk drug substance [326] (in other words, an active pharmaceutical ingredient for compounding) can be a component of an FDA-approved drug product. However, since the bulk drug substance itself does not meet one of those definitions, compounded immunosuppressives made from a bulk drug substance are not included in the benefit. Accordingly, a compounded formulation that meets one of the three proposed definitions must be compounded from the FDA-approved drug.

Comment: One commenter disapproved of the proposal and requested it be limited to coverage of compounded drugs that are in an FDA-designated shortage. The commenter cited patient safety, efficacy, and quality concerns, as compounded drugs are not reviewed by the FDA. The commenter also expressed concern that including compounded drugs in the immunosuppressive therapy benefit could lead to medication cost increases due to supply constraints.

The commenter also raised billing concerns, including that dosage adjustments in compounded formulations make billing monitoring more challenging and the use of Not Otherwise Classified (NOC) billing and payment codes adds to the complexity of making correct payments.

Response: We thank the commenter for their feedback. Because of the limited scope of this proposal to the coverage of compounded immunosuppressives from FDA-approved drugs, we believe the safety, efficacy, and quality concerns relative to the commercial formulations to be minimal. The aim of the proposal is to allow coverage under Part B for certain liquid compounded immunosuppressives that may not be available as an FDA-approved product so that individuals who require such formulations can receive the most clinically appropriate therapy. To minimize safety concerns, we limited these compounded versions to orally and enterally administered versions and did not permit compounded versions with other routes of administration that may have more safety considerations (for example, intravenously administered drugs).

To the commenter's concern about access and cost increases, we estimate the patient population of these compounded immunosuppressive drugs is currently no more than 2,000 patients a year.[327] We do not believe a patient population of this size will have a significant impact on compounding pharmacy resources or the costs of compounded drugs.

We acknowledge the commenter's concern regarding the billing for compounded immunosuppressive drugs with a NOC billing and payment code. In order to ensure correct payments in processing claims under the revised benefit, MACs could require providers and suppliers who bill for compounded immunosuppressive drugs to include information necessary (for example, the name of the drug, NDC, total dosage, and the method of administration) in the narrative field, or Item 19 of claim form CMS–1500 or electronic claim

[322] Silva RME, Portela RDP, da Costa IHF, et al. Immunosuppressives and enteral feeding tubes: An integrative review. J Clin Pharm Ther. 2020;45:408–418. *https://doi.org/10.1111/jcpt.13093.*

[323] Goorhuis JF, Scheenstra R, Peeters PM, Albers MJ. Buccal vs. nasogastric tube administration of tacrolimus after pediatric liver transplantation. Pediatr Transplant. 2006 Feb;10(1):74–7. *https://doi:10.1111/j.1399–3046.2005.00402.*x. PMID: 16499591.

[324] Liverman, R, Chandran, MM, Crowther, B. Considerations and controversies of pharmacologic management of the pediatric kidney transplant recipient. Pharmacotherapy. 2021 Jan;41(1): 77–102. *https://doi.org/10.1002/phar.2483.*

[325] Fine RN, Becker Y, De Geest S, et al. Nonadherence consensus conference summary report. *Am J Transplant.* 2009; 9(1): 35–41. *doi: 10.1111/j.1600–6143.2008.02495.x.*

[326] *https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding*

[327] There were a total of 2,662 Medicare Part D prescription drug events (PDEs) for compounded immunosuppressive drugs in CY 2023.

equivalent and/or request additional documentation.

After consideration of public comments, we are finalizing as proposed to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or have been determined by a MAC, in processing a Medicare claim, to be reasonable and necessary for this specific purpose as outlined in the immunosuppressive drug benefit at § 410.30(a).

c. Immunosuppressive Refill Policy and Supplying Fee

Section 303(e)(2) of the MMA added section 1842(o)(6) of the Act which requires the Secretary to pay a supplying fee (less applicable deductible and coinsurance) to pharmacies for certain Medicare Part B drugs and biologicals, as determined appropriate by the Secretary, including for immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

In the CY 2005 PFS, we established a supplying fee of $50 for the initial oral immunosuppressive prescription supplied in the first month after a transplant (69 FR 66312 through 66313). In the CY 2006 PFS, we established a supplying fee of $16 for all subsequent prescriptions after the initial prescription supplied during a 30-day period (70 FR 70233 through 70236).

Following the CY 2006 rulemaking, we issued program instruction [328] to the MACs that prohibits payment for refills of immunosuppressive drug prescriptions in most circumstances and limits payment for prescriptions to 30-day supplies. We stated in Chapter 17 of the Medicare Claims Processing Manual that contractors should limit payment for prescriptions to those of 30-day supplies, except in special circumstances, because dosage frequently diminishes over time; it is not uncommon for the provider to change the prescription from one drug to another; and coinsurance liability on unused drugs could be a financial burden to the beneficiary.

We have heard from interested parties that both the 30-day limit on supplies and prohibition on payment for refills no longer align with current practice for treating patients on maintenance immunosuppression regimens who are prescribed a stable dosage for months or years and receive refillable supplies for several months' use at a time. Frequent dosage adjustments for some immunosuppressive drugs that require therapeutic drug monitoring and dose titration based on blood concentrations, such as tacrolimus, tend to occur more often in newly transplanted recipients, and less frequently once patients are on stable regimens.[329] Other immunosuppressive drugs, such as mycophenolate mofetil, do not require routine therapeutic drug monitoring and have fixed recommended dosages per labeling where patients may be maintained on stable dosages for several months unless patients experience complications.[330] Transplant recipients must take immunosuppressive drugs on a lifelong basis to prevent rejection, maintain allograft function, and, for some transplanted organs, prevent death. Most patients are eventually prescribed stable maintenance immunosuppressive drug dosages post-transplant for extended periods of time. For example, liver transplant guidelines recommend review of the immunosuppressive drug regimen at least every 6 months.[331] For transplant beneficiaries, we believe that the limitation on payment to a maximum 30-day supply of immunosuppressive therapy by our program instruction is an unnecessary burden that poses a greater risk to adherence than does the potential for a sudden change in dosage needs. There is considerable concern among providers and advocates that interrupted access to immunosuppressive drugs caused by running out of or having insufficient medication supply can decrease medication adherence, increase risk of organ transplant rejection, and ultimately decrease the rate of survival of transplant recipients.[332] [333] We agree with interested parties that it would be beneficial to patients to reduce barriers that complicate access to immunosuppressive medication and reasonable for CMS to make programmatic changes consistent with this objective.

Accordingly, we proposed two changes regarding supplying fees and refills for immunosuppressive drugs. First, we proposed to allow payment of a supplying fee for a prescription of a supply of up to 90 days. To reflect this proposal, we proposed to revise § 414.1001 to allow payment of a supplying fee to a pharmacy for first prescriptions and for prescriptions following the first prescription for greater than a 30-day supply. We proposed additional modifications at § 414.1001 to combine paragraphs (a) (for supplying fees) and (b) (for supplying fees following a transplant). Accordingly, we also proposed to remove paragraph (b) and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively. We stated that further study the supplying fee amounts for immunosuppressive drugs is needed and did not propose to make any changes to the supplying fee amounts at this time (meaning the current 30-day supplying fees would apply to any amount of days' supply). The dispensing and supplying fees under Part B (§ 414.1001) have been shown to be higher than dispensing fees paid in the commercial market.[334] So, until additional study is done regarding input costs for dispensing drugs billed to Medicare Part B and subsequent notice-and-comment rulemaking can be done, if appropriate, in response to such information, we aim to continue the current fee amounts regardless of the days' supply dispensed. Second, we proposed to allow payment of refills for these immunosuppressive drugs. Under this proposal, the prescribing healthcare provider may adjust the days' supply up to 90 days and allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable State laws.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

[328] Section 80.3, Chapter 17 of the Medicare Claims Processing Manual.

[329] Tacrolimus [package insert]. Northbrook, IL: Astellas Pharma, Inc.; 2022. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/050708s055,010115s007lbl.pdf.*

[330] Cellcept [package insert]. San Francisco, CA: Genentech USA, Inc.; 2022. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050722s050,050723s050,050758s048,050759s055lbl.pdf.*

[331] Lucey MR, Terrault N, Ojo L, et al. Long-term management of the successful adult liver transplant: 2012 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Liver Transpl. 2013 Jan;19(1):3–26. doi: 10.1002/lt.23566.

[332] Nelson J, Alvey N, Bowman L, et al. Consensus recommendations for use of maintenance immunosuppression in solid organ transplantation: Endorsed by the American College of Clinical Pharmacy, American Society of Transplantation, and the International Society for Heart and Lung Transplantation. *Pharmacotherapy.* 2022; 42:599–633. *doi: 10.1002/phar.2716.*

[333] Chisholm MA, Lance CE, Williamson GM, Mulloy LL. Development and validation of an immunosuppressant therapy adherence barrier instrument. *Nephrol Dial Transplant.* 2005 Jan;20(1): 181–188. *https://doi.org/10.1093/ndt/gfh576.*

[334] *https://www.pcmanet.org/rx-research-corner/mandating-pharmacy-reimbursement-increase-spending/08/31/2021/#:~:text=The%20average%20dispensing%20fee%20in,the%20state's%20Medicaid%20FFS%20rate.*

Comment: Two commenters expressed support for both allowing a supplying fee for a prescription of a supply for up to 90 days, rather than 30 days as is the case under current regulation, and to allow refills for an immunosuppressive drug. One commenter affirmed the proposal would reduce barriers to treatment and in so doing reduce the occurrence of organ rejection.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing as proposed to allow payment of a supplying fee for a prescription of a supply of up to 90 days and to allow refills for an immunosuppressive drug based on the individual circumstance of the beneficiary in accordance with applicable State laws.

d. General Comments

Comment: Several commenters requested we clarify that patients who receive stem cell transplants have access to the immunosuppressive therapy benefit.

Response: Our regulations at § 410.30(b) specify the immunosuppressive therapy is available to individuals who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits. Stem cells are taken from various tissues throughout the body, such as blood and bone marrow.[335] [336] [337] Therefore, stem cells are included in the meaning of a ''tissue,'' as it is used in § 410.30(b), and individuals who receive a stem cell transplant are eligible for the immunosuppressive therapy benefit, so long as they also otherwise meet the eligibility requirements. We also note that both DME MACs recognize recipients of stem cell transplants as eligible for the immunosuppressive therapy benefit.[338]

e. Out of Scope Comments

Comment: We received comments on topics that were outside the scope of the proposed rule. Those topics included: (1) coverage for all other compounded drugs that are part of treatment plans for pediatric Medicare beneficiaries and (2) a request that we work with compounding pharmacy interested parties if we consider changes to immunosuppressive supplying fee amounts in the future.

Response: We implemented section 1861(s)(2)(J) of the Act, which provides coverage for health services including prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which Medicare payment is made, in the Immunosuppressive Therapy final rule (60 FR 8951 through 8955). As we finalized in section III.A.4.b, § 410.30(a) describes drugs that have approved labeling with indications for preventing or treating the rejection of a transplanted organ or tissue or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue; drugs that have been approved for marketing by FDA and determined by a MAC to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue; and drugs that are a compounded formulation with active ingredients derived only from either of the first two groups of covered drugs. Drugs with indications for other conditions not described in § 410.30(a), such as mineral deficiencies or hypertension, would not be covered under the immunosuppressive therapy benefit.

Regarding changes to supplying fee amounts, we noted in the CY 2025 PFS proposed rule that further study for input costs for dispensing drugs billed to Medicare Part B is needed and could propose, if appropriate, changes to fee amounts in future notice-and-comment rulemaking. As the comment we received was about the amount of the supplying fee, it is outside the scope of this rulemaking. However, we welcome engagement with interested parties regarding supplying fees for immunosuppressives.

As such, while these comments are out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

5. Blood Clotting Factors (§ 410.63)

a. Background

Hemophilia is a genetic bleeding disorder resulting in a deficiency of coagulation Factor VIII (hemophilia A) or coagulation Factor IX (hemophilia B) due to mutations in the respective clotting factor genes.[339] [340] Prophylactic use of clotting factors has been proven to improve quality of life by preventing joint bleeds but requires maintenance therapy, usually throughout the life of the patient. Preventing joint damage early is crucial because the initial damage will progress, irrespective of whether further bleeds occur in the affected joints.[341] Currently, clotting factor treatments include: plasma-derived products, which are virally inactivated and made from human donor plasma; recombinant products, such as recombinant Factors VIIa, VIII, IX, X, XIII, which are created using genetically engineered cells and recombinant technology; and a monoclonal antibody product that binds to specific receptor sites of missing clotting factor, which is needed for effective hemostasis.[342] [343] Individuals with hemophilia generally self-infuse clotting factor at home, often learning to do so in childhood.[344] [345] [346]

Section 2324 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) added subparagraph (I) to section 1861(s)(2) of the Act to provide Medicare Part B coverage of blood clotting factor treatments for hemophilia patients who are competent to use such factors to control bleeding without medical supervision (that is, self-administered), and items related to the administration of such factors; this is codified at § 410.63(b). As set forth in section 1842(o)(1)(C) of the Act, payment for clotting factor product is the amount provided for under section 1847A of the Act.

[335] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52879.*

[336] *https://www.cancer.gov/about-cancer/treatment/types/stem-cell-transplant.*

[337] *https://www.cancer.org/cancer/managing-cancer/treatment-types/stem-cell-transplant/types-of-transplants.html.*

[338] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52474.*

[339] *https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-a,* accessed April 9, 2024.

[340] *https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b,* accessed April 9, 2024.

[341] Aledort LM, Haschmeyer RH, Pettersson H. A longitudinal study of orthopaedic outcomes for severe factor-VIII-deficient haemophiliacs. The Orthopaedic Outcome Study Group. J Intern Med. 1994 Oct;236(4):391–9.

[342] Srivastava A, et al. Haemophilia. 2020;26(suppl 6):1–158.

[343] *https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2483adba-fab6-4d1b-96c5-c195577ed071.*

[344] GAO–03–184 Medicare: Payment for Blood Clotting Factor. *www.gao.gov/assets/gao-03-184.pdf.*

[345] Valentino, L. A., Baker, J. R., Butler, R., Escobar, M., Frick, N., Karp, S., . . . Skinner, M. (2021). Integrated Hemophilia Patient Care via a National Network of Care Centers in the United States: A Model for Rare Coagulation Disorders. Journal of Blood Medicine, 12, 897–911. *https://doi.org/10.2147/JBM.S325031.*

[346] *https://www.hemophilia.org/bleeding-disorders-a-z/treatment/current-treatments,* accessed April 9, 2024.

In January of 2003, the Comptroller General of the United States published a report entitled ''Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost'' [347] (hereinafter referred to the January 2003 report). Among other things, the January 2003 report found that ''providers incur additional costs associated with delivering clotting factor that are not separately reimbursed by Medicare.'' Specifically, the January 2003 report cited delivery costs generated in inventory management, specialized refrigerated storage, shipping, and the provision of ancillary supplies such as needles, syringes, and tourniquets to patients that were not accounted for by Medicare payment for the clotting factor product alone.

After the release of the January 2003 report, section 303(e)(1) of the MMA amended section 1842(o) of the Act by adding a new paragraph (5), requiring the Secretary to establish a furnishing fee for the items and services associated with the furnishing of blood clotting factor. Specifically, section 1842(o)(5) of the Act requires that for clotting factors furnished on or after January 1, 2005, the Secretary shall provide for a separate payment to the entity which furnishes blood clotting factors for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Accordingly, the clotting factor furnishing fee was codified at § 410.63(c), which states that the furnishing fee is added on a per unit basis to the clotting factor.

In 2005, CMS established a furnishing fee of $0.14 per unit of clotting factor. The clotting factor furnishing fee is increased by the percentage increase in the Consumer Price Index (CPI) for Medical Care for the 12-month period ending with June of the previous year, as required by section 1842(o)(5)(C) of the Act, and updated annually in chapter 17, section 80.4.1 of the Medicare Claims Processing Manual. For 2024, the clotting factor furnishing fee is $0.250 per unit. Chapter 17 of the Medicare Claims Processing Manual, section 80.4.1 indicates that ''CMS includes this clotting factor furnishing fee in the nationally published payment limit for clotting factor billing codes'' along with the pricing file, which denotes which HCPCS codes have the furnishing fee added. The payment limit in the pricing file includes the payment limit for the clotting factor product (under methodology in section 1847A of the Act) plus furnishing fee.

As was the case at the time the clotting factor furnishing fee regulations were originally finalized, we continue to believe the products eligible for payment of the clotting factor furnishing fee and those eligible for payment as clotting factor products are the same subset of products: that is, self-administered clotting factor products, as described above. Similar to section 1861(s)(2)(I) of the Act, section 1842(o)(5) of the Act specifically contemplates that clotting factors are self-administered. In particular, section 1842(o)(5)(A)(ii) of the Act specifies that the furnishing fee can take into account ''ancillary supplies and patient training for the self-administration of such factors.'' As stated in the CY 2005 PFS final rule, the furnishing fee accounts for the costs associated with supplying the clotting factor, including patient training necessary for self-administration of such factors (69 FR 47523; 69 FR 66311). Thus, the clotting factor furnishing fee, as implemented, pays for services and supplies in connection with the patient's self-administration of the product.

We note that section 1842(o)(5)(A) of the Act directed the Secretary to ''review[. . .] the January 2003 report'' when establishing the separate payment for entities which furnish blood clotting factors to the patient. The January 2003 report refers to self-administration of clotting factor and the benefits beneficiaries receive from home-use of the product throughout the report. For example, the January 2003 report states, ''Individuals with hemophilia generally self-infuse clotting factor. Clotting factor can be infused on demand, when a bleeding episode occurs, or for prevention, known as prophylactic use. By self-infusing, individuals can avoid waiting for care at a medical facility.''

Most notably, for purposes of understanding the Medicare clotting factor payment inadequacy that was addressed by Congress by adding the furnishing fee, the January 2003 report states ''[t]he method of delivery of clotting factor has implications for Medicare payment. Most outpatient drugs covered by Medicare are administered in a physician's office. When a beneficiary visits a physician in order to receive a drug, the physician receives one payment from Medicare for the drug and another payment through the physician fee schedule for administering the drug. Clotting factor, however, is generally not administered in a physician's office.'' That is, the January 2003 report highlighted that Medicare payment for clotting factor, in particular, was inadequate because there are costs associated with supplying the clotting factor, but because it is self-administered, the furnishing of clotting factor was generally not eligible for the administration fee. Generally, the January 2003 report noted that payment for supplying other outpatient drugs covered by Medicare Part B were adequate because they are eligible for the administration fee. Again, as stated above, Congress addressed this issue by creating the furnishing fee for these self-administered clotting factor products in the MMA.

More recently, gene therapies have been FDA-approved for the treatment of hemophilia. These gene therapies introduce a functional gene to the patient, which provides the genetic information needed for the patient to produce the missing or nonfunctional protein. A viral vector in the gene therapies, engineered with adeno-associate virus, delivers the functional copy of the clotting factor gene into the patient's liver cells. The viral vector then releases the functional gene which integrates into the cell's DNA and starts producing the missing clotting factor protein (that is, Factor VIII or Factor IX) to restore normal clotting function.

In the case of hemophilia A or B, the gene therapy introduces the functional gene that enables the patient to produce Factor VIII or Factor IX, respectively, on their own. Unlike clotting factors, which promptly restore balance in the coagulation cascade at the point of deficiency or bridge activated Factor IX and Factor X to restore the function of missing activated Factor VIII,[348] allowing for stable blood clot formation and hemostasis, the gene therapies do not directly integrate into the coagulation cascade.[349] [350] In the coagulation cascade, clotting factors become activated in response to damaged tissues or exposure to collagen at the injury site. This activation initiates the conversion of prothrombin to thrombin. Thrombin then converts fibrinogen into fibrin strands, forming the blood clot. Clotting factors restore normal clotting function by replacing deficient factors through repeated, dose-adjustable infusions or injections. In contrast, a single administration of gene therapies maintains a consistent and adequate level of clotting factors over the long term by enabling the self-

[347] *https://www.gao.gov/assets/gao-03&-184.pdf.*

[348] Genentech, Inc. Hemlibra (emicizumab-kxwh) injection, for subcutaneous use. South San Francisco, CA: Genentech, Inc.; 2023. Package insert.

[349] Hoffman, M., & Monroe, D.M. (2001). A cell-based model of hemostasis. *Thrombosis and Haemostasis,* 85(6), 958–965.

[350] Schenone M., Furie B.C., Furie B. The blood coagulation cascade. *Curr Opin Hematol.* 2004 Jul;11(4):272–7.

production of the clotting factor proteins—an indirect method that relies on the patient's cells to increase clotting factor levels. However, as the self-production of clotting factor proteins takes time, the sustained outcomes of gene therapies may take several weeks to fully manifest. Interested parties have asked if CMS considers these gene therapies to be clotting factors for which the clotting factor furnishing fee would be paid.

Gene therapies for hemophilia are administered via a one-time, single-dose intravenous infusion in a setting where personnel and equipment are immediately available to treat infusion-related reactions. They are not typically administered by the patient in his or her home, and close monitoring is required for at least three hours after the end of the infusion.[351] While these gene therapy products may have a similar goal to clotting factor products, in that both products are designed to improve outcomes for patients with hemophilia, gene therapy products prompt the body to make clotting factors, but are not clotting factors themselves. Given that the administration would occur incident to a physician service (that is, the product is not self-administered), the differing mechanism of action from replacing deficient factors (that is, triggering the body to make clotting factors rather than infusing clotting factors into the body), and the requirement of close monitoring by a healthcare professional post-infusion, these gene therapies do not have the characteristics described in the January 2003 report that is referenced in section 1842(o)(5) of the Act, which the Secretary relied on in drafting § 410.63(c). Therefore, they do not constitute ''clotting factors'' for purposes of Medicare payment.

Accordingly, gene therapies for hemophilia are eligible for payment as drugs or biologicals under Part B as part of (or incident to) a physician's service. The ''incident to'' coverage is limited to drugs that are not usually self-administered and the physician generally must incur a cost for the drug and must bill for it. Furnishing entities will bill for its administration, and the administration fees will reflect the resources necessary to furnish the drug. For example, certain CPT codes for administering drugs include preparation of the dose and patient monitoring. Specifically, CPT codes 96401–96549 (chemotherapy administration and nonchemotherapy injections and infusions) include clinical labor activities such as clinical staff preparation of chemotherapy agent(s) as well as evaluation and management services.[352]

For the reasons explained above, we do not believe gene therapies for hemophilia meet the definition of a clotting factor for purposes of Medicare payment, but even if they did, they still would not be eligible for the furnishing fee because the costs associated with furnishing these gene therapies would already be reflected in applicable administration codes paid under the Physician Fee Schedule. In accordance with § 410.63(c)(1), a clotting factor furnishing fee is not payable when the costs associated with furnishing a clotting factor are paid through another payment system. In this case, the payment system is the payment system established under the Physician Fee Schedule. Furnishing fees for drugs that are physician administered would result in physicians being paid twice for incidental costs of administering the drug because the furnishing fee is intended to compensate for supplies like needles, syringes, and tourniquets as well as storage costs, and so is the Part B payment for administering the drug. We do not believe this double payment is appropriate, nor do we believe this is what Congress intended in directing CMS to establish a clotting factor furnishing fee.

Accordingly, we proposed to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. Additionally, we proposed to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the Physician Fee Schedule. That is, we proposed to clarify through revisions to § 410.63 that clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Four commenters expressed general support of our proposal to clarify that only self-administered blood clotting factors be eligible for furnishing fees. One of these commenters agreed with our proposal that cell and gene therapies used to treat hemophilia are not clotting factors.

Response: We thank the commenters for their support.

Comment: Two commenters disagree with our interpretation of section 1861(s)(2)(I) of the Act. One commenter stated that section 1861(s)(2)(I) of the Act addresses only coverage of self-administered clotting factors under Medicare Part B but does not dictate which products are eligible to receive a furnishing fee. Another commenter stated that our interpretation of section 1861(s)(2)(I) of the Act is incorrect because they state the phrase ''without medical or other supervision'' describes a capability of certain patients, not a limitation on the definition of clotting factors themselves. Further, one of the commenters stated that if Congress had intended to limit clotting factors to self-administered products in section 1861(s)(2)(I) of the Act, they could have used explicit language to that effect, as they did in section 1861(s)(2)(A) of the Act.

Response: Section 1861(s)(2)(I) of the Act provides Medicare Part B coverage of blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical or other supervision (that is, self-administered), and items related to the administration of such factors; this is codified at § 410.63(b). Treatments for hemophilia that are not self-administered but rather administered in a setting where personnel and equipment are immediately available do not fit the description of coverage set forth in section 1861(s)(2)(I).

Commenters compared the language used in the Social Security Act for clotting factor and coverage of ''medical and other health services.'' Specifically, they noted section 1861(s)(2)(A) of the Act, which provides for Medicare Part B coverage of ''services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service.'' Commenters stated that because the same exact words were not used to describe the limits of these two different subsets of coverage, that is, medical and other health services and clotting factor, then Congress could not have meant the same thing. We disagree. The two different statutory provisions function differently within the statute and refer to coverage of different items that are distinct from one another. It is not necessary for Congress to use the same language in different parts of the statute to describe coverage of different items

[351] Carvalho M., Sepodes B., Martins AP., Patient access to gene therapy medicinal products: a comprehensive review BMJ Innovations 2021;7:123–134.

[352] Section 30.5, Chapter 12 of the Medicare Claims Processing Manual.

and services. Here, context, and the words themselves, show that the two different phrases have the same meaning.

Comment: Three commenters disagree with our interpretation that section 1842(o)(5) of the Act requires a clotting factor be self-administered in order to be eligible for the furnishing fee, citing what the commenters stated was Congress's choice to reference self-administration in section 1842(o)(5)(A)(ii) of the Act, and not in section 1842(o)(5)(A)(i) of the Act or elsewhere in the paragraph. The commenters state that this shows that the furnishing fee is not limited to self-administered clotting factors. The commenters stated that they believe this provision merely establishes the furnishing fee payment for clotting factor products and they believe nothing in this provision prohibits a clotting factor product that is not self-administered from being eligible for the furnishing fee. One of these commenters stated that they believe our interpretation limiting section 1842(o)(5) of the Act to self-administered clotting factors is unlawful. Another commenter argued that neither the statute's legislative history nor the January 2003 report included in the statute demonstrate Congressional intent to require that blood clotting factors be self-administered to receive the furnishing fee.

Response: The products eligible for payment of the clotting factor furnishing fee and those eligible for payment as clotting factor products are the same subset of products: that is, self-administered clotting factor products. Section 1842(o)(5) of the Act provides for the payment of a furnishing fee to an entity that furnishes clotting factors. Like section 1861(s)(2)(I) of the Act, section 1842(o)(5) specifically contemplates that clotting factors are self-administered. In particular, section 1842(o)(5)(A)(ii) of the Act, which was amended after the release of the January 2003 report, specifies that the furnishing fee can take into account ''ancillary supplies and patient training for the self-administration of such factors.'' CMS set the clotting factor furnishing fee through rulemaking, taking into account the costs associated with supplying the clotting factor, including patient training necessary for self-administration of such factors (see 69 FR 47523; 69 FR 66311). Thus, the clotting factor furnishing fee, as implemented, pays for services in connection with the patient's self-administration of the product.

Such a payment for furnishing of a product would be inappropriate for a product that cannot be self-administered and requires significant medical supervision. Rather, physician-administered clotting factors are eligible to receive a separate administration fee under Part B as part of (or incident to) a physician's service.

Comment: Two commenters opposed CMS's clarification that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS. One commenter argued that the PFS is not another payment system, and that the administration fees providers will bill for does not negate the need for the costs the furnishing fee covers for physician-administered gene therapies for hemophilia. The commenter claims that providing both fees would not result in duplicate payment.

Response: In accordance with § 410.63(c)(1), a clotting factor furnishing fee is not payable when the costs associated with furnishing a clotting factor are paid through another payment system. In this case, the payment system is the payment system established under the PFS. Furnishing fees for drugs that are physician administered would result in physicians being paid twice for incidental costs of administering the drug because the furnishing fee is intended to compensate for supplies like needles, syringes, and tourniquets as well as storage costs, and Part B payment is meant to capture the costs associated with administering the drug. We do not believe this double payment would be appropriate.

Comment: One commenter argued that the January 2003 report defines blood clotting factor in a way that includes gene therapies.

Response: Because gene therapies did not exist at the time when the statute and January 2003 report were written, they could not have contemplated such a therapy at that time. Furthermore, gene therapies treating hemophilia are not clotting factors themselves and do not interact directly with the coagulation cascade; rather, they are genetic treatments that enable the body to produce its own clotting factors. Because gene therapies are not themselves clotting factors, they are not eligible for the clotting factor furnishing fee.

Comment: One commenter urged CMS to clarify that there is an exception to the eligibility of the furnishing fee for when a patient needs a blood clotting factor for hemophilia and surgery while in the hospital, contending that absent the recommendation, there could be a significant impact on hospitals due to lack of payment.

Response: Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay. This is codified at 42 CFR 410.63(c)(1).

Comment: We received comments on topics that were outside the scope of the proposed rule. Those topics included establishing payment for providers for educating patients on cell and gene therapies and engaging with stakeholders to gather input on potential impacts of classification decisions and to consider developing a framework that can accommodate the evolving landscape of hemophilia treatments without requiring frequent regulatory updates.

Response: While these comments are out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

After consideration of public comments, we are finalizing as proposed to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered. In response to comments, we are also clarifying in § 410.63(b) that therapies that enable the body to produce clotting factor and do not directly integrate into the coagulation cascade are not themselves clotting factors for which the furnishing fee applies. Additionally, we are finalizing the proposed clarification at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X, of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are

furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) sessions furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount per visit. As of April 1, 2021, all RHCs are subject to statutory upper payment limits determined in accordance with section 1833(f) of the Act, as amended by section 130 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148)), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were initially designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. These nearly all-inclusive rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated and an AIR is derived from these aggregate expenditures. The FQHC PPS base rate is updated annually by the percentage increase in the FQHC market basket reduced by a productivity adjustment. For CY 2025, we proposed to rebase and revise the FQHC market basket to reflect a 2022 base year; see section III.B.7 of this final rule.

2. General Care Management Services in RHCs and FQHCs

a. Background

We have been engaged in a multi-year examination of coordinated and collaborative care services in professional settings, and as a result established codes and separate payment in the PFS to independently recognize and pay for these important services. The care coordination included in services, such as office visits, does not always adequately describe the non-face-to-face care management work involved in primary care and similar care relationships. Payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay.

Before we get into the detailed background of our RHC and FQHC payment policies for care coordination services, we want to acknowledge that we have used several terms to describe these services and are providing clarification. We use the terms ''care coordination'' services interchangeably with the term ''care management'' services in preamble and manual guidance to describe the type of work discussed above. We began to use the term ''general care management'' when we established the HCPCS code G0511 for CY 2018. Use of ''general care management'' is meant to describe certain non-face-to-face care management work involved in primary care that we have identified as appropriate for separate payment as discussed in the following paragraphs.

As we discussed in the CY 2016 PFS final rule (80 FR 71081 through 71088), to address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for chronic care management (CCM) services when CCM service requirements are met. We explained that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Although many RHCs and FQHCs pay for coordination of services within their own facilities and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are generally not included in the RHC or FQHC payment because in general, although a few of the services required for CCM payment may be provided by some RHCs and FQHCs on occasion, the systematic provision of care management, the level and intensity of care coordination, and the interoperability of care plans with external providers is not typically found in RHCs or FQHCs Therefore, separate payment was established in the CY 2016 PFS final rule (80 FR 71080 through 71088) for RHCs and FQHCs that furnish CCM services. We believe the non-face-to-face time required to coordinate care is not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique components of CCM services.

In the CY 2018 PFS final rule (82 FR 53169 through 53180), we finalized revisions to the payment methodology for CCM services furnished by RHCs and FQHCs and established requirements for general behavioral health integration (BHI) and psychiatric collaborative care management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2018. We also initiated the use of HCPCS codes G0511 and G0512. HCPCS code G0511 is a general care management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general

BHI services are furnished to a patient in a calendar month. HCPCS code G0512 is for psychiatric CoCM and can be billed by RHCs or FQHCs when at least 60 minutes of qualified psychiatric CoCM services are furnished to a patient in a calendar month.

For CY 2018 the payment amount for HCPCS code G0511 was set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. That is, for CY 2018 the 3 codes that comprised HCPCS code G0511 were CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*).

In the CY 2019 PFS final rule (83 FR 59683), we explained that another CCM code was introduced for practitioners billing under the PFS, CPT code 99491, which would correspond to 30 minutes or more of CCM furnished by a physician or other qualified health care professional and is similar to CPT codes 99490 and 99487. Therefore, for RHCs and FQHCs, we added CPT code 99491 as a general care management service and included it in the calculation of HCPCS code G0511. Starting on January 1, 2019, RHCs and FQHCs were paid for HCPCS code G0511 based on the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 (83 FR 59687).

In the CY 2021 PFS final rule (85 FR 84697 through 84699), we explained that the requirements described by the codes for principal care management (PCM) services were similar to the requirements for the services described by HCPCS code G0511; therefore, we added HCPCS codes G2064 and G2065 to HCPCS code G0511 as general care management services for RHCs and FQHCs. Consequently, effective January 1, 2021, RHCs and FQHCs are paid when a minimum of 30 minutes of qualifying PCM services are furnished during a calendar month. The payment rate for HCPCS code G0511 for CY 2021 was the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and PCM codes (HCPCS codes G2064 and G2065). We noted that in the CY 2022 PFS final rule (86 FR 65118), HCPCS codes G2064 and G2065 were replaced by CPT codes 99424 and 99435. Therefore, for CY 2022 the payment rate for HCPCS code G0511 was the average of the national non-facility PFS payment rate for CPT codes 99490, 99487, 99484, 99491, 99424, and 99425).

In the CY 2023 PFS final rule (87 FR 69735 through 69737), we included chronic pain management (CPM) services described by HCPCS code G3002 in the general care management HCPCS code G0511 when at least 30 minutes of qualifying non-face-to-face CPM services are furnished during a calendar month. We explained since HCPCS code G3002 is valued using a crosswalk to the PCM CPT code 99424, which is currently one of the CPT codes that comprise HCPCS code G0511, there was no change made to the average used to calculate the HCPCS code G0511 payment rate to reflect CPM services.

Most recently, in the CY 2024 PFS final rule (88 FR 79071 through 79073) we included the CPT codes that are associated with the suite of services that comprise remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs. In addition, we included community heath integration (CHI), principal illness navigation (PIN), and PIN—peer support services in HCPCS code G0511 when these services are furnished by RHCs and FQHCs (88 FR 79073 through 79081). We noted that for each of these newly included services that they must be medically reasonable and necessary, meet all requirements, and not be duplicative of services paid to RHCs and FQHCs under the general care management code for an episode of care in a given calendar month. We also clarified RHCs and FQHCs may bill HCPCS code G0511 multiple times in a calendar month, as long as all of the requirements are met and resource costs are not counted more than once (88 FR 79075).

Additional information on care management requirements is available on the CMS Care Management web page and on the CMS RHC and FQHC web pages.[353] [354] [355]

b. Regulatory Update (§ 405.2464(c))

During our development of the proposals discussed in sections III.B.2.c. and III.B.2.d. of this final rule, we determined that the language located in § 405.2464(c) could use additional information to streamline and provide clarity on our payment policy for care coordination services. For example, using consistent terms, effective dates, and the description of the basis of payment. Therefore, we proposed technical changes to § 405.2464(c) to accurately reflect the iterations of our payment policy for care coordination services as detailed in this background section.

We received a few comments on the proposed technical changes to § 405.2464(c) to accurately reflect the iterations of our payment policy for care coordination services. The following is a summary of the comments we received and our responses.

Comment: One commenter stated they were encouraged to learn that CMS proposed revisions to § 405.2464(c). The commenter stated that the average health care inflation rate has increased 3.5 percent per year over the past 4 years and that it appeared that actuarial analysis underlying the changes made last year were based on historical utilization and reimbursement, not provider expenses to provide these services. The commenter further stated that expansion of population health management requires a sustainable and viable reimbursement schema. Another commenter, who supported the proposed technical changes to § 405.2464(c), stated that this change represented a significant improvement in how care management services are billed and reimbursed and that it aligned with broader goals to enhance flexibility and accuracy in reimbursement, ensuring fair compensation for the full spectrum of care management services.

Response: We thank commenters for their support of the proposed technical changes to § 405.2464(c) to accurately reflect the iterations of our payment policy for care coordination services.

After consideration of public comments, we will finalize our proposed technical changes to § 405.2464(c) to accurately reflect the iterations of our payment policy for care coordination services.

c. Payment Policy for General Care Management Services

As discussed previously, in the last few years of PFS payment rules we have expanded the scope of care management services billable using HCPCS code G0511. Prior to CY 2024, HCPCS code G0511 was based on the national average non-facility PFS payment rate for each base code identified as billable general care management services. That is, we added each payment rate divided by the total number of codes to arrive at the payment amount for HCPCS code G0511. This payment amount was a flat

[353] *https://www.cms.gov/medicare/payment/fee-schedules/physician/care-management.*

[354] *https://www.cms.gov/center/provider-type/rural-health-clinics-center.*

[355] *https://www.cms.gov/medicare/payment/prospective-payment-systems/federally-qualified-health-centers-fqhc-center.*

rate that was not subsequently adjusted for locality.

In the CY 2024 PFS final rule (88 FR 79076 through 79079), we explained continuing to calculate the value of HCPCS code G0511 using an approach based on an average may no longer be appropriate payment for those services since we are simply dividing by the number of codes that comprise HCPCS code G0511. As that number of services with lower payment rates increases, the payment rate per service decreases. We noted that while the policy may address providing a payment for furnishing non-face-to-face services, the magnitude of the value may not appropriately account for the costs. Therefore, we finalized a revised methodology for the calculation of HCPCS code G0511 by looking at the actual utilization of the services. We used a weighted average of the services that comprise HCPCS code G0511. For the utilization data of the services, we used the most recently available utilization data from the services paid under the PFS in the physician office setting. We explained that the physician office setting may provide an appropriate proxy for utilization of these services in the absence of actual data because this setting most closely aligns with the types of services furnished in RHCs and FQHCs since they typically furnish primary care.

To ensure we accounted for payments accurately, we explained that we looked at PFS utilization of the base code for the service and any applicable add-on codes used in the same month as well as any base codes reported alone in a month for all of the services comprising general care management (that is, the array of services that made up HCPCS code G0511). We believed we needed to account for the payment associated with the base code along with an applicable add-on code in our calculation as this demonstrates a complete encounter. Then to arrive at the payment rate for HCPCS code G0511 for CY 2024, we took the weighted average of the base code and add-on code pairs, in addition to the individual base codes for all of the services that comprise HCPCS code G0511 by using the CY 2021 PFS utilization.

We determined that this approach was a more accurate representation of the payment since it is consistent with practitioners billing under the PFS, and it accounts for the additional time spent in care coordination.

Subsequent to the issuance of the CY 2024 PFS final rule, interested parties have requested that CMS give them the ability to bill Medicare for each of the care management services that comprise HCPCS code G0511 when they are furnished in RHCs and FQHCs. RHCs, FQHCs, and associations supporting access to health care for rural populations have expressed concerns regarding the transparency of the services being billed with HCPCS code G0511. We noted, in the CY 2024 PFS final rule we stated that HCPCS code G0511 could be billed multiple times in a calendar month for each care management code that comprised HCPCS code G0511 as long as all requirements were met, there was no overlapping of resource time and services were furnished in accordance with CPT coding guidelines and conventions. However, providing this guidance triggered questions on how CMS tracks which general care management service is being furnished if the bundled code is reported so they would know when it was appropriate to bill multiple care management services on a single claim. RHCs and FQHCs have also requested the ability to bill the add-on codes that describe additional minutes spent on furnishing care management services and often ask for guidance on how to account for additional time spent.

We have also heard from interested parties that RHCs and FQHCs would not find it burdensome to report the actual HCPCS code that describes the care management service furnished, which was the main concern we had when we implemented HCPCS code G0511 (82 FR 53172). We understand that RHCs and FQHCs have become more sophisticated with billing and therefore reporting multiple codes has become less burdensome than in CY 2018 when we implemented G0511. In addition, we have heard that RHCs and FQHCs are interested in having more exposure and recognition in playing their part in the delivery of quality primary care and believe that this could be achieved with data that shows their utilization of services which could also be used in future payment refinements.

Due to these concerns, we reevaluated our payment policy for care management services. We agree with interested parties that it is important to identify the actual services being furnished and understand the utilization of these services, especially given our strong interest in their volume and their contribution to initiatives on health equity and social needs of services in the care coordination space. Therefore, we proposed to require RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code, G0511. The current list of base and add-on codes that make-up G0511 are listed in Table 28, titled ''General Care Management HCPCS Codes and Descriptors.'' Under this proposal, HCPCS code G0511 would no longer be payable when billed by RHCs and FQHCs. We noted that the payment amounts for some services that make up G0511 are less than the payment amount for G0511 and if an RHC or FQHC mostly furnishes these services, they could see a potential decline in payment. We also proposed to allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. This could potentially offset any decrease in payments. Payment for these services would be the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We believe that these proposals promote transparency in billing and payment and allowing RHCs and FQHCs to bill the individual care management codes would take into account the complexity of the service and the time spent furnishing the service.

TABLE 28: General Care Management HCPCS Codes and Descriptors

HCPCS code	Short Descriptors	Long Descriptors
99091	Collj & interpj data ea 30 d	Collection and interpretation of physiologic data (e.g. Blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99424	Prin care mgmt phys 1st 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month
99425	Prin care mgmt phys ea addl 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99426	Prin care mgmt staff 1st 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month
99427	Prin care mgmt staff ea addl 30	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent

HCPCS code	Short Descriptors	Long Descriptors
		adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional per calendar month (List separately in addition to code for primary procedure)
99437	Chrnc care mgmt phys ea addl 30	Chronic care management services, provided personally by a physician or other qualified health care professional, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline, comprehensive care plan established, implemented, revised or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99439	Chrnc care mgmt staf ea addl 20	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99453	Rem mntr physiol param setup	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial set-up and patient education on use of equipment
99454	Rem mntr physiol param dev	Remote monitoring of physiologic parameter(s) (e.g. Weight, blood pressure, pulse oximetry, respiratory flow rate) initial device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
99457	Rem physiol mntr 1st 20 min	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Rem physiol mntr ea addl 20	Remote physiologic monitoring treatment services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)
99474	Self-meas bp 2 readg bid 30d	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
99484	Care mgmt svc bhvl hlth cond	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional time, per calendar month, with the following required element: initial assessment or follow-up monitoring, including using applicable validated rating scales, behavioral health care planning about behavioral or psychiatric health problems, including revision for patients not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy,

HCPCS code	Short Descriptors	Long Descriptors
		pharmacotherapy, counseling, or psychiatric consultation, continuity of care with an appointed member of the care team
99487	Cplx chrnc care 1st 60 min	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or substantial revision of comprehensive care plan, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99489	Cplx chrnc care ea addl 30	Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, establishment or significant revision of comprehensive care plan, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)
99490	Chrnc care mgmt staff 1st 20	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
99491	Chrnc care mgmt phys 1st 30	Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of physician or other qualified healthcare professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored
98975	Rem ther mntr 1st setup&edu	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); initial set-up and patient education on use of equipment
98976	Rem ther mntr dev sply resp	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
98977	Rem ther mntr dv sply mscskl	Remote therapeutic monitoring (e.g. therapy adherence, therapy response); device(s) supply with scheduled (e.g. daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days

HCPCS code	Short Descriptors	Long Descriptors
98980	Rem ther mntr 1st 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Rem ther mntr ea addl 20 min	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (list separately in addition to code for primary procedure)
G0140	Nav srv peer sup 60 min pr m	Principal Illness Navigation – Peer Support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following: • Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition ++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. ++ Facilitating patient-driven goal setting and establishing an action plan. ++ Providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan. • Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. • Practitioner, Home, and Community-Based Care Communication ++ Assist the patient in communicating with their practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s). • Health education-Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. • Developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals.

HCPCS code	Short Descriptors	Long Descriptors
		++ Periodic administration of SDOH survey tools and monitoring of related SDOH, that is not separately billed. PIN services may address newly discovered SDOH if the practitioner determines they are significantly impacting the practitioner's ability to diagnose or treat the high-risk condition(s). • Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals. Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.
G0146	Nav srv peer sup addl 30 pr m	Principal Illness Navigation—Peer Support, additional 30 minutes per calendar month (List separately in addition to G0140)
G3002	Chronic pain mgmt 30 mins	Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care, e.g. physical therapy and occupational therapy, and community-based care, as appropriate. Required initial face-to- face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (when using G3002, 30 minutes must be met or exceeded)
G3003	Chronic pain mgmt addl 15m	Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calenda month. (List separately in addition to G3002. When using G3003, 15 minutes mut be met or exceeded).
G0323	Care manage beh svs 20mins	Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with an/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team)
G0019	Comm hlth intg svs sdoh 60 mn	Community health integration (CHI) services by certified or trained auxiliary personnel under the direction of the

HCPCS code	Short Descriptors	Long Descriptors
		physician/other Qualified Healthcare Professional (QHP), including a community health worker located in the patient's community; 60 minutes per calendar month, in the followin activities: • Holistic personal assessment, performed in order to better understand the individualized context of the intersection between the identified social determinants of health (SDOH(s)) and problem(s) addressed in the CHI initiating visit (required only during the first month CHI services are provided). • Conducting a holistic personal assessment to understand patient's life story, needs, goals and preferences, including understanding cultural and linguistic factors. • Setting personalized goals and creating action plans. • Providing tailored support as needed to accomplish the billing practitioner's treatment plan. • Periodic administration of SDOH survey tools and monitoring of related SDOH, that is not separately billed. As new SDOH that may affect the diagnosis and treatment of problem(s) in the initiating visit are identified, these SDOH may be focused on for CHI services. • Practitioner, Home, and Community-Based Care Coordination. • Coordination with practitioner, home, and community-based services. • Communication to and from practitioners, home and community-based services, and hospital, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial needs, functional deficits, goals, and preferences, including cultural and linguistic factors. • Coordination of care transitions between and among health care practitioners and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. • Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address SDOH that the billing practitioner identifies as significantly limiting their ability to diagnose or treat the problem(s)identified in the CHI initiating visit. • Health education- Helping patients contextualize health education provided by the patient's treatment team with their individual needs, goals, and preferences, and SDOH that affect problem(s) identified during the initiating visit and educating the patient on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services addressing SDOH, in ways that are more likely to promote personalized and effective treatment of their problem(s) identified during the initiating visit. • Health care access/health system navigation Helping the patient arrange access to medical care, including securing

HCPCS code	Short Descriptors	Long Descriptors
		medical or community-based appointments, identifying appropriate providers for care needs, identifying appropriate community -based resources for SDOH related to problem(s) identified during the initiating visit, and for accessing all clinical care services necessary. • Facilitating behavioral change necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach treatment goals for the problem(s) addressed in the CHI initiating visit. Facilitating and providing social and emotional support for the patient related to coping with the problem(s) addressing during the CHI initiating visit, related SDOH, and adjusting daily routines to better meet diagnosis and treatment goals for those problems .
G0022	Comm hlth intg svs addl 30 m	Community health integration services, each additional 30 minutes per calendar month (List separately in addition to G0019)
G0023	Pin srv 60 min pr m	Principal Illness Navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities: • Person-centered assessment, performed to better understand the individual context of the serious, high-risk condition. ++ Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors. ++ Facilitating patient-driven goal setting and establishing an action plan. ++ Providing tailored support as needed to accomplish the practitioner's treatment plan. • Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. • Practitioner, Home, and Community-Based Care Coordination ++ Coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home and community-based service providers; and caregiver (if applicable). ++ Communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, preferences, and desired outcomes, including cultural and linguistic factors. ++ Coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. ++ Facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address SDOH need(s).

HCPCS code	Short Descriptors	Long Descriptors
		• Health education—Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. • Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. • Health care access/health system navigation. ++ Helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them. ++ Providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable. • Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. • Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. • Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.
G0024	Pin srv addl 30 min pr m	Principal Illness Navigation services, additional 30 minutes per calendar month (List separately in addition to G0023).

We proposed revisions at § 405.2464(c) to reflect the proposed payment method for care management services furnished in RHCs and FQHCs beginning January 1, 2025.

We received several comments on our proposal to permit RHCs and FQHCs to report and bill under the individual codes that make up the general care management HCPCS code G0511.

The following is a summary of the comments we received and our responses.

Comment: Many commenters were very supportive of our proposal to unbundle HCPCS G0511 and require RHCs and FQHCs to report and bill for the actual codes that make up the general care management HCPCS code G0511. One commenter stated that they appreciated CMS' proposed steps to harmonize access to payment for asynchronous remote monitoring across the Medicare system.

Response: We thank the commenters for their support.

Comment: Although many commenters support our proposal to unbundle HCPCS G0511 and require RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code G0511, many commenters had additional requests/recommendations. A few commenters urged CMS to establish adequate reimbursement rates to ensure health centers continued financial viability and stated that although this proposal makes a lot of sense, the financial implications of a reduced payment for some of the services could jeopardize sustainability. These commenters implored CMS to ensure payment rates accurately reflect the cost of providing these services as CMS calculates the reimbursement rates for all these different general care management services. These commenters requested that CMS ensure sufficient reimbursement for all services previously under the HCPCS code G0511 to promote financial stability for health centers. Another commenter stated that CMS must ensure reimbursement rates are sufficient to enable providers to adopt high-value applications of software-based technologies. This commenter also recommended that CMS, alongside with ensuring adequate reimbursement, work with medical specialty societies to define high-value remote patient monitoring applications and develop clinical guidelines to help providers deliver evidence-based care. One commenter requested that CMS reconsider the approach of encouraging other codes to be utilized to offset the potential decline in reimbursement from HCPCS code G0511 to CPT code 99490 (*chronic care management services*). The commenter explained that for example, an FQHC in the Southeastern U.S. that was billing 1,000 CCM patients using HCPCS code G0511 would likely need to bill the additional 20-minute code (99439) for at least 500 patients each month to make up the difference in net reimbursement after factoring in

the cost of care. The commenter further explained that while this is certainly possible, many CCM patients do not need or want an additional 20 minutes of care, especially when factoring in the potential for an additional cost share each month. The commenter shared concerns that FQHCs will suffer from this change by both (i) not being able to successfully replace the lost reimbursement through CPT code 99439 (or other additional codes) and (ii) seeing a decline in CCM participation from patients opting out of the program due to additional cost sharing. The commenter requests that CMS consider maintaining the G0511 reimbursement rate for 99490 in 2025.

Finally, other commenters had specific requests related to RPM/RTM services. Some commenters stated that reimbursement rates for Remote Patient Monitoring (RPM) have been flagged to potentially generate lower reimbursement rates, which could result in health centers, especially smaller health centers with limited budgets, struggling to provide this crucial service to their patients.

Response: We noted above and in the proposed rule that the payment amounts for some services that make up G0511 are less than the payment amount for HCPCS code G0511 and if an RHC or FQHC mostly furnishes these services, they could see a potential decline in payment. We also proposed to allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter. Payment for these services would be the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. These payment rates reflect the cost of services provided and are in line with services in other comparable settings.

Comment: In addition to supporting our proposal to unbundle HCPCS code G0511, a few commenters requested that CMS waive co-insurance for these services. One commenter supported the elimination of co-insurance for care management programs, stating that removing coinsurance will eliminate a significant obstacle for patients requiring ongoing care management, especially those with chronic conditions needing frequent monitoring and intervention. The commenter stated that eliminating coinsurance will increase access to necessary care management services, encourage more consistent patient engagement with their care plans, and potentially reduce overall healthcare costs by preventing complications, decreasing hospital admissions, and ensuring timely and appropriate care. Another commenter urged CMS to waive the 20 percent copay as we have with AWV's to accelerate the adoption by physicians and participation by patients or at the very least allow the physicians to make the decision if they wish to waive the 20 percent copay for those who do not have the ability to pay. This commenter further urged CMS to allow RHC's to be able to conduct an AWV the same day as an office visit as they noted they believe it is often difficult either logistically or financially for many in the rural healthcare setting to make 2 trips, and as a result they do not believe as many patients whose only access to healthcare that is being served by a RHC are benefiting from AWV's.

Response: As we stated in the CY 2018 PFS final rule (82 FR 53178), we are aware that the copayment and/or deductible in RHCs and the copayment in FQHCs can be a barrier for some beneficiaries, but we do not have the statutory authority to waive these charges. Because these services are typically furnished non-face-to-face, and therefore, are not visible to the patient, it is important that adequate information is given to patients during the consent process on cost-sharing responsibilities and the benefits of care management services. RHCs and FQHCs should also provide information on the availability of assistance to qualified patients in meeting their cost-sharing obligations, or any other programs to provide financial assistance, if applicable. We note that Part B coinsurance would apply for the unbundled codes that make up the list of codes included in HCPCS code G0511, as mandated for Part B services by section 1833(a)(1) of the Act. Regarding the comment about AWVs, we thank the commenter for this feedback, but note that it is out of the scope of this final rule.

Comment: Many other commenters who supported the proposal requested that CMS implement a transition period for at least one year to allow time for providers to either continue to bill under HCPCS code G0511 or under individual codes proposed for CY 2025 to ensure continued access to care and ease the transition for providers. Other commenters suggested that a transition period would also help to ensure that a patient beginning treatment in 2024 does not lose access to that treatment in 2025 as reimbursement models change. Other commenters stated that the transition period would help providers begin to prepare for the proposed changes since the addition of the new codes to G0511 in the past years complicated billing for these providers. A few commenters stated that the transition period will allow the greatest access to care management services for patients and simplify compliance for providers that are still new to billing these services. Other commenters' transition requests were specific to RPM/RTM services. These commenters noted they believe that the shift in RHC and FQHC reimbursement for RPM would lead to patients being cut off from care. They also requested that CMS create, at a minimum, a one-year transition period for patients and providers who have only just begun offering and receiving RPM services at RHCs and FQHCs because of the harmful impact of this change on RPM access.

Response: We understand why some commenters might want a transition. We would expect those individual RHCs/FQHCs that have the capability to bill the individual HCPCS codes that make up HCPCS code G0511 to do so. However, we recognize that some RHCs/FQHCs may need more time to implement systems changes needed to incorporate the change for billing purposes. These changes should be on a facility basis and not on a patient-by-patient or claim-by-claim basis. To this end, we were persuaded by the commenters' requests and are allowing 6 months RHCs and FQHCs to come into compliance. We are allowing facilities at least until July 1, 2025, to enable them to be able to update their billing mechanisms. During this period during which RHCs and FQHCs bring themselves into compliance, RHCs and FQHCs shall continue reporting G0511. However, RHCs and FQHCs that have the infrastructure in place to report the individual HCPCS codes that describe the individual services may do so. We want to clarify that at the facility level when billing Medicare, RHCs and FQHCs should report these services with G0511 or the individual codes, but not both.

Comment: A few commenters who were also supportive of our proposal also requested that CMS provide additional resources and support to help FQHCs transition to the new billing method and meet the increased documentation requirements when billing for individual general care management codes previously included in HCPCS code G0511, including providing the following resources: updated cost reporting instructions to help FQHCs understand the specific requirements for each service code and ensure accurate documentation;

comprehensive training guides, such as FAQs, to educate FQHC staff on the detailed documentation requirements, time tracking, and compliance with each service code; access to technical assistance; and support to help FQHCs implement new billing systems and processes effectively. Another commenter recommended that CMS provide clear guidelines for documentation and billing purposes for when FQHCs can bill, for how much time, and how many times per month. Additionally, the commenter encouraged CMS to issue guidance for understanding what is not allowed to be billed concurrently.

Response: We encourage interested parties to review the guidance on all of the various care coordination services on our website.[356] We will provide subregulatory guidance updates and educational resources, including updates to the RHC and FQHC Medicare Benefit Policy Manual, CMS MLN publications, and various web pages including the RHC and FQHC web pages and CMS' Care Management web page.

Comment: One commenter urged CMS to implement a policy to allow FQHCs/RHCs to bill for Community Health Integration (CHI), Principal Illness Navigation (PIN) and Principal Illness Navigation Peer Support (PIC–PS) CHI/PIN/PIN–PS, using the same set of HCPCS billing codes available to traditional providers with no cap or limit on the volume of services rendered to a beneficiary per calendar month. This commenter stated that the requirement that only one provider bill for CHI/PIN/PIN–PS at a time, while simultaneously requiring FQHCs/RHCs to bill for a range of care management services under the same code, places FQHCs/RHCs at considerable risk of having their claims denied as being for duplicate services. The commenter identified barriers to adopting CHI/PIN/PIN–PS including: the risk of a claim denial because another provider is rendering a different service coded under the same HCPCS code (G0511), and the lack of clarity regarding the volume of CHI/PIN/PIN–PS that can be provided to a beneficiary during a calendar month.

Response: As proposed in the CY 2025 proposed rule (89 FR 61596, 61782), we would like to reiterate that we proposed to unbundle the codes that make up HCPCS G0511, including CHI/PIN/PIN–PS, and require RHCs and FQHCs to bill the individual codes that make up the general care management codes HCPCS code G0511. The current billing policies and requirements for the care coordination codes remain applicable. In addition, regarding the comment about the requirement that only one provider bill for CHI/PIN/PIN–PS, we would also like to reiterate that as we stated in the CY 2024 PFS final rule (88 FR 78923), we finalized a policy of only allowing one provider to bill CHI.

Comment: We received several comments from the RHC and FQHC community requesting CMS modify other bundled codes or provide separate unbundled payments for additional services. Many commenters suggested that CMS make changes to HCPCS code G0512. Some of those suggested changes included: allow FQHCs/RHCs to utilize the 99 set of HCPCS codes (99492, 99493, and 99494) in addition to the CPT Time Rule, unbundle HCPCS code G0512 to support the adoption of CoCM, and to reconsider the ongoing use of HCPCS code G0512 for Collaborative Care management services in RHCs and FQHCs and instead harmonize and unify the coding for Collaborative Care using the dedicated CPT codes. Other commenters also requested that CMS allow additional codes to be added to the list of HCPCS code G0511 that we proposed to unbundle. One commenter commended CMS's proposal to allow clinicians in RHCs and FQHCs to bill individual care management codes but urged CMS to include CPT code 99483, Cognitive Assessment and Care Planning Services, among the eligible codes. Other commenters advocated for payment parity for all care management services in RHC and FQHC settings and supported the elimination of HCPCS G0511 and adopt the full complement of Fee-for-Service (FFS) codes including any new care management code in the future such as Atherosclerotic Cardiovascular Disease (ASCVD). Another commenter stated that they would support RHCs being eligible for reimbursement under the HCPCS code G2211 code, as primary care clinicians in other settings are. This commenter noted they believe this would help both CMS and RHCs fully account for the additional time, intensity, and practice expense inherent to longitudinal care that HCPCS code G2211 was designed to capture.

Another commenter requested guidance to understand how these care management codes should be billed, as more FQHCs enter value-based care through the Medicare Shared Shavings Program, Making Care Primary (MCP) Model, or other CMMI models.

Response: We thank you for your support and appreciate your feedback regarding unbundling of HCPCS code G0512 and the addition of other services such as Cognitive Assessment and Care Planning Services, and Atherosclerotic Cardiovascular Disease (ASCVD) risk assessment service, and HCPCS code G2211 services. Regarding HCPCS code G0512, we did not propose to unbundle those services in the same way as HCPCS code G0511; however, we can evaluate further and contemplate for future rulemaking. Since cognitive assessment and care planning and the ASCVD risk assessment services happen in face-to-face visits with a provider, they would be included in the RHC AIR and the FQHC PPS and not be paid separately. Regarding HCPCS code G2211, RHCs and FQHCs in most cases are not paid according to complexity of the patient. Except for the services paid outside of the all-inclusive rates, we pay an encounter rate. HCPCS code G2211 is bundled into the RHC AIR and the FQHC PPS and not paid separately. Since we did not make any proposals regarding these services, these comments are out of scope. However, we will consider your feedback for future rulemaking. Finally, the CMS programs (MSSP or CMMI models) that currently use HCPCS code G0511 are aware of the changes we are making and will evaluate their programs accordingly.

After consideration of public comments, we are finalizing our proposal as proposed with a modification to permit RHCs and FQHCs 6-months to come into compliance, to enable those RHCs/FQHCs to be able to update their billing systems. We will also finalize the technical corrections at § 405.2464(c) to reflect the proposed payment method for care management services furnished in RHCs and FQHCs beginning January 1, 2025.

d. New Codes for Advanced Primary Care Management (APCM) Services

As discussed in section II.G of this final rule, HHS and CMS have been analyzing opportunities to strengthen and invest in primary care in alignment with the goals of the HHS Initiative to Strengthen Primary Care.[357] Research has demonstrated that greater primary care physician supply is associated with improved population-level mortality and reduced disparities,[358] and also that

[356] Care Management | CMS (*https://www.cms.gov/medicare/payment/fee-schedules/physician/care-management*).

[357] U.S. Department of Health and Human Services. (2023). Primary Care: Our First Line of Defense. *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf*.

[358] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005–2015. *JAMA Intern Med*.

establishing a long-term relationship with a primary care provider leads to reduced emergency department (ED) visits,[359] improved care coordination, and increased patient satisfaction.[360] HHS recognizes that effective primary care is essential for improving access to healthcare, for the health and wellbeing of individuals, families, and communities, and for achieving health equity. The first coordinated set of HHS-wide actions to strengthen primary care, as part of the Initiative, is in primary care payment; for example, adjusting payment to ensure it supports delivery of advanced primary care. CMS Innovation Center models, described in section II.G.2.a.(1) of this final rule, reflect the ongoing work within HHS and the unified, comprehensive approach to HHS primary care activities that we are accomplishing through our current statutory authorities and funding.

In recent years, we have implemented significant changes aimed at better capturing the resources required for care management services, including chronic care management (CCM), principal care management (PCM), and transitional care management (TCM) and more recently, community health integration (CHI), principal illness navigation (PIN) and PIN-peer support services. For RHCs and FQHCs, we have established payment for these suites of care coordination services outside of the RHC AIR and FQHC PPS.

In section II.G.2.b. of this final rule, we proposed to establish coding and make payment under the PFS for a newly defined set of APCM services described and defined by three new HCPCS G-codes. This new coding would reflect the recognized effectiveness and growing adoption of the advanced primary care approach to care. It would also encompass a broader range of services and simplify the billing and documentation requirements, as compared to existing care management codes. The proposed coding for APCM incorporates elements of several existing care management services into a bundle that we have already considered to be care coordination services paid separately to RHCs and FQHCs using HCPCS code G0511 (for example, CCM and PCM). In addition, the coding for APCM incorporates elements of communication technology-based services (CTBS) into a bundle that we have already considered to be virtual communications paid separately to RHCs and FQHCs using HCPCS code G0071. For example, remote evaluation of patient videos/images, virtual check-in, and e-visits. Therefore, to allow RHCs and FQHCs the ability to simplify the billing and documentation requirements associated with furnishing APCM services we proposed to allow RHCs and FQHCs to bill for these services and receive separate payment. Consistent with section II.G.2.b. of this final rule, the APCM code sets vary by the degree of complexity of patient conditions (that is, non-complex and complex CCM for multiple chronic conditions or PCM for a single high-risk condition), and whether the number of minutes spent by clinical staff or the physician or non-physician practitioner (NPP) is used to meet time thresholds for billing. In the CY 2025 proposed rule, we proposed to adopt the three new APCM codes GPCM1, GPCM2, and GPCM3 and the finalized HCPCS codes are as follows: G0556, G0557 and G0558, respectively. For further discussion on the proposed HCPCS codes G0556, G0557, and G0558, please see section II.G.2.b. of this final rule.

As we have established previously, care coordination services are RHC/FQHC services and as such, we proposed to align once again with the PFS and adopt the new codes for APCM services. Additionally, allowing separate payment for APCM services in RHCs and FQHCs is intended to reflect the additional time and resources necessary for the unique components of care coordination services.

Further, in alignment with our proposal earlier in this section to require RHCs and FQHCs to utilize the same coding as when billing under the PFS and no longer use HCPCS code G0511, which described many care coordination services, we proposed to require RHCs and FQHCs when furnishing APCM to use the more specific coding, that is, the three HCPCS G-codes described above. We would pay for these services in addition to the RHC AIR or FQHC PPS because we consider these services as non-face-to-face services and similar to other care management services such as chronic care management, principal care management, and remote physiological monitoring, where these services are not captured in the RHC AIR or FQHC PPS payment. Similarly, we proposed that payment for these services would be paid at the PFS non-facility rate.

It is important to note that if RHCs and FQHCs report these new codes, they are per calendar month bundles. If the RHC/FQHC decides to bill for APCM then they would not bill for certain other individual services. For further discussion on duplicative services and concurrent billing restrictions with regard to APCM policies, we refer readers to section II.G.2.d. of this final rule.

We received several comments on our proposal to require RHCs and FQHCs when furnishing APCM services to use the three newly created HCPCS G-codes created for the PFS and paid at the PFS non-facility rate.

The following is a summary of the comments we received and our responses.

Comment: A few commenters fully supported our proposal to establish coding and making payment under the PFS for the three new HCPCS G-codes for APCM services. One commenter stated that these codes will also provide payment for services that are often already provided but for which they are often not compensated and urged CMS to support all care integration efforts. One commenter stated that RHCs and FQHCs are critical sources of primary care for low-income beneficiaries, including those with intellectual and developmental disabilities (IDD) who are dually eligible and/or often turned away by private medical practices. Another commenter stated that these new codes will likely give RHC providers flexibility in choosing the most appropriate care management option for their patients and the clinic's capacity—whether they elect to perform and bill for individual care management services, or the consolidated codes based on complexity of patient conditions. The commenter appreciated the clarity regarding which care management services can be billed simultaneously with APCM codes versus those that are considered duplicative.

Response: We thank the commenters for their support of our proposal to require RHCs and FQHCs when furnishing APCM services to use the three newly created HCPCS G-codes created for the PFS and paid at the PFS non-facility rate. We agree that adopting these three new HCPCS G-codes will give RHCs and FQHCs providers the flexibility to choose the most

2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624. *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393.*

[359] Willemijn L.A. Schäfer et al., ''Are People's Health Care Needs Better Met When Primary Care Is Strong? A Synthesis of the Results of the QUALICOPC Study in 34 Countries,'' Primary Health Care Research and Development 20 (2019): e104. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609545/.*

[360] Michael J. van den Berg, Tessa van Loenen, and Gert P Westert, ''Accessible and Continuous Primary Care May Help Reduce Rates of Emergency Department Use: An International Survey in 34 Countries,'' Family Practice 33, no. 1 (Feb. 2016): 42–50. *https://academic.oup.com/fampra/article/33/1/42/2450446.*

appropriate care management option for their patients and the clinic's capacity.

Comment: Although a few commenters fully supported our proposal to adopt the three new HCPCS G-codes for APCM services, other commenters were generally supportive and had additional requests/recommendations. Many commenters recommended that CMS allow a coinsurance waiver for FQHC and RHC patients who consent to using APCM services. These commenters stated many health center patients are financially vulnerable and that while health centers can place this co-insurance obligation on the sliding fee scale, patients have historically been wary of monthly payment requirements for general care management services. The commenters stated that waiving co-insurance costs of APCM for FQHC patients alleviates potential financial barriers to care and will help maintain patient enrollment in receiving these vital services. Some commenters expressed their concern about the burden a monthly cost-sharing responsibility will have on health center patients and recommended CMS allow a co-insurance waiver for FQHC patients who consent to using APCM services to help alleviate patient cost burdens, while another commenter urged CMS to examine any existing authority to permit health centers to waive co-pays to alleviate cost burdens to patients, whether it is done by working with OIG, incorporating flexibilities from demonstration models, or working with Congress. One commenter urged CMS to waive the applicable co-pay for APCM services furnished in RHCs/FQHCs or at the very least allow physicians to make the decision if they wish to waive the 20 percent copay for those who do not have the ability to pay.

Response: We thank commenters for their support and feedback. Regarding commenters' requests for waiving coinsurance costs, we note that we do not have any statutory authority that would allow us to waive the applicable coinsurance for APCM services. For more detail, please refer to section II.G2.2.

Comment: One commenter, who supports our proposal to adopt the three new APCM HCPCS G-codes, requests further clarification. The commenter does not recommend that these bundled payments include CHI and PIN services as the payment would be inadequate and the CHI and PIN provide different but complementary services. The commenter stated that if care management code G0511 is eliminated, FQHCs would need to be allowed to bill CHI and PIN separately and distinctly in addition to the APCM codes. The commenter requests clarification and guidance on the time constraints for FQHCs and billing for APCM services versus general care management services, which they stated could burden an FQHC's ability to bill these codes.

Another commenter stated that CMS is proposing to mandate both RHCs and FQHCs to bill individual codes that make up the general care management HCPCS code G0511 using three new G-codes, GPCM1, GPCM2, and GPCM3. The commenter stated that to offset decreases in payment for services that make up G0511, CMS proposes to include these add-on codes for additional time spent when the minimum threshold of time is met to adjust for a complete encounter. The commenter further stated that CMS believes that this will promote transparency in billing and payment, and it will also account for the complexity of the service and the time for each service. The commenter stated that while they appreciated the steps CMS is taking to improve primary care, these care management codes will only further create administrative burdens for practices and confusion for patients, as mentioned previously and that the introduction of three new G-codes will cause the conversion factor to decrease and reduce reimbursement. The commenter urged CMS to delay implementation and involve stakeholders in this conversation. One commenter requested that APCM bundle codes exclude CHI and PIN services.

Response: We note that CHI and PIN may be billed concurrently with APCM. We think that these services are unique and serve specific needs not otherwise met by the proposed APCM coding and believe that these services are additive to APCM services, and do not represent duplication of services, as long as time and effort are not counted more than once, requirements to bill the other services are met, and the services are medically reasonable and necessary. In response to the comment about the use of the three new APCM codes and G0511, we again reiterate that general care management services that make up HCPCS G0511 include chronic care management (CCM), principal care management (PCM), chronic pain management (CPM), general behavioral health integration (BHI), remote physiologic Monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), and principal illness navigation-peer support (PIN–PS). As stated in the CY 2025 PFS proposed rule (88 FR 61782), we proposed to require RHCs and FQHCs to bill the individual codes that make up the general care management HCPCS code, G0511. The APCM codes are not included in the list of codes that make up HCPCS G0511. Therefore, we will not be delaying the implementation of adopting the APCM codes. If RHCs and FQHCs provide APCM, they should report the APCM codes.

Comment: One commenter requested that CMS develop additional resources/technical assistance, beyond cost reporting instructions, to help health centers understand how to take up this new APCM bundled payment option.

Response: We thank the commenter for their feedback. We will issue sub-regulatory guidance to help health centers understand how to take up the APCM bundled payments via updating multiple resources including the RHC and FQHC Medicare Benefit Policy Manual, MLN publications and the RHC and FQHC web pages.

Comment: Some commenters requested that CMS monitor and evaluate the use of APCM services at RHCs and FQHCs to help reveal any potential barriers to uptake. These commenters state that they would appreciate CMS' diligence in monitoring RHCSs and FQHCs usage to inform whether future tweaks to APCM services would make them more accessible in rural settings.

Response: We thank the comments for this recommendation and will take this into consideration as we evaluate APCM.

After consideration of public comments, we are finalizing our proposal to require RHCs and FQHCs when furnishing APCM services to use the three newly created HCPCS G-codes created for the PFS paid at the PFS non-facility rate effective January 1, 2025, as proposed.

e. Request for Information—Aligning With Services Paid Under the PFS

As we discuss in section III.B.2.a. of this final rule, over the last several years we have been increasing our focus on care coordination. These services have evolved to focus on preventing and managing chronic disease, improving a beneficiary's transition from the hospital to the community setting, or on integrative treatment of patients with behavioral health conditions. We have acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for

certain categories of beneficiaries. Therefore, under the PFS we have proposed new services over the years that practitioners billing under the PFS can be paid separately under the PFS. We have noted previously that RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. Therefore, we have proposed payment policies for RHCs and FQHCs that complement the new services for care coordination under the PFS to align the RHC and FQHC resource cost for those services with payment.

The increase in frequency of this complementary rulemaking has triggered us to consider operational efficiencies internally that we believe could result in more transparency and clarity for interested parties. Since RHCs and FQHCs are generally paid under encounter-based payment systems, we have not systematically analyzed all services paid under the PFS (nor do we analyze all new services proposed) to determine if they are included as a part of the visit versus are eligible for additional payment. Another reason that we do not analyze every code is because frequently codes created under the PFS for billing practitioners are to more appropriately account for resources paid under the PFS. Codes for these purposes are not applicable for RHCs and FQHCs since they are not paid under the PFS.

Generally, for PFS services that are a part of the office visit, there is no separate payment under the RHC AIR or FQHC PPS payment methodologies. On the contrary, care coordination services where the focus is on care management, coordination, or certain activities needed to manage chronic illnesses or adapt to new models of care, we have allowed separate payment for RHCs and FQHCs.

We solicited comment on how we can improve the transparency and predictability regarding which HCPCS codes are considered care coordination services. Our goal is to classify care coordination services on the PFS in a way that makes it automated in the downstream effect on RHCs and FQHCs. We stated that we believe establishing a streamlined policy regarding which services are separately paid for RHCs and FQHCs versus included as part of the visit is more transparent. In addition, a policy where codes are communicated and updated through subregulatory guidance may be more efficient.

We received a few comments in response to our request for information about how we can improve transparency and predictability regarding which HCPCS codes are considered care coordination services.

Comment: One commenter expressed their appreciation for our seeking comment on improving transparency and predictability regarding which codes are considered care coordination services but noted that CMS also did not propose to allow RHCs to bill for six new G codes associated with interprofessional behavioral health consultations. The commenter noted they believe there is a significant opportunity for this to be utilized in Rural Health Clinics (RHCs) as many of these providers integrate other specialty providers in their provision of comprehensive care. The commenter urged CMS to provide RHCs with the same opportunities to bill for these types of services that do not meet the traditional definition of a face-to-face encounter, in recognition of the broader set of services provided in the primary care setting. Another commenter suggested that that any services which are partially paid for under the PFS and partially paid under RHC or FQHC payment rates be considered care coordination and therefore should be reimbursed under one payment system. This commenter also urged CMS to choose one payment system and use it throughout Medicare and stated that having only one system for payment will lower overhead costs, and therefore, will save administrative time and money. The commenter also stated that practitioners are well aware that there are different payment systems and sometimes will be reimbursed in different ways, but that when there is a question as to which system is used, it results in wasted time trying to figure out which is the proper system, and then, if the wrong system is billed, there could be additional time spent trying to fix the mistakes that were made. Another commenter noted CMS could establish a clear classification system on the PFS and that this system should automatically translate the impact of these codes to RHCs and FQHCs. The commenter stated that by distinguishing services that are separately payable from those included in visit payments, CMS could provide greater clarity. The commenter agreed that a policy where codes are communicated and updated through subregulatory guidance may be more efficient.

Response: We recognize that there are varying perspectives on how we can improve transparency and predictability regarding which HCPCS codes are considered care coordination services. We appreciate the depth of consideration different interested parties have offered in their comments as we continue to evaluate.

Comment: Another commenter, who appreciated the opportunity to opine on our request for information expressed serious concerns regarding billing practices by RHCs who utilize providers to furnish services in non-rural areas, particularly in skilled nursing facilities (SNFs). The commenter stated that the Balanced Budget Act of 1997(BBA) required CMS to finalize location requirements to decertify non-rural RHCs, which CMS initially proposed in 2003 and 2008 but explained the 2003 rule was past the statutory deadline and the 2008 rule was never finalized. This commenter expressed concern that, in the absence of location requirements, some RHCs have exploited this gap by continuing to operate in areas that are no longer rural or underserved, including in non-rural skilled nursing facilities (SNFs). The commenter urged CMS to examine and report on the billing practices of RHCs operating outside rural areas to understand the cost of reimbursing for RHC services, particularly SNF stays, that are billed in non-underserved or rural locations. The commenter stated that addressing these issues would benefit both the Medicare program by decreasing costs from paying higher RHC rates in urban locations and allow non-RHCs to compete when providing SNF services. The commenter further recommended that CMS consider regulatory changes that would limit RHCs from adding providers that primarily serve patients in non-rural settings.

Response: We thank the commenter for this important feedback.

3. Services Using Telecommunications Technology

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish payment for RHC and FQHC services that are provided as Medicare telehealth services by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, requires that the Secretary develop and implement payment

methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. We established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume.

In the CY 2022 PFS final rule with comment period (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in-person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar changes for Medicare telehealth services for behavioral health paid under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

In addition, we revised the regulation under § 405.2463 to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record (86 FR 65210 and 65211).

As discussed in the CY 2023 PFS final rule (87 FR 69738), the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022) included the extension of several Medicare telehealth flexibilities established during the PHE for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE. Specifically, Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements for Medicare telehealth services for behavioral health and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19. Therefore, in the CY 2023 PFS final rule (87 FR 69737), we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions.

In the CY 2024 PFS final rule (88 FR 79065), we discussed that the CAA, 2023 (Pub. L. 117–328, December 29, 2022) further extended the Medicare telehealth flexibilities for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ends prior to that date. Specifically related to RHCs and FQHCs, section 4113(c) of the CAA, 2023 amended section 1834(m)(8) of the Act to extend payment for RHC and FQHC services provided as Medicare telehealth services for the period beginning on the first day after the end of the COVID–19 PHE and ending on December 31, 2024, if the PHE ends prior to that date. We noted that payment continued to be made under the methodology established for Medicare telehealth services furnished by FQHCs and RHCs during the PHE, which is based on payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS.

We explained that section 4113(d) of the CAA, 2023 continues to delay the in-person requirements for Medicare telehealth services for behavioral health and for mental health visits furnished by RHCs and FQHCs via telecommunications technology. That is, for RHCs and FQHCs, in-person visits will not be required until January 1, 2025, or, if later, the first day after the end of the PHE for COVID–19. Therefore, we stated that we will continue to apply the delay of the in-person requirements under Medicare for mental health services furnished by RHCs and FQHCs via telecommunications technology. We noted that the PHE for COVID–19 under section 319 of the Public Health Service Act ended on May 11, 2023.[361] Therefore, we revised the regulations under §§ 405.2463 and 405.2469 again to reflect these provisions (88 FR 79066 through 79067).

[361] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

b. Direct Supervision Via Use of Two-Way Audio/Video Communications Technology

Under Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner. See section II.D.2.a. of this final rule for the discussion regarding direct supervision for services provided using telecommunications technologies under the PFS.

In the CY 2024 PFS final rule (88 FR 79067), we explained that extending this definition of direct supervision for RHCs and FQHCs under our regulations at §§ 405.2413, 405.2415, 405.2448, and 405.2452 through December 31, 2024, would align the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023. In addition, we were concerned about an abrupt transition to the pre-PHE policy of requiring the physical presence of the supervising practitioner beginning after December 31, 2024, given that RHCs and FQHCs have established new patterns of practice during the PHE for COVID–19. We also believed that RHCs and FQHCs would need time to reorganize their practices established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. Similar to services furnished in physician office setting, RHC and FQHC services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care coordination services which may be furnished under general supervision. For CY 2024, we continued to define ''immediate availability'' as including real-time audio and visual interactive telecommunications through December 31, 2024, and solicited comment on whether we should consider extending the definition of ''direct supervision'' to permit virtual presence beyond December 31, 2024.

(1) Proposal for CY 2025

In the CY 2024 PFS proposed rule, we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs; for instance, if certain types of services are more or less likely to present patient safety concerns, or if this flexibility would be more appropriate when certain types of auxiliary

personnel are performing the supervised service. We were also interested in potential program integrity concerns such as overutilization or fraud and abuse that interested parties may have in regard to this policy.

Comments provided were overall supportive of our proposal to continue to define ''immediate availability'' to include availability through virtual means, stating that it will benefit healthcare providers while greatly enhancing patient access to quality care, particularly in underserved areas. Commenters also noted that direct supervision has become increasingly challenging and the option to provide virtual direct supervision has enhanced the quality and provision of healthcare services beneficiaries have received in medically underserved, rural communities.

We note that in section II.D.2.a. of this final rule, there is a proposal to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), but only for the following subset of incident-to services described under § 410.26, (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a Professional Component/Technical Component indicator of '5'; and (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of* a physician or *other qualified health care* professional). In addition, under the PFS we proposed for all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, to continue to define ''immediate availability'' to include real-time audio and visual interactive telecommunications technology only through December 31, 2025.

After evaluating the information gathered through the comment solicitation, we believe that we should maintain the current flexibility in RHCs and FQHCs as it continues to support access and preserve workforce capacity. We believe that there is value in allowing RHC and FQHC services to be furnished under direct supervision where virtual presence meets the definition of ''immediately available'' as status quo, so that we may further evaluate the services along with the analysis occurring for the remaining services that we are contemplating under the PFS. We noted that there may be nuances in the RHC and FQHC settings since generally payment is at the AIR or PPS rate and not at the individual service code level to carve out services limited/obvious services from other services. We could seek to establish a final policy in RHCs and FQHCs once a final policy is determined under the PFS, to avoid confusion since they are taking an incremental approach at the code level for CY 2025.

Therefore, we proposed to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

Comment: Commenters supported this proposal. A commenter stated that requiring the supervising practitioner to be physically present would delay care in many instances.

Response: After consideration of public comments, we are finalizing as proposed to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

c. Services Furnished Through Telecommunications Technology

As discussed above, section 3704 of the CARES Act directed the Secretary to establish payment for RHC and FQHC services provided as Medicare telehealth services by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, required that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for COVID–19. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. Therefore, we established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume. RHCs and FQHCs bill for these telehealth services using HCPCS code G2025.

In the CY 2022 PFS final rule with comment period (86 FR 65211), we revised the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner. We revised the regulations under § 405.2463 to state that an RHC or FQHC mental health visit can also include encounters furnished through interactive, real-time, audio/video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We noted that these changes aligned with similar changes for Medicare telehealth services for behavioral health paid under the PFS. We also noted that this change allows RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person.

The temporary authority under section 1834(m)(8) of the Act was extended by statute through the end of CY 2024, meaning that under current law and absent additional changes in regulation, RHCs and FQHCs could not continue to be paid under Medicare Part B for RHC and FQHC services (other than mental health visits) furnished as Medicare telehealth services after December 31, 2024.

(1) Payment for Medical Visits Furnished Via Telecommunications Technology

Widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of technology beyond the PHE. During the PHE, RHCs and FQHCs, much like other health care providers, have had to change how they furnish care in order to meet the needs of their patients. RHCs and FQHCs heavily utilized the temporary authority to be paid for their services when provided as Medicare telehealth services during the PHE. Eliminating flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology for over 4 years and

resuming payment solely for in-person, face-to-face medical visits after December 31, 2024, would cause disruptions in access to services from RHC and FQHC practitioners. This would be particularly problematic for the underserved populations that these settings furnish services to since it could fragment care. We believe that we need to preserve the flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology temporarily and to do so through an approach that these settings are familiar with in order to mitigate burden. Technologies used in this space and the quality of care associated with them continue to evolve. We believe that it would be prudent to allow time to engage with interested parties while we consider how to incorporate services furnished through telecommunications technology on a more permanent basis.

For these reasons, we proposed, on a temporary basis, to allow payment for non-behavioral health visits (hereafter referred to in this discussion as ''medical visit services'') furnished via telecommunications technology. We proposed to facilitate payments using an approach that closely aligns with the mechanism we have used during the PHE and subsequent extensions that end on December 31, 2024. That is, RHCs and FQHCs would continue to bill for RHC and FQHC medical visit services furnished using telecommunications technology, including services furnished using audio-only communications technology, by reporting HCPCS code G2025 on the claim. Since the costs associated with medical visit services furnished via telecommunications technology are not included in the calculations for the RHC AIR methodology and FQHC PPS, we believed that we needed to propose a proxy that would represent such resources used when furnishing these services. Therefore, we proposed to continue to calculate the payment amount for these services billed using HCPCS code G2025 based on the average amount for all Medicare telehealth services paid under the PFS, weighted by volume for those services reported under the PFS. We believe that continuing to use this weighted average is appropriate during this interim period while we contemplate permanent policies for these services since there is a wide range of payment rates for the Medicare telehealth services paid under the PFS. We believe that RHCs and FQHCs generally furnish services that are similar to and at a frequency the same as physicians and other practitioners paid under the PFS. While we do not have actual cost information, we believe that this weighted average is an appropriate proxy since it addresses certain resource costs experienced by professionals and would mitigate any potential over or under payments. Costs associated with these services would continue to not be used in determining payments under the RHC AIR methodology or the FQHC PPS.

We believe that the proposed approach would preserve the telecommunication technology flexibility under which RHC and FQHC services have been furnished for over 4 years and would not impact access to care for Medicare beneficiaries who currently benefit from these services while CMS contemplates next steps. We solicited comment on whether there may be other payment methodologies that may be a proxy for costs associated with medical visit services furnished via telecommunications technology and why those payment methodologies may be more appropriate than the rate based on a weighted average of the Medicare telehealth services paid under the PFS.

We proposed to amend § 405.2464 by adding new paragraph (g) to reflect our proposed payment policy for medical visit services furnished in RHCs and FQHCs via telecommunications technology for CY 2025.

(2) Alternative Considered for Payment of Medical Visits Furnished Via Telecommunications Technology

We considered reevaluating the regulations regarding face-to-face visit requirements for encounters between a beneficiary and an RHC or FQHC practitioner in light of contemporary medical practices. That is, we considered proposing a revision to the regulatory requirement that an RHC or FQHC medical visit must be a face-to-face (that is, in-person) encounter between a beneficiary and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time, audio and video telecommunications technology. This would result in payment for services furnished via telecommunication technology to be made under the RHC AIR methodology and under the FQHC PPS, similar to how we revised the regulations for RHC and FQHC mental health visits. We believe interested parties may prefer the per visit payment that aligns with the RHC AIR or FQHC PPS. However, we did not propose this alternative because we determined that it would have unintended consequences, especially in cases where the RHC AIR or FQHC PPS per-visit rates would be significantly higher than the PFS rate that would apply if other entities furnished the same service to the same beneficiary in the same location.

We believe that temporarily continuing to pay for RHC and FQHC medical visit services furnished via telecommunication technologies in the same manner as we have done over the past several years would preserve the flexibility for RHCs and FQHCs to continue access to care, mitigate administrative burden, and mitigate potential program integrity concerns. However, we solicited comment on the alternative proposal we considered. That is, revising the definition of a medical visit to include interactive, real-time, audio/video telecommunications technology which would result in a uniform per-visit payment under the RHC AIR methodology or FQHC PPS.

Comment: Commenters supported our proposal to pay for medical visit services furnished by RHCs and FQHCs via telecommunications technology for CY 2025, stating that it will benefit these healthcare providers while greatly enhancing patient access to quality care, particularly in underserved areas.

Response: We appreciate the support of the commenters.

Comment: Many commenters expressed a preference for our alternative considered, whereby we would change the definition of a visit to include interactive, real-time, audio/video telecommunication technology, resulting in a uniform per-visit payment under the RHC AIR methodology or FQHC PPS for medical visit services. Commenters stated that this approach would ensure that RHCs and FQHCs receive consistent and timely reimbursement for providing these services via telecommunications technology. One commenter asked CMS to elaborate on what we described as potential unintended consequences of adopting this approach, stating that there has been no widespread fraud, abuse, or other unintended consequence resulting from the changed definition of a mental health visit, so there is no logical reasoning on which to base the belief that changing the definition of a medical visit would have those negative results. According to this commenter, offering lower reimbursement to safety net providers through a crude special payment rule because it is just a continuation of current policy is not reducing administrative burden; rather it continues to limit safety net providers' ability to invest in these important technologies. The commenter stated that if there are program integrity concerns, CMS has the ability to monitor utilization of services delivered

using telecommunications technology through a simple modifier code, and address issues if they arise; however, they asserted that simply continuing the disparate policy is not an appropriate guardrail and continues to have the potential to limit access to care.

Response: We recognize that under the current statute, RHCs and FQHCs will no longer provide their services as a distant site for Medicare telehealth services after the end of CY 2024. While further legislative extensions of Medicare telehealth flexibilities adopted during the PHE for COVID–19 are possible, we proposed an approach that would allow us to continue making payment for RHC and FQHC medical visit services provided via telecommunications technology as we have for several years during and after the PHE for COVID–19 while we consider the implications of incorporating payment for these services into the RHC AIR and FQHC PPS in the future.

We note that before the PHE for COVID–19, we tended to presume that nearly all Medicare services that involve interaction between a practitioner and a patient are to be delivered in person in a face-to-face encounter except, as in section 1834(m) of the Act, where the statute specifically addressed payment for service delivery via interactive telecommunications technology. As the use of telecommunications technology in health care delivery has become more sophisticated and prevalent, our views have been evolving. For example, in the context of opioid use disorder (OUD) treatment services by an Opioid Treatment Program (OTP), we explained that the requirements of section 1834(m) of the Act do not apply to these services because they are not furnished by a physician or other practitioner, but instead are furnished by the OTP; and no physician or practitioner can be paid separately for these services because payment is made through the bundled payment to the OTP (84 FR 62658, 62645). In light of our experience with the proliferation of telecommunications technology-based services during the PHE for COVID–19, we have recognized that we could take a similar approach with RHC and FQHC services, as evidenced by the changes we made to our regulations in the CY 2022 PFS final rule for RHC and FQHC mental health visits provided via telecommunications technology, as well as our proposal in the CY 2025 PFS proposed rule for RHC and FQHC medical visit services.

We believe our proposed approach allows us to ensure immediate access to care for beneficiaries currently relying on RHCs and FQHCs while we continue to monitor and analyze information made available to us in order to develop, propose, and finalize more permanent policy in future rulemaking, particularly given the potential for congressional action. We are therefore finalizing as proposed to continue to pay through CY 2025 for these services furnished by RHCs and FQHCs via telecommunications technology as they have been during and after the PHE through the end of CY 2024; however, we will continue to evaluate and may consider this issue again in future rulemaking.

After consideration of public comments, we are finalizing as proposed to continue to make payment through CY 2025 for RHC and FQHC medical visit services furnished via telecommunications technology using the payment amount based on the average amount for all Medicare telehealth services paid under the PFS, weighted by volume.

d. In-Person Visit Requirements for Remote Mental Health Services Furnished by RHC and FQHCs

Section 123 of the CAA, 2021 amended section 1834(m)(7) of the Act to require that a beneficiary must receive an in person, non-telehealth service from the physician or practitioner 6 months prior to initiation of the telehealth mental health services and direct the Secretary to establish an appropriate frequency for provision of subsequent periodic in person, non-telehealth services. As amended by section 4113(d)(1) of CAA, 2023 (Pub. L. 117–328), this requirement applies to all mental health services provided beginning on January 1, 2025.

In the CY 2022 PFS final rule with comment (86 FR 65210), we revised the regulation under § 405.2463 to apply this provision to RHCs and FQHCs, to state that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

As discussed in the CY 2023 PFS final rule (87 FR 69738), the CAA, 2022 included the extension of a number of Medicare telehealth flexibilities established during the PHE for COVID–19 for a limited 151-day period beginning on the first day after the end of the PHE. Division P, Title III, section 304 of the CAA, 2022, delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by RHCs and FQHCs via telecommunications technology until the 152nd day after the end of the PHE for COVID–19.

The CAA, 2023 (Pub. L. 117–328, December 29, 2022) extended the Medicare telehealth flexibilities enacted in the CAA, 2022 for a period beginning on the first day after the end of the PHE for COVID–19 and ending on December 31, 2024, if the PHE ended prior to that date. While the CAA, 2021 only applied to the PFS, we implemented similar policies for RHCs, FQHCs, and hospital outpatient departments. As noted above, the in-person visit requirements are currently set to take effect for services furnished on or after January 1, 2025.

However, given concerns from interested parties on the impact of enforcing these requirements after multiple years of delay, we proposed an additional extension. We proposed to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

Comment: Commenters supported our proposal to continue to delay the in-person visit requirement for these services, stating that this requirement is unnecessary and a barrier to care. Commenters also requested that we permanently remove this requirement.

Response: After consideration of public comments, we are finalizing our proposal to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026. We may consider an additional extension in future rulemaking.

4. Intensive Outpatient Program Services (IOP)

a. Background

As we discussed in the CY 2024 OPPS final rule (88 FR 81838) section 4124 of Division FF of the CAA, 2023 established Medicare coverage for intensive outpatient program (IOP)

services furnished by a hospital to its outpatients, or by a community mental health center (CMHC), a FQHC or a RHC, as a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024.

IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to conditions such as depression, schizophrenia, and substance use disorders. We noted an IOP is thought to be less intensive than a partial hospitalization program (PHP).

This new provision mandated several areas of policy to implement an IOP program, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs, all of which are discussed in the CY2024 OPPS final rule (88 FR 81838 through 81845). We made corresponding regulation changes for IOP services at §§ 405.2400, 405.2401, 405.2410, 405.2411, 405.2446, 405.2462, 405.2463, 405.2464, 405.2468, and 405.2469.

b. Update to Special Payment Rules for Intensive Outpatient Services

As we discussed in the CY 2024 OPPS final rule (88 FR 81841), section 4124(c) of the CAA, 2023 further amended section 1834(o) of the Act and section 1834(y) of the Act, to provide special payment rules for both FQHCs and RHCs, respectively, for furnishing IOP services. Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(A) to require that payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. In addition, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(A) to require that payment for IOP services furnished by RHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

In the CY 2024 OPPS final rule (88 FR 81841), we provided a detailed discussion of the final CY 2024 payment rate methodology for IOP. CMS finalized two payment rates, a 3- and a 4- or more services per day, for IOP services for hospitals and CMHCs. However, for RHCs and FQHCs we established a 3-service per day payment rate. We stated that we believed it was appropriate to establish the payment rate where the utilization is typically structured to be days with 3 or fewer services and solicited comment on whether the hospital-based IOP payment rate for 4-service days would be appropriate for RHCs and FQHCs. Although we previously stated that we would review the data and consider a 4 or more services per day for future rulemaking, we considered it further. We believed that we should provide parity for IOP services across the various settings with site neutral payments while continuing to monitor access to these services. Therefore, we proposed to provide payment for 4 or more services per day in an RHC/FQHC setting. Additionally, as required in section 4124(c)(2) of the CAA, 2023 we proposed to align with the 4 or more-services per day payment rate for hospital outpatient departments. As we stated with the 3-services per day, the 4 or more services per day payment rates would also be updated annually.

We received several comments on our proposal to provide payment for 4 or more IOP services per day in an RHC/FQHC setting and align such payment with the 4 or more-services per day payment rate for hospital outpatient departments, which would be updated annually.

The following is a summary of the comments we received and our responses.

Comment: Many commenters were very supportive of our proposal to establish payment for 4 or more services per day in an RHC/FQHC setting and align such payment with the 4 or more services per day payment rate for hospital outpatient departments, which will be updated annually. One commenter stated that they supported and appreciated CMS' proposal to align payment rates with those of hospitals and community mental health centers, which the commenter believes will promote fairness and consistency in reimbursement for IOP services, regardless of the setting. A few commenters stated that this will provide parity and site-neutral payments for IOP services across different settings. Some commenters stated that they are hopeful that adding the 4 or more services per day will encourage rural uptake.

Response: We agree with supporters that adding the 4 or more services per day payment for IOP service will promote fairness and consistency in reimbursement for IOP services and also believe that the additional payment will provide parity and site-neutral payments for IOP services.

Comment: Although commenters on a whole support our proposal to establish a 4-service day payment for IOP services, a few also noted some concerns. One commenter noted that payment and recruiting staff are barriers to establishing IOP programs. Another commenter stated that the payment rate is not adequate for RHCs associated with a critical access hospital, but also hoped that allowing a 4-service day payment rate will encourage more uptake for IOP services.

Response: Regarding concerns about the payment rate, we believe that establishing a 4 or more-service day payment will provide parity for IOP services across the various settings, with site neutral payments. As discussed in the CY 2024 OPPS final rule, 88 FR 81844, we finalized implementation of the special payment rules for IOP services furnished in RHCs and FQHCs. We explained that the payment rate determined for IOP for 3 services per day for hospital-based IOPs is the payment rate for IOP services furnished in RHCs. In other words, payment for IOP services furnished in RHCs would be based on the hospital-based rates and not the RHC AIR. We also explained that for IOP services furnished in FQHCs, the payment is based on the lesser of a FQHC's actual charges or the IOP determined rate. That is, payment for IOP services furnished in FQHCs would be based on the hospital-based rate and not the FQHC PPS. In the CY 2025 PFS proposed rule, we proposed to provide payment for 4 or more services per day in an RHC/FQHC setting, which is also based on the hospital-based payment rate for IOP services and not the RHC AIR or the FQHC PPS. The estimated for 4 or more IOP services is $413.50.

After consideration of public comments, we are finalizing our proposal to establish a payment for 4 or more services per day in an RHC/FQHC setting and as required in section 4124(c)(2) of the CAA, 2023, aligning that payment with the 4 or more-services per day payment rate for hospital outpatient departments. These payment rates will be updated annually.

c. Technical Correction (§§ 405.2410 and 405.2462)

In the CY 2024 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems final rule with comment (88 FR 81844) we finalized revisions to §§ 405.2410, 405.2462, and 405.2464 in the regulations to reflect the payment amount for IOP services and

how the Medicare Part B deductible and coinsurance are applied in RHC's and FQHC's. For RHCs, the beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts at an amount not to exceed 20 percent of the clinic's reasonable charges for IOP services. For FQHC's, the beneficiary is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the service or the IOP rate. We revised the regulatory requirements at § 405.2410, ''Application of Part B deductible and coinsurance'' and § 405.2462(j), ''Payment for RHC and FQHC Services'' to reflect how the Medicare Part B deductible and coinsurance are applied to IOP services.

During a recent review of our regulations at §§ 405.2410(c) and 405.2462(j), we noticed that both sections had errors. That is, § 405.2410(c) does not reflect the correct policy that is applicable for beneficiary coinsurance when they receive IOP services in RHCs and FQHCs. With regard to the error at § 405.2462(j), we inadvertently left language specific to RHCs in the introductory text when it should have been its own paragraph. Therefore, we proposed revisions to § 405.2410 to reflect the correct policy applicable for beneficiary coinsurance as described above in the previous paragraph. We also proposed revisions to § 405.2462(j) to accommodate the new paragraph (j)(1).

The following is a summary of the comments we received and our responses.

Comment: Many commenters were very supportive of our proposal to revise § 405.2410(c) to correct policy applicable for beneficiary coinsurance. These commenters expressed their appreciation of the clarification. Commenters stated that this correction means that FQHC beneficiaries do not have to meet a deductible before Medicare begins to cover their services. They further stated that simplifying this structure ensures that health center patients can receive necessary behavioral health services without the barrier of high upfront costs, making it easier for them to seek timely care. Additionally, they stated that this change enhances affordability and predictability of the coinsurance amount and provides financial relief and certainty for beneficiaries, thereby further promoting health equity and access to essential services. We did not receive any comments related to § 405.4662(j).

Response: We thank commenters for their support of our proposal to revise § 405.2410(c) to reflect the correct policy applicable for beneficiary coinsurance.

As we did not receive public comments on our proposed revisions to § 405.2462(j) to accommodate the new paragraph (j)(1). Therefore, we are finalizing as proposed.

After consideration of public comments, we are finalizing our proposal to revise § 405.2410 to reflect the correct policy applicable for beneficiary coinsurance and to revise § 405.2462(j) to accommodate the new paragraph (j)(1).

5. Payment for Preventive Vaccine Costs in RHCs and FQHCs

a. Background

Section 1833(a)(3)(A) of the Act specifies that services described in section 1861(s)(10)(A)—pneumococcal, influenza and COVID–19 vaccines and their administration—are exempt from the RHC and FQHC payment limit of 80 percent of reasonable costs. Therefore, payment for pneumococcal, influenza and COVID–19 vaccines and their administration in RHCs and FQHCs is governed by the statute at section 1833(a)(1)(B) of the Act, which requires payment at 100 percent of reasonable cost. For RHCs, this means we don't include costs associated with these vaccines and their administration in determining the AIR; and that such vaccines and administration are not subject to the payment limit. For FQHCs, these costs are not included under the FQHC PPS. Please see section III.H.2.c. of this final rule for more information on hepatitis B vaccines and their administration in RHCs and FQHCs.

In the April 3, 1996 FQHC final rule (61 FR 14657), we codified at § 405.2466(b)(1)(iv) that, for RHCs and FQHCs, payment for pneumococcal and influenza vaccines and their administration is 100 percent of Medicare reasonable cost, which is paid as part of the annual reconciliation through the cost report. In the CY 2022 PFS final rule (86 FR 65207), we made conforming changes in that section to include the COVID–19 vaccine and its administration.

b. Revisions to Current Policy

In the May 2, 2014 RHC/FQHC PPS final rule (79 FR 25449), we addressed commenters' recommendations that CMS apply a consistent approach to payment for Part B vaccines. One commenter specifically recommended that CMS allow RHCs and FQHCs to bill for Part B vaccines at the time of service, either with or without an encounter for a visit. The commenter stated that those bills could be paid using national Part B rates, to be followed by an annual reconciliation on the cost report between the payments and the reasonable costs of the vaccines and their administration. This commenter wished to reduce the time between vaccine administration and payment, and to enable the documentation on individual patient claims that these vaccines were furnished. Commenters generally asserted that streamlining Part B vaccine payment would help ensure broad vaccine access for Medicare beneficiaries.

In response to these comments, we responded that we did not believe that any changes in our billing policies were necessary. We stated that RHCs and FQHCs are accustomed to reporting and receiving payment for the reasonable costs of Part B vaccines and their administration through the annual cost report, and we believed that an annual reconciliation between vaccine payments and reasonable costs would create an additional administrative burden for FQHCs and MACs. We also noted that as of January 1, 2011, FQHCs have been required to report pneumococcal and influenza vaccines and their administration on a patient claim with the appropriate HCPCS and revenue codes when furnished during a billable visit. Please note that this is not a requirement for RHCs.

In the CY 2022 PFS final rule (86 FR 65207), in which we made conforming regulatory changes at § 405.2466(b)(1)(iv) to include the COVID–19 vaccine, we received several comments regarding the timing of vaccine payments for RHCs and FQHCs. These comments echoed the sentiments expressed by the commenters on the same topic in the 2014 final rule mentioned above, and while they were out of the scope of our proposals for CY 2022, we will elaborate on them here. These commenters expressed appreciation for measures taken by CMS in April 2021 to make lump-sum payments for COVID–19 vaccine administration available to RHCs and FQHCs in advance of cost report settlement, but commenters emphasized that those payments were only a temporary solution. Commenters suggested CMS to update the RHC and FQHC cost report to ensure adequate, permanent reimbursement for COVID–19 vaccines. Commenters added that RHCs and FQHCs have experienced challenges with burdensome reporting requirements and data collection, as well as slow distribution of payments from MACs. Another commenter stated that RHCs and FQHCs should not have to wait until settlement of cost report to

be reimbursed for other preventive vaccines, and that delayed payment may hinder them from immunizing Medicare beneficiaries.

While we did not respond directly to those comments in the CY 2022 PFS final rule, as they were out of scope of the policies that were finalized at the time, we did make clarifications regarding payment for preventive vaccines and their administration in the RHC and FQHC Frequently Asked Questions (FAQs) that accompanied the publication of the CY 2022 PFS final rule.[362] In those FAQs, we clarified that the conforming change made to § 405.2466(b)(1)(iv) to reflect coverage and payment for COVID–19 vaccines in RHCs and FQHCs did not reflect any other payment policy changes regarding payment for Part B vaccines and administration in those settings. We reiterated that RHCs and FQHCs are paid 100 percent of reasonable cost through their cost report for Part B vaccines and their administration. Since there is a gap in time from when costs are incurred in RHCs and FQHCs for furnishing vaccines and when payment is received, the Medicare Administrative Contractors (MACs) could provide early payments in the form of lump sum payments to RHCs and FQHCs in March of 2021 to facilitate COVID–19 vaccinations. RHCs and FQHCs can request additional lump sum payments from their MAC at any time.

Since the publication of the CY 2022 PFS final rule, we have given additional consideration to the comments discussed above. During and since the COVID–19 PHE, we have especially promoted efforts aimed at facilitating increased access to vaccinations for both Medicare enrollees and all Americans. Vaccination promotion efforts also dovetail with CMS' overarching strategic priorities of expanding health care access and advancing health equity. For CY 2025, we have identified the issue of vaccination in RHCs and FQHCs as an area where payment policy can be updated to improve access to preventive vaccines for Medicare enrollees.

In the CY 2025 PFS proposed rule (89 FR 61794), we proposed to allow RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service. Based on the policy changes found in sections III.M. and III.H.2.c. of this final rule, this revision in policy will include all four Part B preventive vaccines: pneumococcal, influenza, hepatitis B, and COVID–19 vaccines. These claims would initially be paid like other Part B vaccine and vaccine administration claims, whose payments are discussed at section III.H.1. of this final rule: vaccine products will be paid at 95 percent of their Average Wholesale Price (AWP), and vaccine administration will be paid according to the National Fee Schedule for Medicare Part B Vaccine Administration. The fee schedule's locality-adjusted payment rate files for CY 2024 can be found on the CMS Vaccine Pricing website *at https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/vaccine-pricing.* Payment rate files for influenza, pneumococcal and hepatitis B vaccine administration can be found under the ''Seasonal Flu Vaccine'' tab, and payment rate files for COVID–19 vaccines can be found under the ''COVID–19 Vaccines & Monoclonal Antibodies'' tab. The CY 2025 payment rates for Part B vaccine administration HCPCS codes G0008, G0009, G0010 and 90480, with the annual update applied for CY 2025, will be made available at the time of publication of the CY 2025 PFS final rule, and Tables XX and XX in section III.H.1.f. of this final rule provide the CY 2025 payment rates for those amounts.

We also clarified that RHC or FQHC providers are eligible to bill HCPCS code M0201 for an in-home additional payment for Part B preventive vaccine administration, provided that a home visit meets all the requirements of both part 405, subpart X, for RHCs and FQHCs services provided in the home, and § 410.152(h)(3)(iii) for the in-home additional payment for Part B preventive vaccine administration. More information regarding the in-home additional payment can be found at section III.H.1.d of this final rule, and payment rates for M0201 can be found together with Part B vaccine administration payment rates mentioned above.

We emphasized that the statute at section 1833(a)(1)(B) of the Act requires that RHCs and FQHCs be paid at 100 percent of reasonable cost for Part B COVID–19 vaccines and their administration. Therefore, payments for these services received at the time they are furnished in RHCs and FQHCs will need to be annually reconciled with the facilities' actual vaccine and vaccine administration costs, including any in-home additional costs, on their cost reports. Due to the operational systems changes needed to facilitate payment through claims, we proposed that RHCs and FQHCs begin billing for preventive vaccines and their administration at the time of service, for dates of service beginning on or after July 1, 2025. This would allow ample time for CMS to release cost reporting instructions and subregulatory guidance with additional billing instructions for RHCs and FQHCs to bill Medicare Part B for preventive vaccines and their administration at the time of service.

We believed that the proposal addressed the comments and requests of stakeholders who have suggested this payment approach over the last several years. We noted that this payment approach was mentioned in the Senate Appropriations Committee's ''Explanatory Statement For Departments Of Labor, Health And Human Services, And Education, And Related Agencies Appropriations Bill, 2021.'' [363] That report referenced a December 2019 white paper by the National Association of Community Health Centers, which noted that ''FQHCs can face significant delays in reimbursement for influenza and pneumococcal vaccines.'' [364] The Committee thus encouraged CMS to promote the ability of FQHCs to bill Part B directly for vaccinations at the time of service, with reconciliation of payments at the time of cost report settlement.

We solicited comment on these proposals. We mentioned that we would especially appreciate comments on the benefits of payments for vaccine costs billed at the time of service, weighed against the potential additional burdens of annual reconciliation of vaccine claims payments against actual vaccine costs.

We received several public comments on the above proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported our proposals to allow RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service. Commenters explained that health centers like RHCs and FQHCs serve as community hubs where patients can receive vaccinations, but that those facilities often operate on financially thin margins. They stated that timelier vaccine payments will allow RHCs and FQHCs to proactively stock and administer some vaccines and will also allow health centers to stock vaccines in other sites around the health center besides their pharmacy, which

[362] RHCs CY 2022 PFS final rule Fact Sheet: *https://www.cms.gov/files/document/rhcs-pfs-faqs.pdf*; FQHCs CY 2022 PFS Final Rule Fact Sheet: *https://www.cms.gov/files/document/fqhcs-pfs-faqs.pdf.*

[363] *https://www.appropriations.senate.gov/imo/media/doc/LHHSRept.pdf.*

[364] *https://www.nachc.org/wp-content/uploads/2023/10/adult-imm-fqhc-white-paper-11-01-2019.pdf.*

will facilitate RHC and FQHC investment in developing robust vaccination programs for their patients. Other commenters appreciated that our proposal will generally alleviate cash flow issues for rural providers.

Other commenters expressed that they appreciate that this proposal streamlines the payment of Part B vaccine claims across more health care settings, which will help minimize administrative burden and paperwork, increase the time physicians can spend with patients, simplify the vaccine billing process and reduce wait times for reimbursement. Some commenters specifically expressed support for our clarification that RHC or FQHC providers can bill for an in-home additional payment for Part B vaccine administration for eligible home visits. Another commenter stated that a policy allowing RHCs and FQHCs to bill for the administration of Part B preventive vaccines at the time of service outweighs any potential burden of annual reconciliation processes. One commenter appreciated that the proposal would be effective for dates of service on or after July 1, 2025, and they concurred with CMS that the additional time would give facilities more time to make necessary operational changes.

Response: We thank commenters for partnering with CMS in our efforts to improve health access and equity, especially for those vulnerable populations that are served by RHCs and FQHCs. We agree that finalizing this proposal will assist RHCs and FQHCs in their operations and specifically in administering preventive vaccines to their patients. We look forward to continuing our work with all our partners to continue facilitating increased access to vaccinations for both Medicare enrollees and all Americans.

Comment: Some commenters asked for additional clarifications regarding our proposed policies. Several commenters recommended that CMS keep in mind that, when releasing cost reporting instructions on the process of billing for Part B vaccines at the time of service, those payments must be reconciled to the FQHCs' reasonable costs during the Cost Reporting process. Another commenter encouraged CMS to issue and implement reporting instructions, subregulatory guidance, and operational system changes as expeditiously as possible to facilitate payment of these claims.

Response: Both in the CY 2025 PFS proposed rule (89 FR 61794) and in our text above, we emphasized that the statute at section 183B(a)(1)(b) of the Act requires that RHCs and FQHCs be paid at 100 percent of reasonable cost for Part B vaccines and their administration, and therefore payments for Part B preventive vaccines and their administration that are received at the time they are furnished in RHCs and FQHCs will need to be annually reconciled with the facilities' actual vaccine and vaccine administration costs, including any in-home additional costs, on their cost reports. In the same paragraphs, we also expressly state our intent to release cost reporting instructions and subregulatory guidance before the July 1, 2025 proposed effective date of this policy, which would contain additional billing instructions for RHCs and FQHCs to bill Medicare Part B for preventive vaccines and their administration at the time of service.

Comment: A number of commenters requested updates and changes to cost reporting instructions and settlement methodology for vaccine costs in RHCs and FQHCs. They stated that the current cost reporting structure averages the costs of all vaccines administered in a facility, include those vaccines that are not recommended for the Medicare population, and thus the averaged cost as reported that does not accurately represent the true expense of RHCs' and FQHCs' vaccine acquisition costs. Commenters mentioned that some RHCs and FQHCs must pay Medicare back after receiving payments based on these cost reporting calculations. The commenters explained that some vaccines recommended for the Medicare population by the CDC's Advisory Committee on Immunization Practices (ACIP) may have a higher cost due to their higher antigen content or adjuvant, as compared to lower doses of the vaccines that are suited for other populations.[365] One commenter stated that our proposal will not fix this underlying issue with RHC and FQHC vaccine costs. These commenters suggested that we change cost reporting instructions to have RHCs and FQHCs only submit costs for those vaccines administered to Medicare enrollees.

Response: We thank commenters for their feedback on these aspects of RHC and FQHC vaccine cost and payment. Based on the policies finalized in both this section and in section III.H. of the proposed rule, several RHC/FQHC cost report updates will be needed for CY 2025, including changes to address hepatitis B vaccine costs. We plan to take these comments into consideration as we make those cost report updates.

Comment: One commenter objected to our proposal. This commenter directly addressed our request for comment on the benefits of payments for vaccine costs billed at the time of service, weighed against the potential additional burdens of annual reconciliation of vaccine claims payments against actual vaccine costs. The commenter stated that the proposal imposes an additional burden of tracking the initial vaccines payments, and then submitting vaccine costs again on the annual cost report in order to ensure reimbursement at 100 percent of reasonable costs. The commenter views the proposal as requiring additional work, but not providing additional reimbursement.

Response: We thank this commenter for their feedback. We acknowledge that there is additional work involved for RHCs and FQHCs to both track payments received from vaccine administration claims, and also reconcile vaccine costs on their cost report. However, based on the overwhelming support received from a significant majority of other commenters on this proposal, several of whom say this policy will ultimately reduce burdens for providers, we are finalizing this policy as proposed.

Comment: We received several comments that were out of the scope of our proposal. One commenter requested that we expand this proposal to combination vaccines that include a component that is covered and paid as a Part B preventive vaccine. Several commenters requested that CMS pay for an ''immunization-only visit'' with nurses and/or pharmacists outside of the FQHC PPS. Commenters stated that this would help improve immunization rates among underserved individuals who seek care at FQHCs. Commenters also asked that CMS permit RHCs and FQHCs to bill for vaccine counseling. Another commenter requested that CMS holistically review its policy on how FQHCs and RHCs can bill for vaccines across programs, including Medicare Part D and Medicaid, and that CMS to provide additional clarity on how FQHCs and RHCs can bill for Medicare Part D covered vaccines. One commenter suggested that CMS expand this proposal to all CDC recommended vaccines.

Response: We thank commenters for their feedback. These comments are outside of the scope of our proposals that are to be finalized here. We plan to take these comments into consideration for further evaluation.

We would like to include a clarification about Part D vaccinations in RHCs and FQHCs. While RHCs and FQHCs cannot currently bill Medicare directly for vaccines and vaccine administration outside of the

[365] *https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm?s_cid=mm7104a1_w.*

pneumococcal, influenza and COVID–19 vaccines, Medicare does cover and pay RHCs and FQHCs for other vaccines and their administration, as part of the FQHC PPS rate and the RHC AIR. Please see the discussions on 79 FR 25449 of the 2014 RHC/FQHC PPS final rule regarding vaccine coverage and payment in RHCs and FQHCs, which elaborate on this point. Please also note that, based on our finalized policies at section III.H.2.c. of this final rule, effective January 1, 2025, Hepatitis B vaccines and their administration will be paid at reasonable cost in RHCs and FQHCs, and they will no longer be included in the RHC AIR or FQHC PPS rate. Please see that section for more information.

After consideration of public comments, we are finalizing these policies as proposed. Effective for dates of service on or after July 1, 2025, RHCs and FQHCs can bill for all four Part B preventive vaccines and their administration at the time of service. RHCs and FQHCs can bill HCPCS code M0201 for an in-home additional payment for Part B preventive vaccine administration, provided that a home visit meets all the requirements of both part 405, subpart X, for RHCs and FQHCs services provided in the home, and § 410.152(h)(3)(iii) for the in-home additional payment for Part B preventive vaccine administration. Payments for these services received at the time they are furnished in RHCs and FQHCs will need to be annually reconciled with the facilities' actual vaccine and vaccine administration costs, including any in-home additional costs, on their cost reports. We plan to release additional guidance implementing these policies in advance of the effective date of July 1, 2025.

6. Productivity Standards

a. Background

Productivity standards for RHCs were first established on March 1, 1978 (43 FR 8260) and updated on December 1, 1982 (47 FR 54163 through 54165), to help determine the average cost per patient for Medicare reimbursement in RHCs. These productivity screening guidelines were intended to identify situations where costs would not be allowed without acceptable justification by the clinic and limits on the amount of payment (57 FR 24967). Physicians, nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) are held to a minimum number of visits per full time employee (FTE), as discussed in section 80.4, chapter 13 of the Medicare Benefit Policy Manual. The productivity standards policy requires 4,200 visits per full-time equivalent (FTE) physician and 2,100 visits per FTE non-physician practitioner (for example, nurse practitioner, physician assistant, or certified nurse midwife). Physician and non-physician practitioner productivity may be combined and if so, the number of visits per full-time equivalent team is 6,300. If actual visits are less than the productivity standards, the average cost per visit will be computed based on the productivity standards rather than actual visits, which would result in the cost per visit to be lower than if actual visits were used. In other words, if the current productivity standards are not met, the results would be a reduction in the cost per visit, which could negatively impact the RHC AIR and reduce payments. There are exceptions to the productivity standards that can be made based on individual circumstances that is at the discretion of the MAC. We note that these standards of 4,200 visits per FTE physician and 2,100 visit per FTE nonphysician practitioner and 6,300 visits per combined FTE have not been updated since 1982. We also note similar requirements to contain costs in this way were not required in FQHCs or other settings paid on reasonable cost.

Interested parties have requested that CMS re-evaluate or remove the productivity standards policy for RHCs because they believe that the environment today is very different than when the RHC benefit began and that the ''visit per FTE'' is too high for practitioners to meet and results in reducing the AIR. They also shared that the productivity standards matter even less now since the implementation of the CAA, 2021 established payment limits for all RHCs.

During the PHE for COVID–19, we issued a combination of emergency authority waivers, regulations, enforcement discretion, and subregulatory guidance to ensure and expand access to care and to give health care providers the flexibilities needed to help keep people safe. RHCs expressed concerns about how the productivity standards may impact them during the PHE. For example, many RHCs had trouble meeting the productivity standards due to a change in the way they staffed their clinics and billed for RHC services with increased telecommunications services. RHCs claimed that they were negatively impacted even more so than other health care settings because of these requirements. We have long standing guidance in the Medicare Benefit Policy Manual, chapter 13, section 80.4 that describes the MAC's role in providing flexibility to grant productivity exceptions to RHCs who experienced disruptions in staffing and services to minimize the burden on RHCs. During the PHE we reminded RHCs of the exception process in FAQs,[366] and provided instructions to MACs to proactively reach out to RHCs reminding them of the exception process and to proactively grant exceptions as necessary.

Section 130 of the CAA, 2021 restructured the payment limits for RHCs beginning April 1, 2021. That is, independent RHCs, provider-based RHCs in a hospital with 50 or more beds, and RHCs enrolled under Medicare on or after January 1, 2021, will receive a prescribed national statutory payment limit per visit increase over an 8-year period for each year from 2021 through 2028. This provision also established payment limits for provider-based RHCs in a hospital with less than 50 beds. See the CY 2022 PFS final rule (86 FR 65199 through 65202) for more detailed discussion.

Since the CAA, 2021 restructured the payment limits for RHCs, and in some cases established payment limits for RHCs beginning April 1, 2021, we believe that applying productivity standards may no longer be necessary. In the CY 2025 PFS NPRM, we stated that the productivity standards are outdated and redundant with the CAA, 2021 provisions and therefore, we proposed to remove productivity standards requirements.

We received several comments on our proposal to remove the productivity standard for RHCs.

Comment: All commenters are very supportive of our proposal to remove the productivity standard for RHCs. A few commenters stated that the productivity standards are outdated and redundant given the payment limits established in the CAA, 2021 provisions. Another commenter stated that reduced burdens and costs coupled with increased access to care can only serve to improve the services provided by these facilities as long as appropriate patient care standards and requirements continue to be met. Another commenter stated that they supported our proposal to remove the productivity standard because in practice, these productivity standards direct RHCs to lean heavily toward advanced practice provider (APP) coverage, due to the lower productivity threshold. This commenter further stated that in other cases, RHCs are attached to hospitals, which necessitates more physician coverage to

[366] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

support the hospital services and in the end, this arbitrarily impacts RHC primary care clinic reimbursement. The commenter believes that penalizing RHCs for an arbitrary rule that forces providers to offer less services, is counterintuitive to the basic reasoning RHCs exist. Another commenter stated that the productivity standards make it difficult for physicians practicing at RHCs to provide the services their patients need because if they spend too much time treating more complex patients and do not reach the productivity standard as a result, then payment rates could be significantly reduced. The commenter further stated that they believe removing the productivity standard would empower physician-led care teams in RHCs to deliver more flexible, patient centered care that can better meet their patients' needs.

One commenter stated that this change will require a cost report and calculation change and suggested that this change be effective for cost reporting periods ending after December 31, 2024. The commenter further stated that for RHCs that do not meet the guidelines for cost reporting periods that have not been final-settled (that is, without a Notice of Program Reimbursement) as of the publication date of the final rule, MACs should be instructed to apply a waiver during final settlement that would eliminate any application of the guidelines.

Response: We agree that the productivity standard is outdated and that removing the productivity standard will eliminate redundancy given the payment limits established by the CAA, 2021. Regarding the comment suggesting that the change be effective for cost reporting periods ending after December 31, 2024, we agree. However, we do not agree with instructing MACs to apply a waiver during final settlement that would eliminate any application of the guidelines as we are striving to have all RHC fiscal year ends for this change be handled consistently.

After consideration of public comments, we are finalizing our proposal to remove the productivity standard for RHCs as proposed with a clarification on timing; effective with cost reporting periods ending after December 31, 2024.

7. Rebasing of the FQHC Market Basket

a. Background

Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC final rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods, and as of January 1, 2016, all FQHCs have been paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI at that time was based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS sustainable growth rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI.) Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based market basket reflecting the operating and capital cost structures for freestanding FQHC facilities (hereafter referred to as the FQHC market basket). A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403). In the CY 2021 PFS final rule (85 FR 84699 through 84710), we rebased and revised the FQHC market basket to reflect a 2017 base year.

For the CY 2025 PFS proposed rule, we proposed to rebase and revise the 2017-based FQHC market basket to reflect a 2022 base year, which would maintain our historical frequency of rebasing the market basket every 4 years. The proposed 2022-based FQHC market basket is primarily based on Medicare cost report data for FQHCs for 2022, which are for cost reporting periods beginning on and after October 1, 2021, and prior to October 1, 2022. We proposed to use data from cost reports beginning in FY 2022 because these data are the latest available complete set of Medicare cost report data for purposes of calculating cost weights for the FQHC market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed FQHC market basket, describe the methodologies for developing the 2022-based FQHC market basket, and provide information on the proposed price proxies. We then present the CY 2025 FQHC market basket update based on the 2022-based FQHC market basket.

b. Overview of the 2022-Based FQHC Market Basket

Similar to the 2017-based FQHC market basket, the proposed 2022-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (we proposed to use 2022 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive expenditure categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket index levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurse practitioners to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC but would not be factored into

the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that FQHCs purchase (FQHC inputs) to furnish care between base periods.

c. Development of the 2022-Based FQHC Market Basket Cost Categories and Weights

We solicited public comments on our proposed methodology, discussed in this section of this rulemaking, for deriving the proposed 2022-based FQHC market basket.

We did not receive public comments on this methodology, and therefore, we are finalizing as proposed.

(1) Use of Medicare Cost Report Data

The major types of costs underlying the proposed 2022-based FQHC market basket are derived from the Medicare cost reports (CMS Form 224–14, OMB Control Number 0938–1298) for freestanding FQHCs. Specifically, we use the Medicare cost reports for eleven specific costs: FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Medical Supplies, Pharmaceuticals, Fixed Assets, and Movable Equipment. A residual category is then estimated and reflects all remaining costs not captured in the 11 types of costs identified previously (such as non-medical supplies and utilities).

The resulting proposed 2022-based FQHC market basket cost weights reflect Medicare allowable costs. We proposed to define Medicare allowable costs centers for freestanding FQHC facilities as the expenses reported on: Worksheet A, lines 1 through 7, lines 9 through 12, lines 23 through 36, and line 66. For the proposed 2022-based FQHC market basket, we proposed to include data from the cost center from Worksheet A, line 66 (Telehealth) as effective for CY 2022 since CMS finalized a proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology and for RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person (86 FR 65208 through 62511). As done with the 2017-based FQHC market basket, we proposed to continue to exclude Professional Liability Insurance (PLI) costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

Later in this section, we explain in more detail how the costs for each of the 11 categories are derived. Prior to estimating any costs, we apply three basic edits. First, we only include the last submitted cost report so there is no double counting of a FQHC provider. Second, we exclude providers that have less than half a year of reported cost data; this edit excludes 175 FQHC providers for 2022. Finally, we remove any providers that did not report net direct patient care expenses on the FQHC cost report Worksheet A, line 37, column 7; this edit excludes 717 FQHC cost reports, or about 29 percent of FQHC providers. If a provider does not have reported costs, then we are unable to use that provider's costs to calculate cost weights. We encourage providers to report net direct patient care expenses when reporting the data. After the three edits, there are 1,713 remaining FQHC providers in the 2022 data set that we use to estimate cost expenditures for, or roughly two-thirds of the total FQHCs in the original Medicare cost report data set.

(a) FQHC Practitioner Wages and Salaries Costs

A FQHC practitioner is defined as one of the following occupations: physicians; nurse practitioners (NPs); physician assistants (PAs); certified-nurse midwife (CNMs); clinical psychologist (CPs); and clinical social workers (CSWs). We proposed to calculate FQHC Practitioner Wages and Salaries Costs using three steps. First, we proposed to calculate FQHC Practitioner Compensation Costs as equal to the net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 23, 25, 26, 29, 30, and 31. These lines represent the total net costs (after reclassifications and adjustments) for physicians, PAs, NPs, CNMs, CPs, and CSWs.

Second, we proposed to further divide the FQHC Practitioner Compensation Costs for these occupations into wages and salaries, employee benefits, and contract labor costs based on the ratios of practitioner wages and salaries, practitioner employee benefits, and practitioner contract labor costs to the sum of these three groups of costs. We do this by applying the ratios of practitioner wages and salaries, practitioner employee benefits, and practitioner contract labor to the net expense FQHC Practitioner Compensation Costs, and the determination of these ratios is described below. We proposed to derive the practitioner wages and salaries costs as the sum of direct care wages and salaries reported on Worksheet A, column 1, lines 23, 25, 26, 29, 30, and 31. These lines represent the wages and salaries costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We proposed to derive the practitioner employee benefits costs for these occupations as the sum of costs reported on Worksheet S–3, part II, column 2, lines 2, 3, 4, 7, 8, and 9. These lines represent the employee benefits costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We proposed to derive the practitioner contract labor costs for these occupations as the costs reported on Worksheet S–3, part II, column 1, lines 2, 3, 4, 7, 8, and 9. These lines represent the contract labor costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. This was the same method used to calculate the ratios to split the FQHC Practitioner Compensation Costs as was done for the 2017-based FQHC market basket. Approximately 56 percent of FQHCs that reported direct patient care wages and salaries costs also reported employee benefits costs data and approximately 99 percent of FQHCs that reported direct patient care wages and salaries costs also reported contract labor cost data on Worksheet S–3, part II for 2022. This is higher reporting than the percent of FQHCs reporting the same data compared to the 2017-based FQHC market basket, which had a 45 percent and 66 percent reporting incidence for the 2017 cost report data. We are encouraged by this improvement in the data and continue to encourage all providers to report these data on the Medicare cost report.

The final step in the process to derive the FQHC Practitioner Wages and Salaries costs is to apply the ratio of practitioner wages and salaries to the sum of practitioner wages and salaries costs, practitioner employee benefits costs, and practitioner contract labor costs times the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as described above. This calculation is

done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The resulting proposed FQHC Practitioner Wages and Salaries costs are equal to the sum of each occupation's wages and salary costs. This is the same methodology that was used for the 2017-based FQHC market basket.

As stated in the CY 2022 PFS final rule (86 FR 65209), effective for CY 2022 FQHC mental health visits furnished using interactive, real-time telecommunications technology are paid for at the same rate as other FQHC visits when these services are furnished in-person; therefore, we proposed to include telehealth wages and salaries costs in the FQHC Practitioner Wages and Salaries cost category. We proposed to derive telehealth wages and salaries by multiplying the net telehealth costs (as reported on Worksheet A, column 7, line 66) times the ratio of telehealth wages and salaries (as reported on Worksheet A, column 1, line 66) to the sum of telehealth costs (the sum of Worksheet A, column 1 and 2, line 66).

(b) FQHC Practitioner Employee Benefits Costs

To calculate FQHC Practitioner Employee Benefits costs, we proposed to use a similar methodology as used to calculate the FQHC Practitioner Wages and Salaries costs. We proposed to apply the ratio of practitioner employee benefits as described above to the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in the section III.B.7.(c)(1)(a) of this final rule. This calculation is done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The FQHC Practitioner Employee Benefits costs are equal to the sum of each occupation's employee benefits costs. This is the same methodology that was used for the 2017-based FQHC market basket. As stated previously, effective for CY 2022, telehealth services are covered under the FQHC PPS; therefore, we proposed to also include in the FQHC Practitioner Employee Benefits the telehealth employee benefits. We proposed to estimate telehealth employee benefits by multiplying telehealth wages and salaries (as described in section III.B.7.(c)(1)(a)) of this final rule times the ratio of total direct patient care facility benefits (Worksheet S–3 part II, column 2, line 1) to total facility direct patient care salaries (the sum of Worksheet A, columns 1 and 2, lines 23 and 25 through 36), which is estimated to be 21 percent on average. This ratio is referred to as the overall employee benefit share and represents the ratio of employee benefits to wages and salaries for all patient care costs reported by FQHCs.

(c) FQHC Practitioner Contract Labor Costs

To calculate FQHC Practitioner Contract Labor Costs, we proposed to use a similar methodology as used to calculate FQHC Practitioner Wages and Salaries and FQHC Practitioner Employee Benefit Costs. We proposed to multiply the ratio of practitioner contract labor, as described above, by the FQHC Practitioner Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in section III.B.7.(c)(1)(a) of this final rule. This calculation is done for each occupation individually (physicians, PAs, NPs, CNMs, CPs, and CSWs). The FQHC Practitioner Contract Labor costs are equal to the sum of each occupation's contract labor costs plus all net expenses reported for Physicians Services Under Agreement from Worksheet A, column 7, line 24. This is the same methodology used for the 2017-based FQHC market basket.

(d) Clinical Staff Wages and Salaries Costs

We proposed to calculate Clinical Staff Wages and Salaries Costs using three steps. First, we proposed to define Clinical Staff Compensation costs as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 27, 28, 32, 33, 34, 35, and 36. Clinical Staff Compensation includes any health-related clinical staff who do not fall under the definition of a FQHC Practitioner. These lines represent the net expenses for visiting registered nurses (RNs), visiting licensed practical nurses (LPNs), laboratory technicians, registered dietician/Certified DSMT/MNT educators, physical therapists (PTs), occupational therapists (OTs), and other allied health personnel.

Second, we proposed to further divide the Clinical Staff Compensation costs for these occupations into wages and salaries, employee benefits, and contract labor costs based on the ratio of clinical staff wages and salaries, clinical staff employee benefits, and clinical staff contract labor costs to the sum of these three groups of costs. We do this by applying the ratio of clinical staff wages and salaries, clinical staff employee benefits, and clinical staff contract labor to the net expense Clinical Staff Compensation costs, and the determination of these ratios is described later in this section. We proposed to derive clinical staff wages and salaries costs as the sum of direct care cost salaries as reported on Worksheet A, column 1, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the wages and salaries costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel. We proposed to derive the clinical staff employee benefits costs for these occupations as the sum of costs reported on Worksheet S–3, part II, column 2, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the employee benefits costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel. Similarly, we proposed to calculate clinical staff contract labor costs for these occupations as the costs reported on Worksheet S–3, part II, column 1, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the contract labor costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel. This was the same method used to calculate the ratios to split the Clinical Staff Compensation net expenses as was done for the 2017-based FQHC market basket.

The final step in the process to derive the Clinical Staff Wages and Salaries costs is to apply the ratio of clinical staff wages and salaries calculated in the prior step to the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as described above. This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Wages and Salaries costs is equal to the sum of each occupation's wages and salary costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(e) Clinical Staff Employee Benefits Costs

To calculate Clinical Staff Employee Benefit costs, we proposed to use a similar methodology as used to calculate the Clinical Staff Wages and Salaries costs. We proposed to multiply the ratio of clinical staff employee benefits, as described above by the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A

column 7) as defined in the section III.B.7.(c)(1)(d) of this final rule. This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Employee Benefits costs are equal to the sum of each occupation's Employee Benefits costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(f) Clinical Staff Contract Labor Costs

To calculate Clinical Staff Contract Labor costs, we proposed to use a similar methodology as used to calculate Clinical Staff Wages and Salaries Costs and Clinical Staff Benefit Costs. We proposed to multiply the ratio of clinical staff contract labor costs, as described above, by the Clinical Staff Compensation costs (representing the net expenses for each occupation as reported on Worksheet A column 7) as defined in the section III.B.7.(c)(1)(d) of this final rule. This calculation is done for each occupation individually (visiting RNs, visiting LPNs, laboratory technicians, registered dietician/ Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel). The Clinical Staff Contract Labor costs are equal to the sum of each occupation's contract labor costs. This is the same methodology that was used for the 2017-based FQHC market basket.

(g) Non-Health Staff Compensation Costs

We proposed to define Non-Health Staff Compensation costs using net expenses (that is, costs after reclassifications and adjustments) as the estimated share of compensation costs from Worksheet A, column 7 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. These lines represent the net expenses for the employee benefits department, administrative & general services, plant operations & maintenance, janitorial, medical records, pharmacy, medical supplies, transportation, and other general services. Since the net expenses for the General Service Cost centers include both compensation and other costs, we estimate the share of net expenses for each general service cost center that reflects compensation costs. First, we estimate a share of non-health staff wages and salaries costs for each general service cost center as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12 divided by Worksheet A, column 1 and 2 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Then, we multiply the Non-Health Staff net expenses (that is, costs after reclassifications and adjustments) by the non-health staff wages and salaries share to derive estimated Non-Health Staff Wages and Salaries costs for each general service cost center (lines 3–7 and lines 9–12). Second, we estimate Non-Health Staff Employee Benefit costs by multiplying the Non-Health Staff Wages and Salaries costs (step one) by the overall employee benefit share as described in section III.B.7.(c)(1)(b) of this final rule, or 21 percent. Finally, we sum the derived Non-Health Staff Wages and Salaries costs and the derived Non-Health Staff Employee Benefits costs for each general service cost center (lines 3–7 and lines 9–12) to calculate Non-Health Staff Compensation costs. This is the same methodology used for the 2017-based FQHC market basket.

(h) Pharmaceutical Costs

We proposed to calculate Pharmaceutical costs as the non-compensation costs for the Pharmacy cost center. We define this as Worksheet A, column 7, line 9 less derived pharmacy compensation costs. Derived pharmacy compensation costs are included in the Non-health Staff Compensation costs described in section III.B.7.(c)(1)(g) of this final rule. We note that the only pharmaceutical costs eligible for inclusion in the FQHC PPS market basket are those reported on line 9 of Worksheet A. These pharmaceutical costs would include only the costs of routine drugs (both prescription and over the counter), pharmacy supplies, and pharmacy services, provided incident to an FQHC visit. Other types of drugs and pharmacy supplies costs not included in this category are those reported on line 67 (drugs charged to patients), line 77 (retail pharmacy), line 48 (pneumococcal vaccine), and line 49 (influenza vaccine, COVID–19, and monoclonal antibody products for treatment of COVID–19), as these costs are reimbursed to FQHC providers outside of the FQHC PPS payment. The derived pharmacy compensation costs are equal to the sum of the estimated pharmacy wages and salaries and pharmacy employee benefits costs. This is the same methodology used for the 2017-based FQHC market basket.

(i) Medical Supplies Costs

We proposed to calculate Medical Supplies costs as the non-compensation costs for the Medical Supplies costs center. We define this as Worksheet A, column 7, line 10 less derived medical supplies compensation costs. Derived medical supplies compensation costs are included in the Non-health Staff Compensation costs described in section III.B.7.(c)(1)(g) of this final rule. The derived medical supplies compensation costs are equal to the sum of the estimated medical supplies wages and salaries and medical supplies benefits costs. This is the same methodology used for the 2017-based FQHC market basket.

(j) Fixed Assets Costs

We proposed to define Fixed Asset costs to be equal to costs reported on Worksheet A, line 1, column 7 of the Medicare cost report. This is the same methodology used for the 2017-based FQHC market basket.

(k) Movable Equipment Costs

We proposed to define Movable Equipment costs to be equal to the capital costs as reported on Worksheet A, line 2, column 7. This is the same methodology used for the 2017-based FQHC market basket.

(2) Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we proposed to trim the data for outliers. For each of the 11 major cost categories, we proposed to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of FQHC providers after basic trims described in section III.B.7.(c) of this final rule. For the proposed 2022-based FQHC market basket, total Medicare allowable costs are equal to total net expenses (after reclassifications and adjustments) reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12; lines 23 through 36, and line 66. This is the same method used to derive total Medicare allowable costs for the 2017-based FQHC market basket with the only difference being that we now include the net expenses for line 66, telehealth because as previously described, effective for CY 2022 CMS finalized the policy for mental health visits furnished using interactive, real-time telecommunications technology to be paid in the same way they currently do when these services are furnished in-person (86 FR 65208 through 62511).

For the FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Pharmaceuticals, Medical Supplies, Fixed Assets, and Movable Equipment cost weights, after excluding cost weights that are less than or equal to zero, we proposed to then remove those

providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the exclusion of outliers. A 5 percent trim is the standard trim applied to the mean cost weights in most CMS market baskets and is consistent with the trimming used in the 2017-based FQHC market basket. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We proposed to then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2022-based FQHC market basket for the given category. This trimming process is done for each cost weight separately.

Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the 11 major cost categories listed. Table 29 provides the resulting cost weights for these major cost categories derived from the Medicare cost reports.

Table 29 displays the proposed 2022-based FQHC market basket cost weights compared to the 2017-based FQHC market basket cost weights.

TABLE 29: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	2022-Based FQHC Cost Report Weights (Percent)	2017-Based FQHC Cost Report Weights (Percent)
FQHC Practitioner Compensation	24.8	28.4
FQHC Practitioner Wages and Salaries	17.1	19.4
FQHC Practitioner Employee Benefits	3.6	4.5
FQHC Practitioner Contract Labor	4.1	4.6
Clinical Staff Compensation	15.3	16.8
Clinical Staff Wages and Salaries	11.8	12.9
Clinical Staff Employee Benefits	2.8	3.1
Clinical Staff Contract Labor	0.6	0.9
Non-Health Staff Compensation	28.4	27.2
Pharmaceuticals	3.2	2.4
Medical Supplies	2.4	2.2
Fixed Assets	5.0	4.4
Movable Equipment	2.2	2.0
All Other (Residual)	18.7	16.5

Note: Totals may not sum to 100.0 due to rounding

As we did for the 2017-based FQHC market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs comprise both wages and salaries and employee benefits for both FQHC Practitioners and Clinical Staff. The contract labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This percentage based on the proposed 2022-based FQHC cost weights is 82.5 percent for FQHC practitioners and 80.8 percent for clinical staff. Therefore, we proposed to allocate 82.5 percent of the FQHC Practitioner Contract Labor cost weight to the FQHC Practitioner Wages and Salaries cost weight and 17.5 percent to the FQHC Practitioner Employee Benefits cost weight. Similarly, we proposed to allocate 80.8 percent of the Clinical Staff Contract Labor cost weight to the Clinical Staff Wages and Salaries cost weight and 19.2 percent to the Clinical Staff Employee Benefits cost weight. Table 30 shows the FQHC Practitioner and Clinical Staff Wages and Salaries and Employee Benefits proposed 2022-based cost weights after the contract labor cost weight has been allocated. Table 30 also includes the comparison of the weights to the 2017-based cost weights for the same categories.

TABLE 30: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	2022-Based FQHC Practitioner	2022-Based Clinical Staff	2017-Based FQHC Practitioner	2017-Based Clinical Staff
Compensation	**24.8**	**15.3**	**28.4**	**16.8**
Wages and Salaries	20.5	12.4	23.1	13.6
Employee Benefits	4.3	2.9	5.4	3.3

*Totals may not sum due to rounding

(3) Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2022 Medicare cost report data into more detailed cost categories, we proposed to use the 2017 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the Bureau of Economic Analysis (BEA). We noted that the BEA benchmark I–O data is used to further disaggregate residual costs in other CMS market baskets. Therefore, we noted that we believe the data from this industry are the most technically appropriate for disaggregation of the residual net expenses since both physician offices and FQHCs provide similar types of care. These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data.* For the 2017-based FQHC market basket, we used the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/ Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the BEA.

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[367] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2017 Benchmark I–O data forward to 2022 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data. We repeat this practice for each year. We then calculate the cost shares that each cost category represents of the 2017 data inflated to 2022. These resulting 2022 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2022-based FQHC market basket. For example, the cost for Medical Equipment represents 7.8 percent of the sum of the ''All Other'' 2017 Benchmark I–O Offices of Physicians Expenditures inflated to 2022. Therefore, the proposed Medical Equipment cost weight represents 7.8 percent of the proposed 2022-based FQHC market basket's ''All Other'' cost category (18.7 percent), yielding a Medical Equipment cost weight of 1.5 percent in the proposed 2022-based FQHC market basket (0.078×18.7 percent = 1.5 percent).

Using this methodology, we proposed to derive six detailed FQHC market basket cost category weights from the proposed 2022-based FQHC market basket residual cost weight (18.7 percent). These categories are: (1) Utilities; (2) Medical Equipment; (3) Miscellaneous Products; (4) Professional, Scientific, and Technical Services; (5) Administrative and Facilities Support Services; and (6) All Other Services.

(4) 2022-Based FQHC Market Basket Cost Categories and Weights

Table 31 shows the cost categories and cost weights for the proposed 2022-based FQHC market basket compared to the 2017-based FQHC market basket. The Total Compensation cost weight of 68.5 percent (sum of FQHC Practitioner Compensation, Clinical Staff Compensation, and Non-health Staff Compensation) calculated from the Medicare cost reports for the proposed 2022-based FQHC market basket is 4.1 percentage points lower than the total compensation cost weight for the 2017-based FQHC market basket (72.6 percent). The decrease in the compensation cost weight between the 2017-based and the proposed 2022-based market basket is stemming from the decreasing FQHC Practitioner and Clinical Staff Compensation cost weights. The proposed 2022-based cost weights for FQHC Practitioner and Clinical Staff Compensation are 5.3 percentage points lower compared to the 2017-based FQHC market basket, while the Non-Health Staff Compensation cost weight is 1.2 percentage points higher. Analysis of the cost report data shows that the decline in the health-related compensation cost weights is stemming from a change in the mix of health-related workers from higher-paid to lower-paid occupations. Specifically, there has been a shift in full time equivalents (FTEs) from physicians to nurse practitioners and a shift from registered and licensed practical nurses to other allied health personnel. Additionally, the proposed 2022-based Pharmaceuticals cost weight, Non-Health Staff Compensation costs weight, and the Capital cost weight, are each roughly 1 percentage point higher than the cost weight in the 2017-based FQHC market basket.

We noted that our analysis of the Medicare cost report data over time shows the general trends in these cost weights (particularly for the Total Compensation and Pharmaceuticals cost weights) began after 2017 with about half of the cost weight changes occurring between 2017 and 2019. Consistent with our historical frequency of rebasing the other CMS market baskets, we believe it is important to rebase the FQHC market basket every four to five years to reflect the more recent data and changing cost structure.

[367] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

TABLE 31: 2022-Based FQHC Market Basket Cost Weights Compared to 2017-Based FQHC Market Basket Cost Weights

Cost Category	2022-based FQHC Market Basket Cost Weight	2017-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**68.5**	**72.6**
FQHC Practitioner Compensation	**24.8**	**28.5**
FQHC Practitioner Wages and Salaries	20.5	23.1
FQHC Practitioner Employee Benefits	4.3	5.4
Clinical Staff Compensation	**15.3**	**16.9**
Clinical Staff Wages and Salaries	12.4	13.6
Clinical Staff Employee Benefits	2.9	3.3
Non-Health Staff Compensation	**28.4**	**27.2**
All Other Products	**9.8**	**8.5**
Pharmaceuticals	3.2	2.4
Utilities	0.5	0.6
Medical Equipment	1.5	1.2
Medical Supplies	2.4	2.2
Miscellaneous Products	2.3	2.2
All Other Services	**14.5**	**12.6**
Professional, Scientific, and Technical Services	8.6	6.4
Administrative and Facilities Support Services	1.5	1.7
All Other Services	4.4	4.5
Capital-Related Costs	**7.2**	**6.4**
Fixed Assets	5.0	4.4
Movable Equipment	2.2	2.0

Note: Totals may not sum due to rounding.

d. Selection of Price Proxies

After developing the cost weights for the proposed 2022-based FQHC market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For most of the cost categories, we rely on using the price proxies based on U.S. Bureau of Labor Statistics (BLS) data, as they produce indexes that best meet the criteria of reliability, timeliness, availability, and relevance, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an

optimal way to stay abreast of the most current data available.

- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

The CPIs, PPIs, and ECIs that we have selected to use in the proposed 2022-based FQHC market basket meet these criteria. Therefore, we believe that they continue to be the best measures of price changes for the cost categories to which they would be applied.

Table 32 lists all price proxies we proposed to use in the proposed 2022-based FQHC market basket. Below is a detailed explanation of the price proxies we proposed for each cost category.

(1) Price Proxies for the 2022-Based FQHC Market Basket

(a) FQHC Practitioner Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians or FQHC Practitioners, and therefore, we proposed to use an index that is based on professionals that receive advanced training similar to those performing at the FQHC Practitioner level of care. This index is consistent with the price proxy used to measure wages and salaries inflation pressure for physicians own time in the Medicare Economic Index (MEI) and is based on the MEI technical panel recommendation from 2012 for more details see the CY 2014 PFS final rule (78 FR 74266 through 74271). Additionally, this is the same price proxy used for the FQHC Practitioner Wages and Salaries cost category in the 2017-based FQHC market basket (85 FR 84708).

(b) FQHC Practitioner Employee Benefits

We proposed to use the ECI for Total Benefits for Private Industry Workers in Professional and Related to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used for the FQHC Practitioner Employee Benefits cost category in the 2017-based FQHC market basket (85 FR 84708).

(c) Clinical Staff Wages and Salaries

We proposed to use the ECI for Wages and Salaries for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1026200000000I) to measure the price growth of this cost category. This cost category consists of wage and salary costs for Nurses, Laboratory Technicians, and all other healthcare staff not included in the FQHC Practitioner compensation categories. Based on the clinical staff composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure wage and salary price pressures for these workers. This is the same price proxy used for the Clinical Staff Wages and Salaries cost category in the 2017-based FQHC market basket (85 FR 84708).

(d) Clinical Staff Employee Benefits

We proposed to use the ECI for Total Benefits for all Civilian Workers in Health Care and Social Assistance to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used for the Clinical Staff Employee Benefits cost category in the 2017-based FQHC market basket (85 FR 84708).

(e) Non-Health Staff Compensation

We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health Staff Compensation cost weight is predominately attributable to administrative, and facility type occupations, as reported in the data from the Medicare cost reports. This is the same price proxy used for the Non-Health Staff Compensation cost category in the 2017-based FQHC market basket (85 FR 84708).

(f) Pharmaceuticals

We proposed to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as the 2018-based Inpatient Prospective Payment System market basket and is the same price proxy used for the Pharmaceuticals cost category in the 2017-based FQHC market basket (85 FR 84708).

(g) Utilities

We proposed to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same price proxy used for the Utilities cost category in the 2017-based FQHC market basket (85 FR 84708).

(h) Medical Equipment

We proposed to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same price proxy used for the Medical Equipment cost category in the 2017-based FQHC market basket (85 FR 84708).

(i) Medical Supplies

We proposed to use a 50/50 blended index that comprises the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We noted that we believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we proposed to combine the two aforementioned indexes to reflect those modes of purchase. This is the same price proxy used for the Medical Supplies cost category in the 2017-based FQHC market basket (85 FR 84708 through 84709).

(j) Miscellaneous Products

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy is appropriate as it reflects a general level of inflation. This is the same price proxy used for the Miscellaneous cost category in the 2017-based FQHC market basket (85 FR 84709).

(k) Professional, Scientific, and Technical Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same price proxy used for the Professional, Scientific, and Technical Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(l) Administrative and Facilities Support Services

We proposed to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same price proxy used for the Administrative and Facilities Support Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(m) All Other Services

We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used for the All Other Services cost category in the 2017-based FQHC market basket (85 FR 84709).

(n) Fixed Assets

We proposed to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category (81 FR 80398). We believe this continues to be the most appropriate price proxy since fixed asset costs in FQHCs should reflect inflation for the rental and purchase of business office space. This is the same price proxy used for the Fixed Assets cost category in the 2017-based FQHC market basket (85 FR 84709).

(o) Movable Equipment

We proposed to continue to use the PPI Commodities for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical movable equipment. This is the same price proxy used for the Movable Equipment cost category in the 2017-based FQHC market basket (85 FR 84709).

(2) Summary of Price Proxies of the 2022-Based FQHC Market Basket

Table 32 shows the cost categories and associated price proxies for the proposed 2022-based FQHC market basket.

TABLE 32: Cost Categories and Price Proxies for the 2022-based FQHC Market Basket

Cost Description	Price Proxies
FQHC Practitioner Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Professional and Related
FQHC Practitioner Employee Benefits	ECI for Total Benefits for Private Industry Workers in Professional and Related
Clinical Staff Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Health Care and Social Assistance
Clinical Staff Employee Benefits	ECI for Total Benefits for All Civilian Workers in Health Care and Social Assistance
Non-Health Staff Compensation	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
Pharmaceuticals	PPI Special Index for Pharmaceuticals for Human Use, Prescription
Utilities	CPI-U for Fuels and Utilities
Medical Equipment	PPI Commodity Index for Surgical and Medical Instruments
Medical Supplies	Composite: PPI Commodity Index for Medical and Surgical Appliances and Supplies (50%) and CPI for Medical Equipment and Supplies (50%)
Miscellaneous Products	CPI-U for All Items Less Food and Energy
Professional, Scientific, and Technical Services	ECI for Total compensation for Private industry workers in Professional, Scientific, and Technical Services
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other Services	ECI for Total Compensation for Private Industry Workers in Service Occupations
Fixed Assets	PPI Industry Index for Lessors of Nonresidential Buildings
Movable Equipment	PPI Commodity Index for Machinery and Equipment

We solicited comments on our proposal to rebase and revise the FQHC market basket to reflect a 2022 base year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to rebase and revise the FQHC market basket from a 2017 base year to a 2022 base year and supported the proposed market basket methodology and results. The commenters stated they appreciated CMS recognizing the financial challenges and using the 2022 cost report data to support the FQHC market basket. These commenters also stated their support that the proposed 2022-based market basket uses a fixed-weight, Laspeyres-type price index, which they stated will provide a reliable measure of price changes over time, and that this method coupled with the use of other reliable data sources ensures that the

market basket accurately reflects the cost trends that FQHCs experience. Finally, several commenters also stated their support for the proposal to include the costs related to telehealth services in the 2022-based FQHC market basket, as it reflects the critical regulatory changes and the expansion of telehealth services that took place in 2022.

Response: We appreciate the commenters' support for the proposed rebasing of the FQHC market basket to reflect a 2022 base year that accounts for changes in the mix of goods and services purchased in providing FQHC services as well as the general methodological approach of using Medicare cost report data, a Laspeyres-type index formula, and the use of publicly available price proxies when available and appropriate.

After consideration of public comments, we are finalizing the methodology for deriving the 2022-based FQHC market basket as proposed without modification effective with the CY 2025 FQHC PPS update.

e. CY 2025 Productivity-Adjusted Market Basket Update for FQHCs

For CY 2025 (that is, January 1, 2025, through December 31, 2025), we proposed to use an estimate of the proposed 2022-based FQHC market basket to update payments to FQHCs based on the best available data. Consistent with CMS practice, we proposed to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2025 FQHC update is based on the four-quarter moving-average percent change of the 2022-based FQHC market basket through the second quarter of 2024 (based on the final rule's statutory publication schedule). At the time of the proposed rule, we did not have the second quarter of 2024 historical data, and therefore, we proposed to use the most recent projection available at the time. Consistent with CMS practice, we estimate the market basket update for the FQHC PPS based on the most recent forecast from IHS Global, Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and total factor productivity (TFP).

Based on IGI's third quarter 2024 forecast with historical data through the second quarter of 2024, the final 2022-based FQHC market basket increase factor for CY 2025 is 4.0 percent. For comparison, the 2017-based FQHC market basket percentage increase is 4.1 percent for CY 2025 based on IGI's third quarter 2024 forecast (with historical data through the second quarter of 2024). The difference between the CY 2025 percentage increase using the 2017-based FQHC market basket and the 2022-based FQHC market basket is due to the lower wages and salaries cost weight for FQHC Provider Wages and Salaries and Clinical Staff Wages and Salaries.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. We have included a productivity adjustment to the FQHC PPS annual payment update since implementation of the FQHC PPS (81 FR 80393) and we proposed to continue to include a productivity adjustment to the proposed 2022-based FQHC market basket. We proposed to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) total factor productivity (TFP), which is the same measure of TFP applied to other CMS market basket updates including the MEI. The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity estimates published by BLS was referred to as multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' (MFP) with ''TFP.'' Please see *https://www.bls.gov/productivity/data.htm* for the BLS historical published TFP data. For the final FQHC market basket update, we proposed to use the most recent historical estimate of annual TFP as published by the BLS. Generally, the most recent historical TFP estimate is lagged two years from the payment year.

Therefore, we proposed to use the 10-year moving average percent change in annual private nonfarm business TFP through 2023 as published by BLS in the CY 2025 FQHC market basket update. We note that TFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of development of the proposed rule the measure of TFP for 2023 had not yet been published by BLS, we proposed to use IGI's first quarter 2024 forecast of TFP. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.*

Using IGI's first quarter 2024 forecast, the productivity adjustment for CY 2025 (the 10-year moving average of TFP for the period ending CY 2023) was projected to be 0.5 percent. Therefore, the proposed CY 2025 productivity-adjusted FQHC market basket update was 3.5 percent, based on IGI's first quarter 2024 forecast. This reflected a 4.0 percent increase in the 2022-based FQHC market basket reduced by a 0.5 percentage point productivity adjustment. Finally, we proposed that the CY 2025 market basket update and the productivity adjustment would be updated to reflect the most recent historical data available for the final rule.

For this final rule, as proposed, we are using the latest historical data for TFP as published by the BLS to determine the productivity adjustment. The 10-year moving average percent change in TFP for the period ending CY 2023 as published by BLS is 0.6 percent. Based on the latest historical data through the second quarter of 2024, the final 2022-based FQHC market basket percentage increase is 4.0 percent. Therefore, the final CY 2025 productivity-adjusted FQHC market basket update is 3.4 percent (4.0 percent FQHC market basket percentage increase reduced by a 0.6 percentage point productivity adjustment).

8. Clarification for Dental Services Furnished in FQHCs

a. Payment for Dental Services Furnished in FQHCs

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') That section of the statute also includes an exception to allow payment to be made for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at 42 CFR 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

Fee for service (FFS) Medicare Parts A and B also make payment for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. In the CY 2023 PFS final rule (87 FR 69663 through 69688), we clarified and codified at § 411.15(i)(3) that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting when the dental services are inextricably linked to, and substantially related and integral to the clinical success of, other covered services. We also added several examples of clinical scenarios that are considered to meet that standard under § 411.15(i)(3) and amended that regulation to add more examples in the CY 2024 PFS final rule (88 FR 79022 through 79029).

In the CY 2024 PFS final rule (88 FR 79038), we received comments requesting we provide payment for inextricably linked dental services in the FQHC setting. Commenters stated that it is critical that CMS consider FQHCs' unique Medicare payment structure and that CMS ensure that policy changes for FQHCs are analogous to any changes made under the PFS. Commenters noted that many FQHCs provide dental services on-site, and health center patients could benefit from the payment policies for dental services inextricably linked to other covered services and suggested that the FQHC billing codes should be edited in tandem. Commenters further noted that ''physicians' services'' component of the Medicare FQHC benefit includes services furnished by dentists. Several commenters urged that the list of billable dental visit codes modified in the proposed rule be added to the list of codes that may be billed in the FQHC setting and requested that any expansion in codes recognized under the PFS for dental-related services also be applied to FQHCs. We acknowledged the commenters concerns and noted our intention to modify operational procedures in the FQHC setting to reflect the expansion of this PFS policy, including updates to billable code lists.

In the CY 2025 PFS proposed rule, we agreed that RHC and FQHC Medicare beneficiaries could benefit from the payment policies established under the PFS for dental services that are inextricably linked to specific medical services. Dentists are defined as physicians in Medicare statute (42 CFR 491.2). Services furnished by physicians are billable visits in RHCs and FQHCs and they could bill for a face-to-face, medically necessary visit furnished by a dentist within their scope of practice. Therefore, we clarified that dental services exactly as described in section II.J and furnished in an RHC or FQHC are RHC and FQHC visits and as such can be paid under the RHC AIR methodology or FQHC PPS.

We would apply and operationalize the dental policies finalized in the CY 2023 and 2024 PFS final rules as applicable also to RHCs and FQHCs and update the FQHC qualifying visit list as appropriate. Consistent with the discussion in section II.J of this final rule, if an RHC or FQHC practitioner believes the dental services for which they submit Medicare claims are inextricably linked to a covered service, a modifier may be reported on an RHC or FQHC claim for payment purposes. The KX modifier would be reported on an RHC or FQHC claim to indicate that the service is medically necessary, and that the provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item. We believe that usage of the KX modifier in the context of claims for dental services inextricably linked to covered services to indicate that the clinician attests that the service is medically necessary, and that the provider has included appropriate documentation is appropriate and will support claims processing and program integrity efforts.

In addition, the GY modifier may be reported on a Medicare claim to indicate that a service is not covered because it is outside of the scope of Medicare coverage authorized by the statute. Denial modifiers should be used when physicians, practitioners, or suppliers want to indicate that the item or service is statutorily non-covered. Use of the GY modifier could support MAC efforts to adjudicate claims and remove from the claims processing pipeline those claims that do not require further processing.

We intend to provide additional instruction and education through subregulatory guidance regarding the usage of the KX and GY modifiers on claims submitted for dental services inextricably linked to covered medical services.

We clarified that when RHCs and FQHCs furnish dental services that align with the policies and operational requirements in the physician setting, we would consider those services to be a qualifying visit and the RHC would be paid at the RHC AIR methodology and the FQHC would be paid under the FQHC PPS.

b. Medical and Dental Visits Furnished on the Same Day

If an RHC or FQHC patient has a medically-necessary face-to-face visit with an RHC or FQHC practitioner, and is then seen by another RHC or FQHC practitioner, including a specialist, for further evaluation of the same condition on the same day, or is then seen by another RHC or FQHC practitioner, including a specialist, for evaluation of a different condition on the same day, the multiple encounters would constitute a single RHC or FQHC visit and be payable as one visit regardless of the length or complexity of the visit, whether the second visit is a scheduled or unscheduled appointment, or whether the first visit is related or unrelated to the subsequent visit.

If the RHC or FQHC patient suffers an illness or injury that requires additional diagnosis or treatment on the same day subsequent to the first visit, or has a medical and a mental health visit on the same day, or an RHC patient has an initial preventive physical exam (IPPE) and a separate medical and/or mental health visit on the same day, then the RHC or FQHC would be paid separately for each visit.

We solicited comment on whether the multiple visits policy should apply to patients who have an encounter with an RHC or FQHC practitioner and a dentist on the same day or should a subsequent encounter with a dentist be considered an exception to this policy and be paid as a separate billable visit. We are interested in understanding when these situations could occur.

We received several public comments on this proposal. The following is a summary of the comments we received.

Comment: Commenters were very supportive of the clarification provided for dental services furnished in RHCs and FQHCs, that is RHCs and FQHCs would align with the PFS and adopt the policies and operational requirements proposed for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered services, and would be paid as a qualifying visit. Commenters stated expanding Medicare coverage of dental services furnished in RHCs and FQHCs would alleviate financial burden, make providing dental services more sustainable, ensure equitable access to care, and improve care coordination.

Response: We thank commenters for their support of the clarification.

Comment: One commenter encouraged CMS to clarify how this payment clarification will be implemented for RHCs and FQHCs and

partner with RHCs and FQHCs to implement the policy.

Response: If an RHC or FQHC practitioner believes the dental services for which they submit Medicare claims are inextricably linked to a covered service, a modifier may be reported on an RHC or FQHC claim for payment purposes. The KX modifier would be reported on an RHC or FQHC claim to indicate that the service is medically necessary, and that the provider has included appropriate documentation in the medical record to support or justify the medical necessity of the service or item, and the dental service would be paid at the RHC AIR methodology or the FQHC PPS. We intend to provide additional instructions and education on the policy and billing requirements for dental services in subregulatory guidance.

Comment: All of the commenters who responded to the comment solicitation believed that the exception to the multiple visit policy should apply to dental visits; that is, RHCs and FQHCs could bill for both a medical visit and a dental visit for a patient on the same day. Commenters noted applying the exception to dental services furnished in RHCs and FQHCs would align with the current exception for a medical visit and a behavioral health visit, and or IOP visit, enhance access to care, and minimize patient burden by reducing travel time, childcare, mobility issues and other logistical challenges. Commenters also noted that same day billing for medical and dental visits ensures accurate reimbursement, reflecting the actual time and resources invested in each patient encounter. One commenter expressed concerns that that if we constrained medical and dental visits to be payable as a single visit, regardless of the length or complexity, this may incentivize clinics to schedule patients for medical and dental visits on separate days and to ensure that integration is realized in the provision of patient care, FQHCs and RHCs should be incentivized to schedule medical and dental visits on the same day.

Response: We appreciate the commenters feedback on the multiple visits policy. We agree with the commenters recommendation and will clarify in subregulatory guidance that RHCs and FQHCs can bill separately for dental services that are inextricably linked to other covered Medicare services on the same day a medical visit is furnished by an RHC or FQHC practitioner. We believe this clarification has the potential to increase access to dental services that are inextricably linked to other covered medical services in underserved areas and that this would help to demonstrate the value of dental services, especially in areas where the need for dental services is high and utilization is low.

After consideration of public comments, we are finalizing as proposed our clarification that when RHCs and FQHCs furnish dental services that align with the policies and operational requirements in the physician setting, we would consider these services to be a qualifying visit, and they would be paid at the RHC AIR methodology or the FQHC PPS. We will issue additional instructions and education through subregulatory guidance on the policy and billing requirements for these services. We are also clarifying in subregulatory guidance that RHCs and FQHCs can bill separately for dental services that are inextricably linked to other covered services on the same day a medical visit is furnished by an RHC or FQHC practitioner.

9. ''Grandfathered'' Technical Refinement

a. Background

We have conducted a review of our regulations and guidance to determine where preferred terms may be used. We found several sections in part 405, subpart X, that use the term ''grandfathered.'' For example, in § 405.2462(f)(1) a ''grandfathered tribal FQHC'' is a FQHC that is operated by a tribe or tribal organization under the Indian Self-Determination and Education Assistance Act (ISDEAA); was billing as if it were provider-based to an IHS hospital on or before April 7, 2000, and is not currently operating as a provider-based department of an IHS hospital.

b. Technical Refinement

We believe language in communication products should reflect and speak to the needs of people in the audience of focus. In an effort to represent an ongoing shift to non-stigmatizing language, we proposed to make a technical change to remove the term ''grandfathered'' from the regulation text in §§ 405.2462, 405.2463, 405.2464, and 405.2469 and replace it with ''historically excepted'' to describe a level of protection provided to certain tribal FQHCs that predates applicable restrictions.

We received two public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the technical change that would remove the term ''grandfathered'' from applicable regulation texts and replace it with ''historically excepted.''

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing our proposal to make a technical change to remove the term ''grandfathered'' from the regulation text in §§ 405.2462, 405.2463, 405.2464, and 405.2469 and replace it with ''historically excepted'' to describe a level of protection provided to certain tribal FQHCs that predates applicable restrictions.

C. Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs)

1. Background and Statutory Authority

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210 enacted December 13, 1977) amended the Act by enacting section 1861(aa) of the Act to extend Medicare and Medicaid entitlement and payment for outpatient services and emergency care services furnished at a rural health clinic (RHC) by physicians and certain other practitioners, and for services and supplies incidental to their services. Other practitioners include nurse practitioners and physician assistants, and subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, certified nurse midwives, marriage and family therapists, and mental health counselors.

We have broad statutory authority to establish health and safety standards for most Medicare and Medicaid participating provider and supplier types. Section 1861(aa) of the Act authorizes the Secretary to establish the requirements that an RHC and Federally Qualified Health Center (FQHC) must meet to participate in the Medicare Program. As required by subparagraph (iv) of the flush material set out after section 1861(aa)(2)(K) of the Act, Medicare certified RHCs must not be a rehabilitation agency or a facility which is primarily for the care or treatment of mental diseases. These statutory requirements are codified in the regulations at 42 CFR part 491 in the Conditions for Conditions for Certification and Conditions for Coverage (CfCs). RHCs and FQHCs must meet these requirements to receive Medicare payment for services. These regulations are intended to protect the health and safety of patients receiving care from these facilities. We note that there are approximately 5,462 Medicare-

certified RHCs and 11,853 Medicare participating FQHCs.

2. Summary of the RHC and FQHC CfCs Proposed Provisions, Public Comments, and Responses to Comments

In accordance with section 1861(aa) of the Act, § 491.9, *Provision of services,* establishes the basic requirements for services RHCs and FQHCs must provide in accordance with applicable Federal, State, and local laws. This CfC also outlines patient care policies, including the development of written policies and the establishment of guidelines for medical management, record-keeping, and drug administration. Additionally, this section specifies the diagnostic, therapeutic, laboratory, and emergency services that RHCs and FQHCs must offer, as well as the necessary agreements or arrangements with other healthcare providers to furnish additional services not available onsite.

Based on feedback from interested parties, including RHC providers and rural health associations, we identified a discrepancy between our guidance and the statute, and regulations. Specifically, interested parties questioned the language in the State Operations Manual *Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs)* as it relates to § 491.9(a)(2). The guidance states that ''RHCs may not be primarily engaged in specialized services.'' [368] The guidance goes on to state that, in this context, ''primarily engaged'' is determined by considering the total hours of an RHC's operation and whether a majority, that is, more than 50 percent, of those hours involve the provision of RHC services. Section 1861(aa)(2)(A) of the Act references an RHC being primarily engaged in ''furnishing to outpatients'' physician services and services furnished by a physician assistant or a nurse practitioner, clinical psychologist or by a clinical social worker, as cross-referenced by sections 1861(aa)(1)(A) and (B) of the Act. This is codified in the CfCs at § 491.9(a)(2), requiring RHCs and FQHCs to be primarily engaged in ''providing outpatient health services.'' Historically we have enforced the standard that RHCs be primarily engaged in providing primary care services based on the policy included in the interpretive guidance.

[368] Centers for Medicare & Medicaid Services. (2020, February 21). State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs) (pp. 63–64). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf.*

a. Basic Requirements (§ 491.9(a))

At § 491.9(a)(2)(i), we proposed to explicitly require RHCs and FQHCs to provide primary care services. Under the proposal, RHCs and FQHCs would continue to be required to provide primary care services to their patient populations, but CMS would no longer determine or enforce the standard of RHCs ''being primarily engaged in furnishing primary care services'' and would no longer consider the total hours of an RHC's operation and whether a majority, that is, more than 50 percent, of those hours involve the provision of primary care services through the survey process. We note that under the authority of section 1865 of the Act, CMS determines compliance with the regulations using surveys conducted by a State survey agency, surveys conducted by accreditation organizations that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS requires RHCs participating in Medicare to demonstrate and maintain compliance with the provisions included in 42 CFR part 491.

We proposed this policy because we believe it provides RHCs with greater flexibility in the services, including specialty services, that they provide by no longer placing parameters on the amount of primary care services they provide.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. Commenters included individuals from the RHC community (including RHCs), rural health associations, professional associations, State mental health associations, and health systems.

Comment: Many commenters expressed their support for the proposal, particularly the flexibility in tailoring services to meet the unique needs of their patient populations and addressing shortages in access to specialty services in rural areas to reduce health disparities and improve health outcomes. Other commenters noted this proposal not only promotes more equitable access to medical services but also aligns better with the intent of the statute, decreases the burden for RHCs, and preserves access to primary care services. Some commenters shared their support for this proposed provision and our consideration of the mobility barriers individuals in rural areas face, noting the importance of having access to services near one's home and that this proposal may minimize unnecessary travel time one may face when accessing specialized services. Additionally, we received multiple comments stressing the importance of RHCs continuing to provide primary care services. However, one commenter recommended that CMS not consider internal medicine, pediatric medicine, and OB/GYN services to be outpatient specialty services and to define ''primary care services'' in alignment with 42 CFR part 5 Appendix A paragraph (B)(3)(a). Two commenters supported this proposal, noting that the proposal would remove the limitation on the total amount of behavioral health services RHCs can provide.

Response: We appreciate the many comments noting support for this proposal and the feedback regarding the positive impacts on access to care that the proposal will support. While primary care services continue to be a critical aspect in addressing health disparities, we recognize that we also need to provide alternative rural points of access to specialty outpatient services, because more traditional points of access, such as hospitals in rural communities, may not be available. Many communities rely solely on RHCs to provide medical services, and this provision aims to reduce barriers to accessing high-quality, comprehensive care.

We appreciate the commenter's suggestion to use the criteria for determining whether there is a shortage of primary care practitioners, set out at 42 CFR part 5, Appendix A, paragraph (B)(3)(a), as a proxy for the amount of primary care services offered. This provision counts the number of M.D.s and D.O.s practicing in the categories of general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology to determine areas having shortages of primary medical care professionals (under section 332(a)(1)(A) of the Public Health Services Act). However, we disagree with the suggestion. The Health Resources and Services Administration (HRSA) is responsible for determining whether a location is in a designated shortage area. As noted in the proposed rule (89 FR 61807), we use the phrase ''the entry point into the health care system'' in the RHC and FQHC CfCs at § 491.9(c)(1) to determine the services considered to be ''primary care.'' This standard is consistent with the language used in the Rural Emergency Hospital Conditions of Participation (CoPs) at § 485.524(a) ''*Additional outpatient medical and health services*'' and follows the Critical Access Hospital CoPs at § 485.635(b)(1)(i) ''*Provision of services.*'' Furthermore, the American Academy of Family Physicians (AAFP) defines primary care practice as follows:

''A primary care practice serves as the patient's entry point into the health care system and as the continuing focal point for all needed health care services.'' [369] However, we do agree with the commenter that RHCs may offer internal medicine, pediatric medicine, and OB/GYN care and that the services that are considered primary care services (with the latter considered primary care services for women's health). We note that one goal of the revised language is to clarify that RHCs can and should provide services that focus on specific areas of medicine from specialists with advanced training and expertise in specific areas of medicine, and CMS will no longer determine if RHCs are ''primarily engaged'' in providing these services.

Lastly, we note that this provision allows RHCs to provide behavioral health services similar to other services for diabetes, cardiovascular disease, and other common conditions. The new regulatory requirement that RHCs must provide primary care services does not remove the statutory requirement that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. We have not codified this statutory language in this final rule (see discussion below). Therefore, RHCs can provide services that focus on the needs of the community (including behavioral health services) as long as they also meet the primary care needs of their community.

Comment: One commenter shared that this policy could facilitate additional rural specialized medical residency rotations, noting Congress' recent approval of 1,200 additional medical residency spots and the Biden-Harris Administration's commitment to expanding medical residency in rural areas. Another commenter noted this proposal could promote more coordinated, patient-centered care across specialties and ease concerns among physicians practicing within their scope. Several commenters noted that certain medical professionals such as pediatricians, geriatricians, allergists, obstetricians, rheumatologists, dermatologists, and endocrinologists are in high demand in rural areas, but patients have difficulty accessing certain professionals. One commenter stated this proposal will aid RHCs in forming partnerships with specialists to promote appropriate access to specialty medications and complex specialty care that may be beyond the scope of practice for many providers currently working in RHCs. The commenters also noted that having access to these specialists will also improve access to care to treat chronic conditions like diabetes and obesity.

Response: Improving the health of rural communities is a top priority for the Biden-Harris Administration and CMS remains steadfast in our commitment to supporting access to care and ensure high quality and safe care. As highlighted by the commenter, efforts have been made to enhance the rural health workforce through specialized medical residency rotations, which RHCs can leverage more effectively with the flexibilities offered through this provision.

Comment: Several commenters expressed concern that the revised language may unintentionally limit access to care in underserved areas. Specifically, the commenters noted that many FQHCs provide services that primarily consist of behavioral health services. Commenters note that FQHCs provide a broad range of services and often serve patients who may not have access to other healthcare settings. They noted that behavioral health services FQHCs provide is in response to community needs. Furthermore, these commenters shared that health centers provide care to over 2.7 million patients with mental health care needs and 300,000 patients with substance use disorders.[370] Further, in 2021 health centers employed over 17,000 full-time behavioral health staff.[371]

Response: After consideration of the public comments and further consultation with HRSA regarding the potential for unintended consequences impacting FQHCs, we agree with commenters who stated that applying this provision to FQHCs may negatively impact patient health and safety. To participate in the Medicare program, FQHCs must be designated under HRSA's Health Center Program either as Health Center Program award recipients or as ''look-alikes.'' As part of this program, HRSA provides oversight to ensure that FQHCs and look-alike FQHCs provide services to meet the full spectrum of healthcare needs in the communities they serve, including primary care services. Section 330 of the Public Health Service Act, 42 U.S.C. 254b, authorizes the Health Center Program. Under this authority, health centers provide required primary health services and additional health services necessary for the adequate support of primary health services to a population that is medically underserved or to a special medically underserved population by providing such services for all residents of the area served by the center. HRSA reviews compliance to ensure health centers provide primary care services during the initial application process and once an organization is a health center through organizational site visits that occur once every 3 years. We believe that withdrawing this proposal for FQHCs would not negatively impact patient care because there are safeguards in place to ensure that a standard of primary care services is provided in health centers. Conversely, under the authority of section 1865 of the Act, CMS is responsible for determining if a Medicare-certified RHC demonstrates and maintains compliance with the provisions included in 42 CFR part 491. Given that HRSA provides oversight over FQHCs and CMS oversees RHCs, there are differences in how they assess compliance with the requirements. As a result, RHCs do not have the same safeguards in place. To preserve access to primary care services in communities served by RHCs, it is essential that each RHC provide some level of primary care services.

Therefore, focusing this provision on RHCs and withdrawing the proposal as it would apply to FQHCs avoids the potential for limiting access to care while ensuring that RHCs and FQHCs provide a standard of primary care services.

Final Rule Action: After consideration of public comments, we are finalizing this requirement as proposed for RHCs with a technical change to finalize at § 491.9(a)(3) and with a modification to withdraw the proposal with respect to FQHCs. This revision will avoid the potential for limiting access to care while ensuring that RHCs and FQHCs provide a standard of primary care services.

This revision will maintain access to primary health and behavioral health services furnished by FQHCs and remove the potential for unintended consequences this provision may impose on FQHCs.

b. Mental Diseases (§ 491.9(a)(2)(ii))

To further clarify the requirements and the intent of the RHC program, we proposed at § 491.9(a)(2)(ii) to codify the statutory requirement in subparagraph (iv) of the flush material set out after

[369] *Primary care.* AAFP. (2019, December 12). *https://www.aafp.org/about/policies/all/primary-care.html.*

[370] National Association of Community Health Centers. (2024). *Community Health Centers: Providers, Partners and Employers of Choice. https://www.nachc.org/wp-content/uploads/2024/07/2024-2022-UDS-DATA-Community-Health-Center-Chartbook.pdf.*

[371] National Association of Community Health Centers. (2023). *Community Health Center Chartbook. https://www.nachc.org/wp-content/uploads/2023/04/Community-Health-Center-Chartbook-July-2023-2021UDS.pdf.*

section 1861(aa)(2)(K) of the Act that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. While this requirement is included at § 491.2, *Definitions—Rural health clinic or clinic,* including this requirement the *Provision of services* CfC at § 491.9(a)(2)(ii) as a separate standard more clearly cites the requirement and allows for a clearer evaluation of compliance with the specific requirement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the goal of our proposal to eliminate confusion regarding the types of services RHCs and FQHCs can provide by codifying the statutory requirement that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. Other commenters appreciated the discussion of the term ''mental disease'' and recognition that the term is outdated and can perpetuate stigma, noting that using language that includes both mental health and substance use disorders is important and consistent with terms used across fields of practice. A couple of commenters supported codifying this requirement as it protects primary care services in rural areas, and one commenter stated that this proposal would ensure appropriate payment for services furnished in an RHC.

Conversely, many commenters opposed codifying this requirement noting that its explicit addition to the CfCs could further amplify confusion amongst providers by seemingly imposing additional restrictions on the types of services RHCs can furnish, preventing them from meeting the needs of the communities they serve. Commenters indicated that the proposal may disincentivize RHCs from delivering behavioral health services, inadvertently creating obstacles to accessing behavioral health services. To prevent unintended consequences and protect access to essential services, many commenters recommended that CMS instead define facilities that are primarily for the care and treatment of mental diseases, such as certified community behavioral health clinics (CCBHCs), community mental health centers (CMHCs), standalone opioid treatment programs (OTPs), psychiatric residential treatment facilities (PRTFs), or facilities that only provide intensive outpatient services. These commenters indicated that defining ''mental diseases'' and not basing it on the facility type would have the potential to limit access to behavioral health services provided in RHCs. If CMS did not accept this recommendation, one commenter recommended CMS use ''behavioral health conditions'' in the CfCs, and another commenter recommended including both ''mental health conditions'' and ''substance use disorders'' in the regulation text, similar to the regulations CMS has adopted for intensive outpatient (IOP) therapy. Furthermore, commenters provided suggestions on how CMS should survey for compliance with this provision. Some commenters believe that if RHCs provide primary care services, there should be no restrictions on the services they provide, urging the advancement of integrated behavioral health services in a primary care setting. These commenters believe RHCs can serve as an access point for behavioral health services and that rural health providers must be flexible to meet the unique needs of the patient population, as opposed to requiring that a percentage of services are of a specific type. Lastly, a few commenters expressed concerns that CMS imposed this requirement on FQHCs, noting that we do not have the statutory authority to do so.

Response: We appreciate the overall feedback received from commenters on this proposal. We understand the various concerns raised by commenters regarding the unintended consequences that this proposal may impose on RHCs, such as impacting access to outpatient services, in particular behavioral health services. We expect RHCs to offer a range of primary health care services to ensure that patients receive the necessary care at the earliest possible point of contact. Our intention in codifying the statutory requirement was not to further restrict the current state of the health care environment or discourage the provision of RHC specialty services or behavioral health services. An RHC may offer such specialty services and behavioral health services to its patients in addition to the primary care services it already provides in accordance with the statute.

As noted previously, while primary care services continue to be a critical aspect in addressing health disparities, we recognize that we also need to provide alternative rural points of access to specialty outpatient services. We recognize that many communities rely solely on RHCs to provide medical services, and our goal in proposing this provision was to provide clarity and reduce barriers to accessing high-quality, comprehensive care, rather than imply that RHCs should restrict or limit the existing services they provide. We are withdrawing this proposal after considering public comments. This decision aligns with the HHS strategic goal to protect and strengthen equitable access to health care,[372] We believe finalizing the standard at § 491.9(a)(3), requiring RHCs to provide primary care services (discussed in the previous section), will support our goal of clarifying the services that RHCs may provide and safeguard access to primary care services while avoiding unintended consequences that may create barriers to accessing care.

We appreciate the commenter's suggestion to include mental health conditions and substance use disorders in the regulation text; however, the IOP therapy provisions the commenter referred to are payment policy and not health and safety standards, such as those set forth in the CfCs. The CfCs set forth the minimum health and safety standards that facilities must comply with to participate in the Medicare and Medicaid programs, and do not impact the amount of payment for services.

We thank the commenters who recommended that we define ''a facility that is primarily for the care and treatment of mental diseases'' as a facility type that primarily provides behavioral health services. As we noted, we have decided to withdraw the proposal, and therefore, this recommendation no longer applies.

Final Rule Action: After consideration of public comments, we are withdrawing this proposal.

c. Laboratory (§ 491.9(c)(2))

We proposed to remove hemoglobin and hematocrit (H&H) (§ 491.9(c)(2)(ii)) from the listed laboratory services that RHCs must perform directly. Interested parties have expressed concerns with the existing laboratory requirements, citing the financial and physical burdens associated with maintaining laboratory tests equipment, as they are ordered infrequently. RHC providers have reported that the H&H laboratory test, in particular, is overly burdensome. RHCs report that when they order laboratory tests that the RHC cannot provide, such as a complete blood count (CBC), their patients are often sent to the nearest hospital that would have a full-service laboratory available to perform the test. In this example, a CBC contains an H&H, so there would be no need for the RHC to perform the H&H if the patient is getting a CBC completed

[372] Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. (2022). Strategic Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare. *https://www.hhs.gov/about/strategic-plan/2022-2026/goal-1/index.html.*

elsewhere. As a result, some RHCs located near hospitals or full-service laboratories may not be utilizing their laboratory equipment and supplies, or they may be utilizing them on a limited basis.

At § 491.9(c)(2)(vi), we proposed to revise the language to ''collection of patient specimens for transmittal to a certified laboratory for culturing.'' We proposed this revision in response to feedback from rural interested parties that this requirement does not reflect current clinical laboratory standards of practice and laboratory techniques for RHCs. Typically, RHCs are not performing primary culturing prior to sending specimens to a certified laboratory. Instead, RHCs collect specimens using appropriate collection and storage techniques and send them to a certified laboratory without initial culturing. Therefore, we proposed to update the language in this standard such that the laboratory services RHCs will be required to provide include the ''collection of patient specimens for transmittal to a certified laboratory for culturing.''

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the proposed changes to remove the hemoglobin and hematocrit (H&H) requirement, as well as the proposed language update to the ''primary culturing'' requirement. Various organizations and entities expressed their support for the proposed change to remove H&H from the CfCs, emphasizing the outdated nature of the requirement, as these tests are usually ordered as part of a larger panel and are frequently referred to offsite laboratories. Commenters noted that removing this requirement would reduce compliance costs and unnecessary equipment and supplies, thereby improving efficiency and patient care.

Response: We thank the commenters for their responses and believe it is important that the requirements reflect current clinical laboratory standards of practice and laboratory techniques.

Comment: One commenter noted that the removal of H&H from the list of required lab services would impact access to this laboratory test. The commenter referenced the preamble in which we explained that RHCs can still choose to maintain the equipment and supplies to provide H&H testing on-site to meet the needs of their patients, and because of this, the larger RHC community is not concerned with this provision impacting access to this test. Furthermore, in the proposed rule, we solicited comments on how removing H&H from the CfCs would impact access to this test. Additionally, we requested comments on data, evidence, and experience related to laboratory services in RHCs, as well as alternative lab services RHCs should provide to meet the needs of their communities. One commenter, in response to this request, cited that according to their data, 82 percent of RHCs indicated that the lab requirement for the ''examination of stool specimens for occult blood'' was no longer frequently ordered or considered the best clinical practice. Therefore, it was no longer necessary to be included in the required labs that RHCs must provide.

Response: There are a few types of fecal occult blood tests (FOBT) used for screening for blood in the stool prior to performing a colonoscopy for colon cancer detection. FOBTs are less invasive than receiving a colonoscopy and can be performed in the office or at home. The national guidelines, including those of the US Preventive Services Task Force (USPSTF) and American Cancer Society, explicitly specify that colorectal cancer (CRC) screening using FOBT should be done at home.[373] [374] However, FOBTs only detect blood in stool, and a colonoscopy would need to be done to find the source of the bleeding if the test result is positive, though FOBTs are limited by false-positive results.[375] [376] Based on the current national standards, we are revising the proposal to remove the examination of stool specimens for occult blood from the list of required labs for RHCs.

We would like to reiterate that § 491.9(d)(1)(iii) requires RHCs to provide prompt access to a Medicare or Medicaid participating provider or supplier that can furnish an H&H laboratory test and any additional and specialized diagnostic and laboratory services the RHC is not equipped to perform. Additionally, this proposal does not prevent RHCs from providing tests not listed in § 491.9. An RHC is free to provide tests consistent with its CLIA certification and can choose a higher level CLIA certification than the certificate of waiver if it wishes to provide tests of higher complexity and comply with all CLIA requirements.

Final Rule Action: After consideration of public comments, we are finalizing this provision with modification by also removing the current requirement that RHCs directly provide ''examination of stool specimens for occult blood.''

d. Comments Outside the Scope of This Rulemaking

Comment: One commenter acknowledged the steps CMS has taken to extend telehealth flexibilities for RHCs and FQHCs but recommends that CMS utilize digital health technologies in every way possible to efficiently improve health outcomes and avoid unnecessary in-person requirements.

Another commenter urged CMS to make permanent the flexibilities issued during the COVID–19 Public Health Emergency related to medical supervision of nurse practitioners in rural and underserved communities. They emphasized the importance of these flexibilities for RHCs and FQHCs located in areas where workforce shortages persist, and this change aligns with statutory requirements for non-physician directed clinics.

Another commenter recommended that the statutory definition of a ''rural health clinic'' include marriage and family therapists and mental health counselors.

Response: We appreciate these comments; however, they are outside the scope of this rule. CMS does not have the authority to change the statute as this is done through an act of Congress.

D. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory

[373] US Preventive Services Task Force, Bibbins-Domingo, K., Grossman, D.C., Curry, S.J., Davidson, K.W., Epling, J.W., Jr, García, F.A.R., Gillman, M.W., Harper, D.M., Kemper, A.R., Krist, A.H., Kurth, A.E., Landefeld, C.S., Mangione, C.M., Owens, D.K., Phillips, W.R., Phipps, M.G., Pignone, M.P., & Siu, A.L. (2016). Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement. *JAMA, 315*(23), 2564–2575. *https://doi.org/10.1001/jama.2016.5989.*

[374] Smith, R.A., Andrews, K.S., Brooks, D., Fedewa, S.A., Manassaram-Baptiste, D., Saslow, D., Brawley, O.W., & Wender, R.C. (2018). Cancer screening in the United States, 2018: A review of current American Cancer Society guidelines and current issues in cancer screening. *CA: a cancer journal for clinicians, 68*(4), 297–316. *https://doi.org/10.3322/caac.21446.*

[375] Mayo Foundation for Medical Education and Research. (2024, July 12). *Fecal occult blood test.* Mayo Clinic. *https://www.mayoclinic.org/tests-procedures/fecal-occult-blood-test/about/pac-20394112#:~:text=The%20test%20isn't%20always,present%20but%20is%20not%20detected.*

[376] Kościelniak-Merak, B., Radosavljević, B., Zając, A., & Tomasik, P.J. (2018, December). *Faecal Occult Blood Point-of-care tests.* Journal of gastrointestinal cancer. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6208834/.*

Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) and reduced by a productivity adjustment and other statutory adjustments but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. A final rule entitled ''Medicare Clinical Diagnostic Laboratory Tests Payment System'' (CLFS final rule), which appeared in the **Federal Register** on June 23, 2016 (81 FR 41036), implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[377]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule, which implemented section 1834A of the Act as required by PAMA (81 FR 41036 through 41101), and this information is also available on the CMS website.[378]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. First, section 105(a)(1) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year so that data reporting would be required during the period of January 1, 2021, through March 31, 2021, instead of January 1, 2020, through March 30, 2020. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applied to the data reporting period

[377] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

[378] *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/pama-educational-resources.*

of January 1, 2021, through March 30, 2021, would be the period of January 1, 2019, through June 30, 2019, which was the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS at § 414.507(d) (81 FR 41036).

Subsequently, section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022, through March 31, 2022. The CARES Act did not modify the data collection period that applied to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs would have been based on the data collection period of January 1, 2019, through June 30, 2019.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024 instead of CY 2023. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2022 through 2024, instead of CYs 2021 through 2023. In the CY 2021 PFS rulemaking (85 FR 50210 through 50211; 85 FR 84693 through 84694), in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021) made additional revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4(b) of PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4 of PMAFSCA, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2022; (ii) reporting is required during the period beginning January 1, 2023, and ending March 31, 2023; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4 of PMAFSCA did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2023, through March 31, 2023) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 4 of PMAFSCA further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2025. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 and 2022 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 4(a) of PMAFSCA further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2023 through 2025, instead of CYs 2022 through 2024. In the CY 2023 PFS rulemaking (87 FR 46068 through 46070; 87 FR 69741 through 69744, 70225), in accordance with section 4 of PMAFSCA, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

Section 4114 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023, through March 31, 2023. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 4114(b) of the CAA, 2023, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2023; (ii) reporting is required during the period beginning January 1, 2024, and ending March 31, 2024; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 4114 of the CAA, 2023 did not modify the data collection period that applies to the next data reporting period for CDLTs. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2024, through March 31, 2024) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as reflected in the definitions of data collection period and data reporting period at § 414.502.

Section 4114(a) of the CAA, 2023 further amended the provisions in

section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2026. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2023 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2023 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2022. Section 4114(a) of the CAA, 2023 further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026, instead of CYs 2023 through 2025. In the CY 2024 PFS rulemaking (88 FR 79083 through 79087; 88 FR 79531), in accordance with section 4114 of the CAA, 2023, we proposed and finalized conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G.

4. Additional Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

On November 17, 2023, section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024) was passed and delayed data reporting requirements for CDLTs that are not ADLTs, and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. Specifically, section 502(b) of the FCAOEA, 2024 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2025, through March 31, 2025, instead of the data reporting period of January 1, 2024, through March 31, 2024. The 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. As amended by section 502(b) of the FCAOEA, 2024, section 1834A(a)(1)(B) of the Act provided that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2024; (ii) reporting is required during the period beginning January 1, 2025, and ending March 31, 2025; and (iii) reporting is required every 3 years after the period described in clause (ii).

Section 502 of the FCAOEA, 2024 did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2025, through March 31, 2025) would continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as reflected in the definitions of data collection period and data reporting period at § 414.502.

Section 502(a) of the FCAOEA, 2024 further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2027. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2024 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2024 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2023. Section 502(a) of the FCAOEA, 2024 further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2025 through 2027.

As a result of the statutory revisions under the FCAA, CARES Act, PMAFSCA, the CAA, 2023, and the FCAOEA, 2024, there have only been two data collection periods for CDLTs that are not ADLTs to date. The first data collection period for these tests occurred from January 1, 2016, through June 30, 2016, and the second occurred from January 1, 2019, through June 30, 2019. Thus far, there has been only one data reporting period for these tests, which took place from January 1, 2017, through March 31, 2017. We have established CLFS payment rates for these tests using the methodology established in PAMA only one time, effective January 1, 2018, based on the applicable information collected by applicable laboratories during the 2016 data collection period and reported to CMS during the 2017 data reporting period.

Additionally, we have applied the phase-in of payment reductions for the first 3 years of PAMA implementation, CY 2018 through CY 2020, whereby reduction of payment rates could not be more than 10 percent per year as compared to the amount established the prior year. However, the phase-in of payment reductions set forth in PAMA for years 4 through 6 after PAMA implementation, whereby payment cannot exceed 15 percent per year as compared to the amount established the prior year, has not yet occurred.

5. Proposed Conforming Regulatory Changes

In accordance with section 502 of the FCAOEA, 2024, we proposed to make conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we proposed to revise the definitions of both the ''data collection period'' and ''data reporting period'' at § 414.502 to specify that for the data reporting period of January 1, 2025, through March 31, 2025, the data collection period is January 1, 2019, through June 30, 2019. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2025. In addition, we proposed to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 502(a) of the FCAOEA, 2024. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2024, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We noted that the CYs 2024 and 2025 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. We also stated that under current law, the CLFS payment rates for CY 2026 through CY 2028 would be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2025, through March 31, 2025.

We received a few public comments on our proposals to conform the regulatory text at 42 CFR part 414, subpart G to FCAOEA, 2024. However, the Continuing Appropriations and Extensions Act, 2025 (CAEA, 2025) (Pub. L. 118–83) was passed on September 26, 2024, after the publication of the proposed rule and close of the comment period. Section 221 of that law delayed data reporting requirements for CDLTs that are not ADLTs as well as the phase-in of payment reductions under the CLFS from private payor rate implementation

under section 1834A of the Act. Specifically, as amended by section 221(b), section 1834A(1)(B) of the Act now provides that, in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that: (i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2025; (ii) reporting is required during the period beginning January 1, 2026, and ending March 31, 2026; and (iii) reporting is required every 3 years after the period described in subparagraph (ii). Essentially, data reporting will now be required during the period of January 1, 2026, through March 31, 2026, instead of January 1, 2025, through March 31, 2025. The 3-year data reporting cycle for CDLTs that are not ADLTs will resume after that data reporting period.

Section 221 of the CAEA, 2025 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2026, through March 31, 2026) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019.

Section 221(a) of the CAEA, 2025 further amends provisions in section 1834A(b)(3) of the Act pertaining to the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2028. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2025 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2025 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2024. Finally, section 221(a) further amends section 1834A(b)(3)(B)(iii) of the Act to specify that the applicable percent of 15 percent will apply for CYs 2026 through 2028.

The following is a summary of the comments we received and our responses.

Comment: Commenters agreed with the proposed conforming regulatory changes pursuant to the FCAOEA, 2024 and understood that this action is necessary.

Response: We appreciate the commenters' support for these regulatory changes that reflect the statutory revisions required by section 502 of the FCAOEA, 2024. As noted above, section 221 of the CAEA, 2025 was passed on September 26, 2024. We believe it is necessary to reflect conforming regulatory text changes pursuant to section 221 of the CAEA, 2025 rather than those we included in the proposed rule that would have conformed to section 502 of the FCAOEA, 2024. Section 221 of the CAEA, 2025 is prescriptive, leaving us no room for interpretation and, as such, is self-implementing. We direct readers to the end of this section for a description of the conforming regulation text changes to 42 CFR part 414, subpart G.

Comment: One commenter expressed concerns over the data collection period (January 1, 2019, through June 30, 2019) that would be utilized for the data reporting period specified in the FCAOEA, 2024 (January 1, 2025, through March 31, 2025). The commenter noted that private payer rates from CY 2019 are severely outdated as the information will be more than 5 years old by the time it is collected and analyzed by CMS. The commenter also expressed concern that the reported data will include codes that are no longer valid and will be missing data on codes that have been created since 2019.

Response: We note that section 502 of the FCAOEA, 2024 and the more recent amendments in section 221 of the CAEA, 2025 did not modify the data collection period at section 1834A(a)(4)(B) of the Act that applies to the next data reporting period for CDLTs that are not ADLTs. Therefore, the next data reporting period for CDLTs that are not ADLTs (January 1, 2026, through March 31, 2026) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502. Because this requirement is statutorily prescribed, we are unable to modify the data collection period. We acknowledge the commenter's concern regarding missing data on laboratory HCPCS codes that have been created since 2019 and note that on average over 100 new codes are created each year.

Comment: One commenter suggested that CMS should conduct aggressive outreach to hospital outreach laboratories and other applicable laboratories that need information and assistance to meet their obligation to report applicable information to CMS, per section 1834A(a)(1)(A) of the Act, and also recommended we send a letter to each independent laboratory and physician office laboratory that qualified as an ''applicable laboratory'' in the 2016 data collection period but that failed to submit applicable information during the 2017 data reporting period, reminding each of its obligation to determine whether it meets the definition now and, if so, to report applicable information in the next data reporting period, or be subject civil monetary penalties. This commenter also stated that CMS should use its authority to impose a civil monetary penalty of up to $10,000 per day on an applicable laboratory for each failure to report or each misrepresentation or omission of applicable information and state publicly our intention to audit applicable laboratories and to impose penalties, when warranted, in order to signal to all applicable laboratories that reporting is not voluntary—it is mandatory.

Response: We appreciate the commenter's recommendations related to outreach for data reporting. Obtaining applicable information from applicable laboratories as required by section 1834A of the Act is necessary to enable us to establish payment rates for CDLTs, and outreach and education activities for applicable laboratories play an important role in achieving this objective. Accordingly, we regularly update the CMS website and have leveraged different media platforms to disseminate various educational materials and other resources to prepare applicable laboratories for data reporting and inform them of changes to reporting requirements. For example, we have released a video [379] on how to determine if a laboratory is an applicable laboratory. We have also conducted two direct mailings to independent and hospital laboratories. Overall, CMS shares the commenter's interest in ensuring all applicable laboratories have the educational resources needed to report accurate and complete data to inform payment rates under the CLFS, and we may consider the submitted recommendations for upcoming data reporting periods.

Additionally, regarding the comments on CMPs, we note that section 1834A(a)(9)(A) of the Act authorizes the Secretary to apply a CMP in cases where the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting applicable information under section 1834A(a) of the Act for a CDLT. In these cases, the Secretary may apply a CMP in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission. We codified this provision in our regulations at § 414.504(e). As we previously stated in the CLFS final rule,

[379] *https://youtu.be/c3eiPYeRA_U.*

which implemented section 216(a) of PAMA (81 FR 41069), in situations where our review reveals that the data submitted is incomplete or incorrect, we will assess whether a CMP should be applied, and if so, determine the appropriate amount based on the specific circumstances.

Comment: One commenter conveyed concerns over the phase-in of payment reductions to CLFS payment amounts that would be required to resume in CY 2025. Specifically, the commenter was concerned about access to care and quality of care issues for nursing home patients resulting from payment cuts to some clinical laboratory services of up to 15 percent per year. The commenter explained that patients in nursing facilities typically have a complex array of post-acute and chronic conditions that frequently require clinical laboratory services to identify new conditions or to monitor the beneficiary's reaction to specific care interventions. According to the commenter, the majority of clinical laboratory services for nursing facility residents are furnished by outside laboratories that drive to the facility and obtain the needed specimen bedside, or the resident must face the costs and disruptions to their daily life and sometimes interrupted rehabilitation care in order to be transported to a hospital or clinical laboratory to obtain needed laboratory services. The commenter expressed concern that access to these services may be disrupted, or the beneficiary might be required to travel further to obtain clinical laboratory services if nearby laboratories close or consolidate due to significantly reduced reimbursement. Another commenter strongly encouraged CMS to work with Congress to find a better solution to setting laboratory rates. The commenter asserted that the current process of collecting data from laboratories is administratively burdensome, and setting CLFS rates based on the median private payor rates (which the commenter believes are most likely rates from large national laboratories that are able to accept low rates in exchange for large volumes of laboratory tests) results in financial harm to small, independent laboratories. Another commenter called for payment for laboratory tests to be sufficient to cover the costs associated with providing these necessary tests to patients and as such, opposed federal mandates that require private-sector reporting of CDLT data.

Response: We appreciate hearing from commenters on these issues and their concerns related to the phase-in of payments reductions, laboratory payment rates and reporting burden under the CLFS. Nevertheless, we note that the phase-in of payment reductions, applicable information reporting, and subsequent determination of payment rates are required under section 1834A of the Act, and any changes would require Congressional action.

In consideration of these public comments, and subsequent amendments made in section 221 of the CAEA, 2025 that amended the requirements we proposed to reflect in regulation per section 502 of the FCAOEA, 2024, we are finalizing the self-implementing conforming changes to the data reporting and phase-in of payment reductions at 42 CFR part 414, subpart G in accordance with section 221 of the CAEA, 2025. Specifically, we are revising the definitions of both the ''data collection period'' and ''data reporting period'' at § 414.502 to specify that for the data reporting period of January 1, 2026, through March 31, 2026, the data collection period is January 1, 2019, through June 30, 2019. We are also finalizing revisions to § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 1, 2026. Finally, related to the requirements for the phase-in of payment reductions we are revising § 414.507(d) to indicate that for CY 2024 and CY 2025, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023 and 2024 respectively, and for CYs 2026 through 2028, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2025 and 2026 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2027 through CY 2029 will be based on applicable information collected during the data collection period of January 1, 2019, through June 30, 2019, and reported to CMS during the data reporting period of January 1, 2026, through March 31, 2026.

E. Medicare Diabetes Prevention Program (MDPP)

The Centers for Medicare & Medicaid Services' (CMS) Medicare Diabetes Prevention Program Expanded Model (hereafter, ''MDPP'' or ''MDPP expanded model'') is an evidence-based behavioral intervention that aims to prevent or delay the onset of type 2 diabetes for eligible Medicare beneficiaries diagnosed with prediabetes. MDPP is an expansion in duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested by CMS through a Round One Health Care Innovation Award (2012–2016).[380] MDPP was established in 2017 as an ''additional preventive service,'' [381] covered by Medicare and not subject to beneficiary cost-sharing, in addition to being available once per lifetime to eligible beneficiaries. To facilitate delivery of MDPP in a non-clinical community setting (to align with the certified DPP model tested by The CMS Innovation Center), CMS created a new MDPP supplier type through rulemaking in the CY 2017 PFS final rule (81 FR 80471), in addition to requiring organizations that wish to participate in MDPP to enroll in Medicare separately, even if they are already enrolled in Medicare for other purposes.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions furnished over 12 months by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction. MDPP sessions must be one hour in length and adhere to a Centers for Disease Control and Prevention (CDC) approved National Diabetes Prevention Recognition Program (National DPP) curriculum.[382] The primary goal of the MDPP expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss from the first core session (81 FR 80465).

Eligible organizations seeking to furnish MDPP began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP on April 1, 2018. As of May 13, 2024, there were 301 approved MDPP suppliers.[383] The most recent MDPP evaluation report, reflected that between April 2018 and December 31, 2021, 4,848 Medicare beneficiaries participated in MDPP, including 2,325 FFS

[380] The Health Care Innovation Awards funds awards to organizations that implemented the most compelling new ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid and Children's Health Insurance Program (CHIP), particularly those with the highest health care needs. The CMS Innovation Center announced the first batch of awardees for the Health Care Innovation Awards on May 8, 2012, and the second (final) batch on June 15, 2012. For more, see *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[381] 42 CFR 410.64—*Additional preventive services.*

[382] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[383] Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Unpublished data.

beneficiaries and 2,523 MA beneficiaries.[384] Through the Diabetes Prevention Recognition Program (DPRP), CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards,[385] which are updated every 3 years. The CDC established the DPRP in 2012 and possesses significant experience assessing the quality of program delivery by organizations throughout the United States, applying a comprehensive set of national quality standards. For further information on the DPP model test,[386] the CDC's National DPP,[387] and DPRP Standards,[388] please refer to the CY 2017 (81 FR 80471) and CY 2018 PFS (82 FR 52976) final rules and related websites.

The Public Health Emergency (PHE) for COVID–19 prompted changes to allow virtual delivery of the MDPP, among other changes (85 FR 84830 through 84841). Changes to MDPP in the CY 2024 PFS final rule (88 FR 78818) included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance while retaining the performance-based payments for diabetes risk reduction (that is, weight loss). Beginning January 1, 2024, payments are made to an MDPP supplier if an MDPP beneficiary attends any core session in the first 6 months or core maintenance session in the second 6 months, allowing payment for up to 22 sessions in a 12-month timeframe. The CY 2024 PFS final rule also extended certain PHE flexibilities, including the option to deliver some or all MDPP sessions via distance learning and for beneficiaries to virtually self-report weight for MDPP distance learning sessions, until December 31, 2027 (88 FR 79241).

CDC released the 2024 DPRP Standards [389] to replace the 2021 DPRP Standards in June 2024. To align MDPP with the 2024 CDC DPRP Standards, we proposed conforming changes to align with CDC delivery modes. These changes are expected to reduce administrative burden, ensure compliance with existing MDPP regulations, and streamline data reporting for MDPP suppliers. In this final rule, we also proposed an additional option for self-reporting weight in an MDPP distance learning session, removing the MDPP bridge payment, and making minor edits to align current rule language pertaining to MDPP with previous rulemaking.

1. Changes to § 410.79 by Amending Paragraphs (b) and (d)(1)

We established MDPP as an expanded model in 2018 based on a Health Care Innovation Award (HCIA) to the National Young Men's Christian Association (YMCA) of the USA (Y–USA), who tested the CDC's National DPP in the Medicare population through their network of YMCAs in multiple U.S. markets (DPP model test).[390] The DPP model test successfully met statutory criteria for model expansion,[391] demonstrating 5 percent weight loss from their starting weight by participants (a key metric of the program's success) along with statistically significant reductions in Medicare spending, emergency department (ED) visits, and inpatient stays.[392] The MDPP expanded model was implemented through the rulemaking process in two phases, in the CY 2017 PFS (81 FR 80459 through 80483) and CY 2018 PFS final rules (82 FR 53234 through 53339).

MDPP went into effect in 2018, with supplier enrollment starting January 1, 2018, and beneficiary enrollment starting April 1, 2018 (82 FR 53237). After nearly 6 years of implementation, through the CY 2024 PFS final rule, we finalized updates to MDPP based on lessons learned since the expanded model's launch, including updates to definitions and the core services period and extended the flexibilities allowed under the PHE for COVID–19 for a period of 4 years (88 FR 79241).

This year we proposed to make conforming changes to § 410.79(b), *Conditions of Coverage,* to align with the 2024 CDC DPRP Standards.[393] In the CY 2018 PFS final rule, we stated our intention to align MDPP with CDC DPRP Standards whenever possible (82 FR 53245). Several commenters encouraged CMS to consider adopting the same definitions for MDPP as CDC uses for the National DPP, including distance learning, online, and combination modalities to better align MDPP and the National DPP. Commenters indicated that the addition of definitions that are consistent with the CDC's definitions will reduce confusion about MDPP (88 FR 79247). To increase this alignment, we worked closely with CDC to update the National DPP and MDPP for CY 2024 final rule (88 FR 79240 through 79256), as well as the 2024 DPRP Standards.[394] We agree in aligning terminology where applicable.

The CY 2024 PFS final rule introduced and defined ''distance learning'' and ''combination delivery'' for MDPP and provided a definition for ''online delivery'' (88 FR 79243). The 2024 CDC DPRP Standards include the following delivery modes with definitions: ''in-person,'' ''distance learning (live),'' ''in-person with a distance learning component,'' ''online (non-live),'' and ''combination with an online component.'' [395] These delivery modes also serve as organization codes for CDC DPRP recognition. Through this final rule, we proposed to amend § 410.79(b) to add a new term for MDPP, ''in-person with a distance learning component,'' defined as ''MDPP sessions that are delivered in person by trained Coaches where participants have the option of attending sessions via MDPP distance learning. These sessions must be furnished in a manner

[384] RTI International. Evaluation of the Medicare Diabetes Prevention Program. November 2022. *https://www.cms.gov/priorities/innovation/data-and-reports/2022/mdpp-2ndannevalrpt.*

[385] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[386] Health Care Innovation Awards. *https://www.cms.gov/priorities/innovation/innovation-models/health-care-innovation-awards.*

[387] *https://www.cdc.gov/diabetes/prevention/index.html.*

[388] *https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.*

[389] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[390] L. Hinnant, S. Razi, R. Lewis, A. Sun, M. Alva, T. Hoerger et al., Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. RTI International. March 2016; *https://www.cms.gov/priorities/innovation/files/reports/hcia-ymcadpp-evalrpt.pdf.*

[391] Paul Spitalnic. Certification of Medicare Diabetes Prevention Program. Mar. 14, 2016. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.*

[392] Rojas Smith. L., Amico, P., Hoerger, T.J., Jacobs, S., Payne. J., & Renaud, J.: Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report Addendum—August 2017 *https://downloads.cms.gov/files/cmmi/hcia-crppm-thirdannrptaddendum.pdf* (pp. 858–914).

[393] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[394] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[395] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

consistent with DPRP Standards for in-person and distance learning sessions.'' The following examples of an acceptable delivery model for the ''in-person with a distance learning component'' delivery mode are provided in the 2024 CDC DPRP Standards: a combination of in-person and distance learning during the core (first 6 months) and core maintenance (second 6 months) phases; some participants within a cohort using the in-person delivery mode and some participants using the distance learning delivery mode; or participants choosing from session to session which mode (in-person or distance learning) they wish to use.[396]

To further align with 2024 CDC DPRP Standards, we also proposed to add a new term at § 410.79(b), ''combination with an online component,'' defined as ''sessions that are delivered as a combination of online (non-live) with in-person or distance learning. These sessions must be furnished in a manner consistent with the DPRP Standards for the modality being used.'' Furthermore, we proposed to remove the ''combination delivery'' term from § 410.79(b), which was added in the CY 2024 PFS final rule (88 FR 79241) and is defined as ''MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.'' We believe that the MDPP ''combination delivery'' term and definition are no longer needed with the addition of ''in-person with a distance learning component,'' which includes any combination of in-person and distance learning sessions.

Lastly, we proposed to modify the current term and definition for ''online delivery'' at § 410.79(b), also added by the CY 2024 PFS final rule (88 FR 79241), to align with the 2024 CDC DPRP Standards.[397] First, we proposed to update the term from ''online delivery'' to ''online'' to align with both the MDPP ''distance learning'' term and CDC DPRP ''online (non-live)'' term. We proposed to revise the definition for the MDPP ''online'' delivery mode to provide that sessions that are delivered one hundred percent (100%) through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. Emails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction. This modified definition adds the term ''non-live'' and further clarifies that Chat bots and AI forums do not constitute live interaction.

In summary, we are revising the ''online'' definition and adding the ''combination with an online component'' term and definition to help align terminology between MDPP and DPRP and prevent confusion about acceptable CDC delivery modes for MDPP. We are confirming that only MDPP ''in-person,'' ''distance learning,'' and ''in-person with a distance learning component'' delivery modes, can be used during the extension of the flexibilities allowed under the PHE for COVID–19, as finalized in the CY 2024 PFS final rule (88 FR 79241), not ''online'' nor ''combination with an online component'' delivery modes.

Furthermore, in the CY 2021 PFS final rule, we established that virtual sessions performed under flexibilities finalized in that rule could only be performed by MDPP suppliers who offered in-person services (85 FR 84830). For the MDPP Extended flexibilities period, we finalized in the CY 2024 PFS final rule to limit virtual delivery to the CDC DPRP definition of ''distance learning'' (88 FR 79243). We stated that the MDPP Extended flexibilities do not include online delivery (or asynchronous virtual), as defined in the CDC DPRP Standards through the ''online'' modality, including virtual make-up sessions (88 FR 79244). A make-up session in MDPP was described in CY 2018 PFS final rule (82 FR 53241) and at § 410.79(a) as ''a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.'' The 2024 CDC DPRP Standards allow for National DPP make-up sessions to be furnished using any delivery mode, including online.[398] In alignment with the CY 2024 final rule, we are proposing to amend § 410.79(d)(1) to clarify that MDPP make-up sessions can only be furnished using the modalities permitted by the CY 2024 final rule for MDPP sessions: distance learning and in-person delivery (88 FR 79243 through 79246). Specifically, we proposed to add the following: ''MDPP make-up sessions may only use in-person or distance learning delivery.''

We proposed to amend § 410.79(b) and (d)(1) and solicited comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the proposed policy, with support received for aligning conditions of coverage with the 2024 CDC DPRP Standards definitions. Commenters universally supported aligning conditions of coverage with the 2024 CDC DPRP Standards definitions (*e.g.,* distance learning, online delivery, and in-person with a distance learning component). Many commenters stated that these terms will allow suppliers to streamline data reporting to the CDC's Diabetes Prevention Recognition Program (DPRP). Some commenters provided recommendations to allow virtual-only providers to offer MDPP asynchronously. Some commenters also suggested that CMS remove the once in a lifetime use of MDPP.

Response: We have responded to previous public comments requesting that CMS allow asynchronous delivery of MDPP and virtual-only providers to offer MDPP in previous rules (85 FR 84472, 84831). The MDPP expanded model was certified as an in-person program and allowing for virtual-only delivery is outside of the model's certification. Virtual-only providers include those that deliver the National DPP services solely by distance learning or online delivery. Although ''telehealth'' is included in CDC's definition of distance learning, CMS stated in the CY 2017 PFS final rule (82 FR 52976, 53235) that MDPP services delivered via a telecommunications system or other remote technologies do not qualify as telehealth services. Additionally, we have stated that through utilizing distance learning, participants may still interact with their

[396] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[397] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[398] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

Coach and other participants in their cohort in real-time, allowing for relationship building and peer support, unlike online delivery which is delivered asynchronously (88 FR 79244). CMS is currently allowing an exception to the once per lifetime requirement for MDPP beneficiaries to restart their MDPP program if their services were interrupted by the PHE for COVID–19 (85 FR 19230, 19283). After consideration of public comments regarding the proposed changes to amend § 410.79(b) and (d)(1), we are finalizing as proposed and will continue to monitor use of this flexibility to approximate the demand for beneficiaries to restart their program for other reasons.

2. Changes to § 410.79(e)(3)(iii)

As part of MDPP's Emergency Policy finalized in the CY 2021 PFS final rule, we allowed for virtual weight collection (88 FR 79249). We summarized our policies for alternatives to the requirement for in-person weight collection at *Alternatives to the requirement for in-person weight measurement* (§ 410.79(e)(3)(iii)), which permit an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary (88 FR 79243). We stated that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording of the beneficiary's weight, with the beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility has allowed suppliers to bill for MDPP beneficiaries achieving weight loss performance goals.

Overall, commenters on the proposed MDPP Extended flexibilities in the CY 2024 PFS rule were very supportive of CMS continuing to allow virtual weight collection (88 FR 79240 through 79256). However, we received several comments regarding barriers suppliers experienced relating to virtual weight collection during the PHE for COVID–19. For example, several commenters recommended that CMS no longer require date-stamped photos to document the self-reported beneficiary weights (88 FR 79249). The commenters also reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. Commenters stated that this risk has prevented organizations from submitting claims accurately, since they have several participants who live alone and attend sessions via distance learning (88 FR 79249). We acknowledged in our responses to these comments that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. We stated that in situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person.

We have continued to hear from MDPP suppliers and interested parties that the requirement to submit a photo with both the beneficiary's weight on the scale and the beneficiary visible is not physically possible. This problem has become even more relevant in CY 2024 as suppliers continue to expand distance learning to help reach beneficiaries in rural and underserved areas, sometimes across state lines. We previously responded that for situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may want to consider collecting weight measurements from the MDPP beneficiary in person (88 FR 79249). However, this may not be a practical option for beneficiaries who have chosen distance learning based on not living within driving distance from an MDPP supplier location. Therefore, we proposed revising § 410.79(e)(3)(iii)(C) to provide that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives 2 (two) date-stamped photos or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, the second photo must show the beneficiary visible in their home, and both photos must be date-stamped. Similar to options in paragraphs (e)(3)(iii)(A) and (B) in § 410.79, this revised option in paragraph (e)(30(iii)(C) is only available for MDPP beneficiaries reporting their weight for an MDPP distance learning session. We are continuing to require the date-stamp on both photos to ensure program integrity in the virtual setting. We proposed to amend § 410.79(e)(3)(iii).

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Similar to comments from previous rules (FR 88 79249, 88 FR 78818), commenters expressed concern about the burden of requiring a date-stamped photo of weight on the lifestyle coaches, suppliers, and beneficiaries due to technology difficulties and/or inexperience, risk of injury, and HIPAA compliance for photo storage. Some commenters suggested further guidance on what constitutes a date-stamped photo, suggesting that CMS allow for metadata to count toward the requirement, and that CMS further align with CDC 2024 DPRP Standards to allow for weight self-attestation in which participants may self-report weight without photo or video evidence. While many commenters supported the new option to *allow* 2 photos instead of just 1 to self-report weight in an MDPP distance learning session, some commenters misinterpreted the proposed regulatory language, commenting that CMS was *requiring* 2 photos instead of 1, thus doubling the amount of photo collection.

Response: After consideration of public comments, we are revising the regulation text in the final rule to reflect that beneficiaries can choose to submit one or two (2) photos for self-reporting weight for an MDPP distance learning session. If a beneficiary is able to capture both themself and their weight on the digital scale in one photo, then they can choose to submit only one photo, or they can choose to submit two photos (one showing their weight on the scale and one showing them visible in their home), if this is more convenient. Our intention was to add flexibility in

self-reporting of weight for MDPP distance learning sessions, not to limit it. The new regulation text we are finalizing through the CY 2025 PFS specifies ''(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives one or 2 (two) date-stamped photo(s) or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit one photo, this photo must show the beneficiary's weight on the scale with the beneficiary visible in their home. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, and a second photo must show the beneficiary visible in their home. All photos must be date-stamped.''

Additionally, regarding the comments requesting that photo metadata be used for the required date-stamp for self-reporting weight during an MDPP distance learning session, at this time we are not further defining what constitutes a date stamp for the purpose of MDPP videos and photos under this regulation. CMS relies on MDPP suppliers to ensure a reasonable and reliable indication of the date connected to a picture or video. A physical date on the photo or video would satisfy this requirement, however, CMS also recognizes that in some cases a technological solution may meet these criteria.

Regarding the National DPP self-attestation of weight, self-reporting of weight was added to MDPP as a flexibility during the PHE (85 FR 19230, 19283). The submission of video or photos remains necessary to ensure program integrity in MDPP. We acknowledge that some MDPP beneficiaries may lack the technology or capacity to provide a date-stamped photograph to document their body weight measurements. In situations in which beneficiaries may be unable to self-report their weight according to the MDPP conditions of coverage, suppliers may consider collecting weight measurements from the MDPP beneficiary in-person.

Lastly, we finalized in the CY 2021 PFS final rule that the flexibilities under § 410.79(e)(3)(iii) and (iv) would only apply only to MDPP suppliers that have and maintain CDC DPRP ''in-person'' recognition (85 FR 84830 and 84831). In the CY 2024 PFS final rule, we extended flexibilities allowed during the PHE for COVID–19 or 4 years, or through December 31, 2027 (88 FR 79241). We also confirmed that that the Extended flexibilities would continue to only apply to MDPP suppliers that have and maintain CDC DPRP ''in-person'' recognition, and that virtual only suppliers were not permitted to furnish the Set of MDPP services because MDPP beneficiaries may elect to return to in-person services, and MDPP suppliers need to be able to accommodate their request (88 FR 79248).

To reduce confusion as MDPP suppliers transition to the new CDC DPRP recognition for ''in-person with a distance learning component,'' we are clarifying that MDPP suppliers can have and maintain either CDC's ''in-person'' or the new ''in-person with a distance learning component'' CDC DPRP code. The 2024 CDC DPRP Standards, implemented in June 2024, introduced and defined the new ''in-person with a distance learning component'' modality and associated code.[399] This new modality and code for recognition include a combination of in-person and distance learning delivery, which are both modalities currently permitted until December 31, 2027 (88 FR 79241). The new MDPP term and definition for ''in person with a distance learning component'' that we are proposing to align with the 2024 CDC DPRP Standards will replace the current MDPP ''combination delivery'' term, which we proposed to remove in this rulemaking. Aligning terminology for delivery of MDPP that involves a combination of in-person and distance learning delivery with the 2024 CDC DPRP Standards would reduce administrative burden to MDPP suppliers and allow them to streamline CDC DPRP data submission (that is, they will not have to submit data for two CDC organization codes). MDPP suppliers will not be required to switch to this new code if they already have an in-person code; it is only being made available for their convenience.

[399] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

3. Changes to § 414.84(a), (c), (d), and (e)

We further proposed to amend § 414.84(a), (d), and (e) to remove the MDPP bridge payment. This payment is no longer necessary in MDPP's CY 2024 FFS payment structure for attendance and could introduce the potential for fraud, waste, or abuse.

The CY 2017 PFS final rule confirmed that a beneficiary may change MDPP suppliers at any time (81 FR 80470). The MDPP bridge payment was introduced in the CY 2018 PFS final rule at § 414.84(a) and is defined as follows: ''Bridge payment means a one-time payment to an MDPP supplier for furnishing its first MDPP session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier'' (81 FR 80470). The CY 2018 PFS final rule specified that an MDPP supplier that had previously been paid either a bridge payment or a performance payment for an MDPP beneficiary was not eligible to be paid a bridge payment for that beneficiary, along with other conditions. An MDPP supplier may only receive one bridge payment per MDPP beneficiary, however, there is no limit on how many MDPP suppliers can receive a bridge payment for the same beneficiary (82 FR 53361).

The CY 2018 PFS final rule also noted that the MDPP bridge payment was intended to be similar (that is, the same amount) to the payment for the first core session furnished by the previous supplier and would be received only if the subsequent supplier did not furnish the first core session to the MDPP beneficiary (82 FR 53361). In the performance-based payment structure, the bridge payment was intended to prevent scenarios where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who changed suppliers during the MDPP services period in the absence of the bridge payment. We stated that the bridge payment was not intended to be a performance payment; rather, it would account for the financial risk a subsequent MDPP supplier took on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period (82 FR 53293). However, such risk is not applicable in an FFS payment structure.

Along with the performance payments for weight loss, the MDPP bridge payment was retained in the CY 2024 Fee Schedule for MDPP (88 FR 79252). Currently, a subsequent MDPP supplier can receive both an attendance payment and a bridge payment for the first session attended by an MDPP beneficiary who switches suppliers. For

example, in CY 2024, if a beneficiary changed suppliers on MDPP session 8, the subsequent supplier could receive both the attendance payment for session 8 ($25) and the bridge payment ($25). The bridge payment for this beneficiary could only be received by this supplier once, but if the beneficiary changed suppliers again (for example, on session 17), the new (second) subsequent supplier could also receive the bridge payment in addition to the payment for session 17 ($25). This could continue as many times as the beneficiary changed suppliers until they have the maximum of 22 sessions paid, across all suppliers, with no maximum on the total number of bridge payments. In the CY 2018 PFS final rule, we noted some program integrity risk that organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encouraged beneficiaries to change suppliers for the purpose of being paid the bridge payment (82 FR 53294). Due to these reasons, we propose to amend § 414.84(a), (d), and (e) to remove reference to, and requirements of the MDPP bridge payment. Per our Regulatory Impact Analysis, we expect removal of the MDPP bridge payment to be budget neutral for the Medicare program. We solicited comment on these proposals, and the comments are addressed below.

Additionally, at § 414.84(c), facilitate Medicare Administrative Contractors (MACs) in processing claims for same day make-up sessions in MDPP, we proposed to require MDPP suppliers to append an existing claim modifier to any claim for G9886 or G9887 that indicates a make-up session that was held on the same day as a regularly scheduled MDPP session. The CY 2018 PFS final rule permits an MDPP beneficiary to have one make-up session on the same day as a regularly scheduled session and for a beneficiary to have one make-up session per week (82 FR 53360), consistent with CDC DPRP Standards.[400] In the CY 2024 PFS final rule, we stated that we wanted to encourage suppliers to schedule make-up sessions on days other than the same day of a regularly scheduled session to avoid claims being rejected or denied under the new CY 2024 FFS payment schedule and to allow beneficiaries to receive the benefit as intended by having access to the full 12 months MDPP service period to build the skills needed to reduce their risk for diabetes (88 FR 79250).

However, since then, we have heard from MDPP suppliers that same day make-up sessions are an essential flexibility that assist an MDPP beneficiary in staying on track with the curriculum and their cohort after an MDPP beneficiary needs to miss a regularly scheduled session. To help prevent potential claim rejections for duplicate services, we proposed to require MDPP suppliers to append a modifier to the applicable G-code for the second session held on the same day as a regularly scheduled MDPP session. Specifically, we proposed to add § 414.84(c)(4), which states that ''Current Procedural Terminology (CPT) Modifier 79 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify an MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.'' We believe this new requirement would contribute minimal additional complexity to the payment structure while creating a flexibility that would have value for the program, particularly for beneficiaries in the core phase of MDPP who may not have transportation to 2 in-person sessions in one week or have the flexibility to make time on more than one day per week for a distance learning session. Additionally, we believe the existing limitation on one make-up session per week would be sufficient to ensure program benefit because whether the make-up session is held on the same day or the next day would likely have minimal impact on program duration and intensity. To clarify, we proposed that the CPT Modifier 79 would only need to be appended to the HCPCS code (G9886 or G9887) that identifies the session that included content from a previously held session that serves as a makeup session for the session the MDPP beneficiary missed, which was held on the same day as a regularly scheduled MDPP session. This modifier would not need to be included on claims for make-up sessions held on different days than regularly scheduled MDPP sessions.

Lastly, with the removal of § 414.84(d), we proposed to amend the current § 414.84(e) to be the new § 414.84(d). We also removed from the new § 414.84(d) the reference to updating the MDPP bridge payment, as the bridge payment has been proposed to be removed from this CY 2025 Physician Fee Schedule rulemaking.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were all supportive of the proposed policies to remove the MDPP bridge payment and to allow Medicare Administrative Contractors (MACs) to process claims for an MDPP make-up session held on the same day as a regularly scheduled session. Many commenters noted these changes will reduce administrative burden, allow suppliers to streamline data reporting, and increase beneficiary flexibilities. Specifically, many commenters stated that same-day makeup sessions will allow MDPP suppliers to streamline data reporting to the CDC and alleviate participant burden by accommodating beneficiaries without access to transportation for multiple program classes within one week.

Response: After consideration of public comments, we are finalizing the changes to the provision to remove the MDPP bridge payment as proposed. To allow MACs to process claims for MDPP make-up sessions held on the same day as a regularly scheduled session, we are finalizing with a technical correction to change CPT modifier 79 to CPT modifier 76. We proposed to add § 414.84(c)(4), which states that ''Current Procedural Terminology (CPT) Modifier 79 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify an MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.'' Upon further review of modifier 79 and the associated description, we are making a technical correction to finalize in § 414.84(c)(4) that Modifier 76 (repeat services by same physician) to be appended to any claim for G9886 or G9887 to identify an MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

4. Aligning Language With Previous Rulemaking in §§ 410.79, 424.205, and 414.84

We proposed minor edits throughout §§ 410.79, 424.205, and 414.84 to update outdated references and align with previous rulemaking pertaining to MDPP terminology, payment structure, and requirements. This includes updating references to the performance-based payments for attendance and ongoing maintenance sessions, which were both removed from the 2024 MDPP Fee Schedule by the CY 2024 PFS final rule (88 FR 79252), as well as including

[400] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

the clarification that suppliers can offer MDPP sessions via distance learning, a flexibility extended by the CY 2024 PFS final rule (88 FR 79241), where applicable.

At § 410.79(b), we proposed to update the definition for the ''Set of MDPP services'' to remove the reference to ''ongoing maintenance'' sessions. All references to and requirements for the MDPP ''ongoing maintenance'' phase were removed by the CY 2024 PFS finale rule (88 FR 79256). We are revising this definition to read: ''Set of MDPP services means the series of MDPP sessions, composed of core sessions and core maintenance sessions, and subject to paragraph (c)(3) of this section offered over the course of the MDPP services period.''

We also proposed § 410.79(e)(3)(iv)(F)(*3*) to state that no more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24 for beneficiaries enrolled before January 1, 2022.

This proposed revision adds the date that the CY 2022 PFS final rule was effective, which is the date when no more MDPP beneficiaries could enroll in ongoing maintenance sessions (86 FR 65317).

At § 410.79(e)(3)(v)(F)(*2*), we proposed to remove the reference to weight measurement at an ongoing maintenance session, so the paragraph provides that for an MDPP beneficiary who began receiving the Set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

At § 424.205(c)(10), we proposed revision to specify in-person and distance learning delivery for MDPP core and core maintenance sessions, to provide that, except as allowed under § 424.205(d)(8), the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

- 16 in-person or distance learning core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.
- 1 in-person or distance learning core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

At § 424.205(f)(1)(ii), we propose to remove reference to the HICN, as Medicare is now using Medicare Beneficiary Identifiers (MBIs),[401] to state: Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, MBI, and age.

At § 424.205(f)(2)(i), we proposed to replace ''whether a core session, a core maintenance session, an in-person make-up session, or a virtual make-up session'' with the two currently permitted types of sessions (that is, in-person and distance learning), to state: Documentation of the type of session (in-person or distance learning).

At § 424.205(f)(5), we proposed to remove the references to the MDPP performance-based payments for attendance in paragraphs (f)(5)(i) and (ii) because these payments were removed in the CY 2024 Fee Schedule for MDPP (88 FR 79252). In their place, we are adding references to the performance payment for the required minimum 5 percent weight loss (82 FR 53289). We also proposed to correct the references to § 414.84(b), and also to remove the reference to the ongoing maintenance sessions from § 424.205(f)(5)(iv).

At § 414.84(b)(1), we proposed to clarify that the performance payment for the required minimum weight loss is made for 5 percent weight loss, as reflected in the CY 2024 Fee Schedule (88 FR 79252), and can be made for a distance learning, as well as an in-person MDPP session, as allowed by the PHE for COVID–19 flexibilities (85 FR 84830 through 84841) and their extension (88 FR 79241). Performance Goal 1 provides that it achieves the required minimum 5-percent weight loss. We make a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person or during a distance learning session during a core session or core maintenance session furnished by that supplier.

Similarly, we proposed to revise § 414.84(b)(2) for 9 percent weight loss. Performance Goal 2 provides that it achieves 9-percent weight loss. We make a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person or in a distance learning session during a core session or core maintenance session furnished by that supplier.

We solicited comments on these proposals.

We did not receive public comments on these provisions, and therefore, we are finalizing as proposed.

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We also established in the CY 2020 PFS final rule new codes and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling.

Since the CY 2020 PFS final rule, we have made several refinements and expansions to services covered under the Medicare OTP benefit. Specifically, we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone (85 FR 84683 through 84692) in the CY 2021 PFS final rule, and a new add-on code and payment for a higher dose of nasal naloxone (86 FR 65340 and 65341) in the CY 2022 PFS final rule. We have also finalized various telecommunications flexibilities, including: to allow OTPs to furnish individual and group therapy and substance use counseling via two-way interactive audio-video telecommunications (84 FR 62630 through 62677 and 84 FR 62919 through 62926) in the CY 2020 PFS final rule, and via audio-only telephone calls when audio-video telecommunications are not available to the beneficiary (86 FR 65342) in the CY 2022 PFS final rule; to allow the OTP intake add-on code to be furnished via two-way interactive audio-video telecommunications when billed for the initiation of treatment with buprenorphine, and via audio-only telecommunications when audio-video telecommunications are not available to

[401] *https://www.cms.gov/training-education/partner-outreach-resources/new-medicare-card/medical-beneficiary-identifiers-mbis.*

the beneficiary, to the extent that these technologies are authorized by the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) at the time the service is furnished (87 FR 69775 through 69777) in the CY 2024 final rule; and to allow periodic assessments to be furnished via two-way interactive audio-video telecommunications as clinically appropriate (85 FR 84690) in the CY 2021 final rule. OTPs may furnish these aforementioned services via telecommunications systems provided all other applicable requirements are met. Additionally, for the purposes of the geographic adjustment, we have clarified, in the CY 2023 final rule, that services furnished via OTP mobile units will be treated as if the services were furnished in the physical location of the OTP for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes, as long as services are medically reasonable and necessary and comply with SAMHSA and DEA guidance (87 FR 69768 through 69777). Lastly, we have made a few changes to various pricing methodologies under the OTP benefit in the 2023 PFS final rule, including: revising our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone by using the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription) to better reflect the changes in methadone costs for OTPs over time (87 FR 69768 through 69777); and modifying the payment rate for individual therapy in the non-drug component of the bundled payment to base the payment rate on the rate for longer therapy sessions that better account for the greater severity of needs for patients with an OUD (87 FR 69768 through 69777).

More recently, for CY 2024, we made further modifications and expansions to covered services for the treatment of OUD by OTPs. In the CY 2024 PFS final rule (88 FR 79089 through 79093), we finalized an extension to allow periodic assessments to be furnished audio-only through the end of CY 2024 when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. In the CY 2024 PFS final rule, we noted that extending these flexibilities another year would allow CMS time to further consider this issue, including whether periodic assessments should continue to be furnished using audio-only communication technology following the end of CY 2024. Lastly, in the CY 2024 Outpatient Prospective Payment System (OPPS) final rule (88 FR 81845 through 81858), we finalized an add-on code for intensive outpatient program (IOP) services furnished by OTPs for the treatment of OUD and added a new paragraph (ix) in the definition of ''Opioid disorder treatment service'' at § 410.67(b) to describe such services. We stated that Medicare would pay for IOP services provided by OTPs if each service is medically reasonable and necessary and not duplicative of any service paid for under any bundled payments billed for an episode of care in a given week, and other applicable requirements are met. We believe that payment for IOP services will improve continuity of care between different treatment settings and levels of care, and further promote health equity for Medicare beneficiaries that may face barriers to accessing treatment, such as racial/ethnic minorities and/or beneficiaries aged 65 or older. We continue to monitor utilization of OUD treatment services furnished by OTPs to ensure that Medicare beneficiaries have appropriate access to care. For CY 2025, we proposed several modifications to the policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Telecommunication Flexibilities for Periodic Assessments and Initiation of Treatment With Methadone

We have finalized several flexibilities for OTPs regarding the use of telecommunications, both during the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19) and outside of the PHE. In the CY 2020 PFS final rule, we finalized a policy allowing OTPs to furnish substance use counseling and individual and group therapy via two-way interactive audio-video communication technology. In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19258), we revised paragraphs (iii) and (iv) in the definition of *opioid use disorder treatment service* at § 410.67(b) on an interim final basis to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 if beneficiaries do not have access to two-way audio-video communications technology, provided all other applicable requirements are met. In the CY 2022 PFS final rule (86 FR 65341 through 65343), we finalized that after the conclusion of the PHE for COVID–19, OTPs are permitted to furnish substance use counseling and individual and group therapy via audio-only telephone calls when audio and video communication technology is not available to the beneficiary. As we explained in the CY 2022 PFS final rule (86 FR 65342), we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary. In the CY 2023 PFS final rule (87 FR 69775 through 69777), we further extended telecommunication flexibilities for the initiation of treatment with buprenorphine outside of the PHE for COVID–19 in paragraph (vi) in the definition of *opioid use disorder treatment service* at § 410.67(b). Specifically, we allowed the OTP intake add-on code to be furnished via two-way, audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. We also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, provided all other applicable requirements are met.

a. Allowing Periodic Assessments To Be Furnished Via Audio-Only Telecommunications on a Permanent Basis

In recent years, we have finalized several telecommunication flexibilities for periodic assessments furnished by OTPs. In the IFC entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27558), we revised paragraph (vii) in the definition of ''Opioid use disorder treatment

service'' at § 410.67(b) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video telecommunication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. In the CY 2021 PFS final rule (85 FR 84690), we finalized our proposal to revise paragraph (vii) in the definition of ''Opioid use disorder treatment service'' at § 410.67(b) to provide that periodic assessments (HCPCS code G2077) must be furnished during a face-to-face encounter, which includes services furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met, on a permanent basis.

Furthermore, in the CY 2023 PFS proposed rule (87 FR 46093), we sought comment on whether we should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID–19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone. In response, several commenters advocated for CMS to continue to allow periodic assessments to be furnished audio-only when video is not available after the end of the PHE. Commenters highlighted that allowing audio-only flexibilities would further promote health equity for individuals who are economically disadvantaged, live in rural areas, are members of racial and ethnic minorities, lack access to reliable broadband or internet access, or do not possess devices with video capability. Commenters also indicated that periodic assessments are no less complex than intake/initial assessments, and thus are equally appropriate for audio-video and audio-only care, and that permitting audio-only flexibilities would allow an opportunity for both the provider and patient to jointly determine that the patient would individually benefit from telehealth services. After considering these comments, we determined that it would be appropriate to allow periodic assessments to be furnished audio-only when video is not available through the end of CY 2023, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and, in a manner consistent with all applicable requirements. We stated our belief that this modification would allow continued beneficiary access to these services for the duration of CY 2023 in the event the PHE terminated before the end of 2023 and that it would also grant additional time for CMS to further consider telecommunication flexibilities associated with periodic assessments.

Moreover, section 4113 of Division FF, Title IV, Subtitle A of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022) extended the telehealth flexibilities enacted in the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022). Specifically, it amended sections 1834(m), 1834(o), and 1834(y) of the Act to delay the requirement for an in-person visit prior to furnishing certain mental health services via telecommunications technology by physicians and other practitioners, Rural Health Clinics (RHCs), and Federally Qualified Health Centers (FQHCs) until dates of service on or after January 1, 2025, if the PHE for COVID–19 had ended prior to that date. Additionally, it extended the flexibilities that were available during the PHE that allowed for certain Medicare telehealth services defined in section 1834(m)(4)(F)(i) of the Act to be furnished via an audio-only telecommunications system through December 31, 2024, if the PHE for COVID–19 had ended prior to that date. The PHE for COVID–19, which was declared under section 319 of the Public Health Service Act, expired at the end of the day on May 11, 2023, so the aforementioned flexibilities were extended through the end of CY 2024.

To better align coverage for periodic assessments furnished by OTPs with the telehealth flexibilities described in section 4113 of the CAA, 2023 for other settings under Medicare, in the CY 2024 PFS final rule (88 FR 79089 through 79093; 79528), we finalized extending the audio-only flexibilities for periodic assessments furnished by OTPs through the end of CY 2024 in paragraph (vii) in the definition of Opioid use disorder treatment service at § 410.67(b). We finalized to allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. In submitted comments supporting the proposal, commenters reiterated evidence showing that audio-only telehealth encounters are more prominent among individuals who are older, Black, Hispanic, American Indian/Alaska Native, Spanish-speaking, living in areas with low broadband access, low-income, and with public insurance, suggesting that the proposal would have positive health equity implications for these populations.[402] Several other commenters raised that audio-only flexibilities are important since many underserved populations may experience challenges in partaking in video-based telehealth services, due to not possessing the needed technological proficiencies to operate video-based services, not having a caregiver able to assist them with appointments, feeling discomfort with the use of video, and because of the cost of high-speed internet and data required for video technologies. Several other commenters shared evidence that audio-only visits produce many of the same benefits as video-based visits,[403] and that patients often report that audio-only visits left them feeling supported and with greater privacy, provided increased access to behavioral health professionals, and helped reduce transportation barriers.[404] Lastly, a large number of commenters requested that CMS make the extension for audio-only periodic assessments permanent beyond CY 2024. Commenters stated that extending this policy permanently would retain a beneficiary's right to decide with their provider how best to receive their care

[402] J.A. Rodriguez et al., ''Differences in the Use of Telephone and Video Telemedicine Visits During the COVID–19 Pandemic,'' The American Journal of Managed Care 27, no. 1 (2021), *https://www.ajmc.com/view/differences-in-the-use-of-telephone-and-video-telemedicine-visits-during-the-covid-19-pandemic;* R.P. Pierce and J.J. Stevermer, ''Disparities in Use of Telehealth at the Onset of the COVID–19 Public Health Emergency,'' Journal of Telemedicine and Telecare (2020): 1–7, *https://doi.org/10.1177/1357633X20963893*; J.E. Chang et al., ''Patient Characteristics Associated with Phone Versus Video Telemedicine Visits for Substance Use Treatment During COVID–19,'' J Addict Med 16, no. 6 (2022): 659–65; C. Shoff, T–C Yang, B.A. Shaw, ''Trends in Opioid Use Disorder Among Older Adults: Analyzing Medicare Data, 2013–2018,'' American Journal of Preventive Medicine 60, no.6 (2021): 850–855, *https://doi.org/10.1016/j.amepre.2021.01.010.*

[403] Danila, M.I., Sun, D., Jackson, L.E., Cutter, G., Jackson, E.A., Ford, E.W., DeLaney, E., Mudano, A., Foster, P.J., Rosas, G., Melnick, J.A, Curtis, J.R., & Saag, K.G. (2022, November). ''Satisfaction with modes of telemedicine delivery during COVID–19: A randomized, single-blind, parallel group, noninferiority trial.'' The American Journal of the Medical Sciences, 364 (5).

[404] Kang A.W., Walton M., Hoadley A., DelaCuesta C., Hurley L., Martin R. ''Patient Experiences with the Transition to Telephone Counseling during the COVID–19 Pandemic.'' Healthcare (Basel). 2021;9(6):663. Published 2021 Jun 2. *doi:10.3390/healthcare9060663.*

and would curtail existing barriers that Medicare beneficiaries with an OUD may face in accessing care. In response to these comments that requested indefinitely extending these audio-only flexibilities for periodic assessments, CMS stated that extending these flexibilities for one additional year at the time would allow the agency time to further examine the issue, including to understand if a permanent extension would be appropriate for patients who are receiving treatment via buprenorphine, methadone, and/or naltrexone at OTPs, and whether proper safeguards are in place so these services can be delivered in a way that would not diminish safety or quality of care for Medicare beneficiaries with an OUD.

We continue to monitor the services provided under the OTP benefit to ensure flexibilities for OUD treatment services are consistent with flexibilities authorized in other settings under Medicare, as medically reasonable and necessary for the diagnosis and treatment of OUD. In the CY 2022 PFS final rule, we revised the regulatory definition of ''interactive telecommunications system'' at § 410.78(a)(3) for Medicare Telehealth services paid under the PFS beyond the termination of the PHE for COVID–19 to allow for inclusion of audio-only services under certain circumstances. Specifically, we redefined ''interactive telecommunications system'' to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to a patient in their home. We also finalized to limit payment for audio-only services to services furnished by a physician or practitioner that has the technical capability at the time of the service to use two-way audio-video telecommunications, but where the patient is not capable of, or does not consent to, the use video technology for the service, and the patient is located at their home at the time of service. Lastly, we clarified that SUD services are considered mental health services for purposes of the expanded definition of ''interactive telecommunications system'' to include audio-only services under § 410.78(a)(3). In short, these flexibilities and policy clarifications that permit audio-only telecommunication flexibilities for the treatment of a SUD, which can include an OUD, already exist under other payment systems in Medicare.

Therefore, to better align coverage for periodic assessments furnished by OTPs with other telehealth services furnished under the PFS for the diagnosis, evaluation, or treatment of a mental health disorder including SUDs, and in response to many supportive comments received in response to the CY 2024 PFS proposed rule that advocated for allowing OTPs to furnish periodic assessments via audio-only telecommunications on a permanent basis, in the CY 2025 PFS proposed rule we proposed to allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025. Under this proposal, we would allow periodic assessments to be furnished via audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met.

We believe permanently extending this flexibility would meaningfully promote access to care for the Medicare population, as supported by our analysis of claims data showing the proportion of telephonic audio-only visits increases with the age of the patient, with 17-percent of visits delivered via audio-only interaction for patients 41–60 years of age, 30-percent for patients 61 to 80 years of age, and 47 percent of visits for patients over 81 years of age.[405] Evidence further reveals that Medicare beneficiaries who are older than 65 years old, racial/ethnic minorities, dual-enrollees in Medicare and Medicaid, or living in rural areas, or who experience low broadband access, low-income, and/or for whom English in not their primary language, are more likely to be offered and use audio-only telemedicine services than audio-video services.[406] Other evidence also suggests that while Tribal populations, including American Indian and Alaska Natives, have the highest rates of OUD prevalence among Medicare beneficiaries, one-third of these populations do not have adequate access to high-speed broadband and continue to rely on audio-only visits.[407] Telemedicine flexibilities have been shown to be feasible and effective for rural patients with an OUD with data supporting that telemedicine flexibilities have helped improve treatment retention in OUD treatment, especially for rural patients who are older and covered by Medicare.[408] Lastly, these audio-only flexibilities would be meaningful for OTPs and their patients because telehealth services have become widely used among SUD treatment facilities as regular service offerings. During the COVID–19 pandemic, SUD treatment facilities increased telemedicine offerings by 143 percent, and as of 2021, almost 60 percent of SUD treatment facilities offer telehealth.[409] Now, telephone-based (that is, audio-only) therapy provided by SUD programs has been found to be one of the most common modes of telehealth for treatment of OUD.[410] Given the prevalence of audio-only modalities of care for the treatment of OUD, permanently extending this flexibility could help prevent disruptions to care in OTP settings that may regularly provide periodic assessments via audio-only telehealth to Medicare beneficiaries. For these reasons, we believe a permanent extension would be appropriate for patients who are receiving buprenorphine, methadone, and/or naltrexone at OTPs, and that proper safeguards are in place so these services can be delivered in a way that would not diminish safety or quality of care for Medicare beneficiaries with an OUD.

[405] Lee, G., & Stewart, K. (n.d.). ''2021 Medicare coverage and payment for audio only services (Telephone e/m).'' AAMC. *https://www.aamc.org/media/55296/download*.

[406] *Rodriguez, J.A., Betancourt, J.R., Sequist, T.D., & Ganguli, I. (2021).* ''Differences in the use of telephone and video telemedicine visits during the COVID–19 pandemic.'' *The American Journal of Managed Care, 27(1), 21–26. https://doi.org/10.37765/ajmc.2021.88573;* Koma, W., Cubanski, J., & Published, T.N. (2021, May 19). ''Medicare and telehealth: Coverage and use during the covid–19 pandemic and options for the future.'' KFF. *https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/; Benjenk, I., Franzini, L., Roby, D., & Chen, J. (2021).* ''Disparities in Audio-Only Telemedicine use among Medicare beneficiaries during the coronavirus disease 2019 pandemic.'' *Medical Care, 59(11), 1014. https://doi.org/10.1097/MLR.0000000000001631.*

[407] Federal Communications Commission. (2020). ''2020 Broadband Deployment Report'' (FCC 20–50). *https://docs.fcc.gov/public/attachments/FCC-20-50A1.pdf;* Centers for Medicare and Medicaid Services, Division of Tribal Affairs. (n.d.). Telehealth and COVID–19. *https://www.cms.gov/files/document/aian-telehealthwebinar.pdf*; Shoff, C., Yang, T.C., & Shaw, B.A. (2021). ''Trends in opioid use disorder among older adults: Analyzing Medicare data, 2013–2018.'' American Journal of Preventive Medicine, 60(6), 850–855. *https://doi.org/10.1016/j.amepre.2021.01.010.*

[408] *Lira, M.C., Jimes, C., & Coffey, M.J. (2023).* ''Retention in telehealth treatment for opioid use disorder among rural populations: A retrospective cohort study.'' *Telemedicine Journal and E-Health, 29(12), 1890–1896. https://doi.org/10.1089/tmj.2023.0044.*

[409] Cantor, J., McBain, R.K., Kofner, A., Hanson, R., Stein, B.D., & Yu, H. (2022). ''Telehealth adoption by mental health and substance use disorder treatment facilities in the covid–19 pandemic.'' Psychiatric Services (Washington, DC), 73(4), 411–417. *https://doi.org/10.1176/appi.ps.202100191.*

[410] *Hughes, P.M., Verrastro, G., Fusco, C.W., Wilson, C.G., & Ostrach, B. (2021).* ''An examination of telehealth policy impacts on initial rural opioid use disorder treatment patterns during the COVID–19 pandemic.'' *The Journal of Rural Health, 37(3), 467–472. https://doi.org/10.1111/jrh.12570.*

Accordingly, we proposed to revise paragraph (vii) of the definition of ''Opioid treatment services'' at § 410.67(b) of the regulations to remove the references to the ''Public Health Emergency, as defined in § 400.200 of this chapter'' and ''through the end of CY 2024,'' in order to reflect that this flexibility would be implemented on a permanent basis. We would continue to state that ''in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.'' We solicited comments on this proposal to permanently extend this audio-only flexibility for periodic assessments. We received many public comments on our proposal to allow OTPs to furnish periodic assessments using audio-only communications technology when video is not available on a permanent basis beginning January 1, 2025. These public comments and our responses to these comments are addressed in the section below.

Comment: We received many comments in support of this proposal. Commenters stated that making this flexibility permanent would significantly expand access to care, especially for patients living in rural regions, racial or ethnic minorities, tribal populations, individuals for whom English is a secondary language, older Medicare beneficiaries, and dual enrollees in Medicare and Medicaid. Commenters also shared that audio-only telecommunication is often the most accessible form of communication for patients with limited access to high-speed broadband internet service, those with lower incomes, individuals with unstable housing, and individuals who lack access to necessary video equipment or do not possess the skills to effectively operate video equipment. Commenters affirmed that beneficiary access to OUD treatment during the COVID–19 PHE increased due to telecommunication flexibilities, especially in remote and underserved communities, demonstrating the need to permanently extend the policy. A few commenters further noted that patients have grown accustomed to accessing services via audio-only telecommunications, and thus, discontinuing the flexibility could disrupt treatment, negatively affect treatment outcomes, and lead to withdrawal symptoms and recurrent opioid use. Other commenters agreed with CMS that audio-only services could be delivered by OTPs in a manner that would not diminish safety or quality of care. Commenters also mentioned that this flexibility would expand options for the modality in which to receive treatment and further promote provider and patient collaborative decision-making to ensure the patient's needs are met. Lastly, one commenter noted that if OTPs are concerned about issues that may arise during a patient's periodic assessment, then they could ask the patient to be seen in person.

Response: We appreciate commenters' overwhelming support of our proposal to permanently allow OTPs to furnish periodic assessments using audio-only telecommunications beginning January 1, 2025. We agree that finalizing this flexibility on a permanent basis will significantly expand access to care, improve patient outcomes while maintaining quality and safety of care, and allow a modality of treatment to be selected to sufficiently meet the needs of the patient.

Comment: One commenter recommended that CMS create a modifier that OTPs may append to claims when OTPs furnish audio-only periodic assessments, since it would allow CMS to track the use of audio-only telecommunications and better evaluate patient outcomes associated with the flexibility.

Response: We thank the commenter for this suggestion. We note that CMS did create modifiers for OTPs to append to claims when billing for OUD treatment services that were furnished via telecommunications technology. Specifically, after the conclusion of the COVID–19 PHE, which ended on May 11, 2023, CMS stated in section 30.5 of Chapter 39 of the Medicare Claims Processing Manual that we expect ''OTPs to add Modifier 93 (Synchronous telemedicine service rendered via telephone or other real-time interactive audio-only telecommunications system) to the claim for counseling and therapy provided via audio-only telecommunications using HCPCS code G2080, as well as for intake activities and periodic assessments furnished using audio-only communication technology.'' We also stated that we expect OTPs to ''add Modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim for counseling and therapy provided via audio-video telecommunications using HCPCS code G2080, as well as for intake activities and periodic assessments furnished using audio and video communication technology.'' Thus, OTPs should append Modifier 93 to claims for OUD treatment services furnished via telecommunications, including for audio-only periodic assessments.

Comment: One commenter urged CMS to not restrict audio-only flexibilities for periodic assessments to specific circumstances, such as when video technology is unavailable to the patient and provider or when the patient does not consent to the use of video technology. The commenter further stated that restricting audio-only flexibilities to cases where only patients lack access to video-based technologies (and not also providers), overlooks scenarios where providers might also face limitations (for example, in emergency situations). The commenter said that it is essential to allow both providers and patients the flexibility to determine the most appropriate modality for their care, without imposing restrictive conditions. Therefore, the commenter requested that CMS delete the language, ''in cases where a beneficiary does not have access to two-way audio video communications'' within paragraph (vii) in the definition of Opioid use disorder treatment service at § 410.67(b) in order to be more inclusive of providers and to not impose restrictions on when audio-only communication technologies are permissible.

Response: We appreciate the commenters' feedback. We understand that there could be limited circumstances where a provider is unable to access audio-video communications technology. However, we believe that allowing audio-only communications technology in situations where a patient does not have access to two-way audio-video communications technology is critical to safeguarding the medical needs of the patient and ensuring that an appropriate modality of care is selected for the patient's condition and circumstance. We do not believe it would be appropriate if audio-only periodic assessments are performed on the basis that the provider does not have access to audio-video communications technology if the audio-only modality of care does not benefit the patient or the treatment of their condition. We believe that OTPs should possess the technical capability at the time the service is furnished to use an interactive telecommunications system (that is, with audio-only and audio-video capabilities) to ensure telecommunication services are a comparable and appropriate substitute for services that would ordinarily be provided in person. CMS continues to maintain that allowing audio-only periodic assessments in cases where a beneficiary does not have access to two-

way audio-video communications achieves the balance of ensuring beneficiaries still have access to care while still maintaining proper safeguards so services can be delivered in a way that would not diminish the safety or quality of care for Medicare beneficiaries with an OUD.

Comment: A few commenters encouraged CMS to work with other federal partners to align and clarify telemedicine regulations for OUD treatment policies. Some commenters also raised the importance of the DEA revising their regulations to clarify post-pandemic rules on telemedicine flexibilities for the prescription of controlled medications (for example, medications for opioid use disorder) ahead of the flexibilities expiring at the end of the year, in order to prevent disruptions in care.[411]

Response: CMS shares the commenters' interest in ensuring the consistency of policies that span across HHS and other agencies. We continue to work with other agencies on these matters, including SAMHSA and the DEA, to ensure high-quality care is accessible to program beneficiaries and that OTPs receive adequate communication and program guidance on various policies across agencies.

After consideration of public comments, we are finalizing our proposal to permanently allow OTPs to furnish periodic assessments via audio-only telecommunications beginning January 1, 2025, so long as all applicable requirements are met, and the use of these technologies are permitted under the applicable SAMHSA and DEA requirements at the time the services are furnished. We are revising paragraph (vii) of the definition of ''Opioid use disorder treatment service'' at § 410.67(b) of the regulations to remove the references to the ''Public Health Emergency, as defined in § 400.200 of this chapter'' and ''through the end of CY 2024,'' in order to reflect that this flexibility will be implemented on a permanent basis. We will continue to state that ''in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.''

b. Use of Audio-Visual Telecommunications for Initiation of Treatment With Methadone

Prior to the PHE for COVID–19, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110–425) amended the Controlled Substances Act and instructed the DEA to issue regulations that required healthcare providers to conduct an in-person examination in the presence of a practitioner prior to prescribing controlled substances (for example, methadone, buprenorphine, etc.) to patients, with certain exceptions. These statutory provisions prevented the distribution and dispensing of controlled substances by means of the internet without at least one in-person medical evaluation before writing a prescription. Similarly, SAMHSA regulations under 42 CFR 8.12(f)(2) have historically required a complete physical evaluation before a patient begins treatment at an OTP. However, after the declaration of the PHE for COVID–19, the DEA and SAMHSA jointly issued flexibilities for prescribing of controlled substances via telehealth to ensure patient therapies would remain accessible. Consequently, OTPs were exempted from the requirement to perform an in-person physical evaluation for any patient who would be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth through an audio-video or audio-only evaluation.[412] At the time, this exemption applied exclusively to patients with an OUD being treated at an OTP with buprenorphine, and it did not apply to new patients initiating treatment with methadone. This meant that new OTP patients starting treatment with methadone would need to still receive an in-person physical evaluation prior to the OTP prescribing methadone. Accordingly, in the CY 2023 PFS final rule (87 FR 69775 through 69777), we revised the regulation in paragraph (vi) of the definition of ''Opioid use disorder treatment services'' at § 410.67(b) to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. CMS also permitted the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary in the CY 2023 PFS final rule (87 FR 69775 through 69777). We stated that section 1834(m)(7) of the Act allows telehealth services for the treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site, including in a patient's home, and that some codes describing new patient office/outpatient visits are already under the Medicare Telehealth list (CPT codes 99202 through 99205). Therefore, we believed that these changes for the initiation of treatment with buprenorphine via audio-only or audio-video telecommunications would also be consistent with existing flexibilities under the PFS. Consistent with SAMHSA and DEA requirements at the time of CY 2023 PFS rulemaking, we also noted that this exemption applied exclusively to OTP patients treated with buprenorphine and did not apply to new patients treated with methadone. Notably, SAMHSA recently finalized and codified this flexibility at § 8.12(f)(2)(v)(B),[413] so that OTPs may use audio-visual or audio-only platforms when evaluating patients who are being admitted for treatment at the OTP with schedule III medications (such as buprenorphine) on a permanent basis.

Furthermore, in their recent final rule published in the **Federal Register** in February of 2024 (89 FR 7528), SAMHSA made updates to full examination requirements for initiation of treatment with methadone at § 8.12(f)(2)(v)(A). Specifically, SAMHSA made revisions to allow for audio-visual telehealth initiation for any new patient who will be treated by the OTP with methadone if a practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. When audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. In finalizing this new flexibility, SAMHSA reasoned that ''evidence underlying the initiation of buprenorphine using

[411] *https://telehealth.hhs.gov/providers/telehealth-policy/prescribing-controlled-substances-via-telehealth.*

[412] *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf; https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs.*

[413] 89 FR 7528, February 2, 2024 (*https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder*).

telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in-person examination flexibilities to treatment with methadone in OTPs (89 FR 7533).'' [414] SAMHSA also noted that video-based telehealth was overwhelmingly supported by commenters for medical intake, periodic medical assessments, and methadone or buprenorphine initiation by OTP practitioners. SAMHSA did not extend the flexibility to allow the use of audio-only telehealth platforms in assessing new patients who will be treated by the OTP with methadone due to safety considerations, as they stated ''methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform (89 FR 7533).'' [415] However, SAMHSA did finalize specific exceptions that would facilitate audio-only initiation of methadone via telehealth. Pursuant to § 8.12(f)(2)(v)(A), when audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications (89 FR 7539). The licensed practitioner would need to be present in the same room as the patient and be available to conduct the visual component of the examination, which would be required to satisfy the requirement for telehealth initiation of treatment with methadone which is through an audio-visual examination. These new flexibilities to allow new patients to initiate treatment with methadone via audio-visual telehealth is significant, as the majority of patients who are being treated at an OTP receive methadone.[416] Methadone is used to treat those with a confirmed diagnosis of OUD, and is a synthetic opioid agonist that eliminates withdrawal symptoms and relieves drug cravings by acting on opioid receptors in the brain.[417] Methadone has been associated with reducing the risk of drug overdose, opioid-related acute care, all-cause mortality, and opioid-related mortality.[418] It has also been shown to retain patients in treatment, reduce consequences of injection drug use such as HIV/Hepatitis C transmission, and contribute to quality of life improvements for patients.[419] However, many barriers currently exist for patients seeking to receive methadone treatment. Currently, only SAMHSA-certified OTPs can dispense and administer methadone for the treatment of OUD as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. This often means that daily travel might be necessary if it is determined that the risks of giving take-home doses outweigh the benefits, unless patients are eligible to receive take-home doses after meeting certain conditions. Most adults in methadone treatment report at least one barrier to accessing treatment, including lack of reliable transportation, distance from home to treatment, and work schedule conflicts.[420] Frequent travel to an OTP also disproportionately impacts rural residents who already face lower odds of finding an OTP in their area, and therefore, must spend nearly 2–5 times the amount of average drive time to access the closest OTP compared to their urban counterparts.[421] Research has also shown that the number of missed doses of methadone increases for residents living longer distances from an OTP. Additionally, people living with disabilities are less likely to receive MOUDs, and some data also shows that many SUD treatment programs are not physically accessible for these populations.[422] The existence of these physical barriers to accessing methadone and treatment at OTP facilities, especially among historically underserved populations, warrants additional considerations to the extent that telehealth flexibilities can mitigate these barriers to accessing care, as long as these flexibilities are medically appropriate and reasonable for the diagnosis and treatment of OUD.

To be consistent with SAMHSA's reforms to telehealth flexibilities for initiation of treatment with methadone at § 8.12(f)(2)(B)(v), past conforming regulations under the Medicare OTP benefit to allow telecommunication flexibilities for initiation of treatment with buprenorphine, and to contribute towards efforts to reduce barriers in accessing care for Medicare beneficiaries seeking treatment with methadone, we proposed to make similar telecommunication flexibilities under the Medicare OTP benefit in the

[414] *Chan, B., Bougatsos, C., Priest, K.C., McCarty, D., Grusing, S., & Chou, R. (2022).* ''Opioid treatment programs, telemedicine and COVID–19: A scoping review.'' *Substance Abuse, 43(1), 539–546. https://doi.org/10.1080/08897077.2021.1967836.*

[415] *https://www.govinfo.gov/content/pkg/FR-2024-02-02/pdf/2024-01693.pdf.*

[416] American Association for the Treatment of Opioid Dependence, National Association of State Alcohol and Drug Abuse Directors, & Opioid Response Network. (2022). ''Technical Brief: Census of Opioid Treatment Programs.'' *https://nasadad.org/wp-content/uploads/2022/12/OTP-Patient-Census-Technical-Brief-Final-for-Release.pdf.*

[417] National Institute on Drug Abuse. (2021, December). ''How do medications to treat opioid use disorder work?'' *https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.*

[418] *Wakeman, S.E., Larochelle, M.R., Ameli, O., Chaisson, C.E., McPheeters, J.T., Crown, W.H., Azocar, F., & Sanghavi, D.M. (2020).* ''Comparative effectiveness of different treatment pathways for opioid use disorder.'' *JAMA Network Open, 3(2), e1920622. https://doi.org/10.1001/jamanetworkopen.2019.20622; Sordo, L., Barrio, G., Bravo, M.J., Indave, B.I., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017).* ''Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies.'' *The BMJ, 357, j1550. https://doi.org/10.1136/bmj.j1550; Larochelle, M.R., Bernson, D., Land, T., Stopka, T.J., Wang, N., Xuan, Z., Bagley, S.M., Liebschutz, J.M., & Walley, A.Y. (2018).* ''Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study.'' *Annals of Internal Medicine, 169(3), 137. https://doi.org/10.7326/M17-3107.*

[419] Mattick, R.P., Breen, C., Kimber, J., & Davoli, M. (2009). ''Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence.'' Cochrane Database of Systematic Reviews, 3. *https://doi.org/10.1002/14651858.CD002209.pub2;* Bruce, R.D. (2010). ''Methadone as HIV prevention: High volume methadone sites to decrease HIV incidence rates in resource limited settings. The International Journal on Drug Policy, 21(2), 122–124. *https://doi.org/10.1016/j.drugpo.2009.10.004;* Alavian, S.M., Mirahmadizadeh, A., Javanbakht, M., Keshtkaran, A., Heidari, A., Mashayekhi, A., Salimi, S., & Hadian, M. (2013). ''Effectiveness of methadone maintenance treatment in prevention of hepatitis c virus transmission among injecting drug users.'' Hepatitis Monthly, 13(8), e12411. *https://doi.org/10.5812/hepatmon.12411;* Carlsen, S.E.L., Lunde, L.H., & Torsheim, T. (2019). ''Predictors of quality of life of patients in opioid maintenance treatment in the first year in treatment.'' Cogent Psychology, 6(1), 1565624. *https://doi.org/10.1080/23311908.2019.1565624.*

[420] Pasman, E., Kollin, R., Broman, M., Lee, G., Agius, E., Lister, J.J., Brown, S., & Resko, S.M. (2022). ''Cumulative barriers to retention in methadone treatment among adults from rural and small urban communities.'' Addiction Science & Clinical Practice, 17(1), 1–10. *https://doi.org/10.1186/s13722-022-00316-3.*

[421] Calcaterra, S.L., Bach, P., Chadi, A., Chadi, N., Kimmel, S.D., Morford, K.L., Roy, P., & Samet, J.H. (2019). ''Methadone matters: What the United States can learn from the global effort to treat opioid addiction.'' Journal of General Internal Medicine, 34(6), 1039–1042. *https://doi.org/10.1007/s11606-018-4801-3;* Jehan, S., Zahnd, W.E., Wooten, N.R., & Seay, K.D. (2024). ''Geographic variation in availability of opioid treatment programs across U.S. communities.'' Journal of Addictive Diseases, 42(2), 136–146. *https://doi.org/10.1080/10550887.2023.2165869.*

[422] Thomas, C.P., Stewart, M.T., Ledingham, E., Adams, R.S., Panas, L., & Reif, S. (2023). ''Quality of opioid use disorder treatment for persons with and without disabling conditions.'' JAMA Network Open, 6(3), e232052. *https://doi.org/10.1001/jamanetworkopen.2023.2052;* West, S.L. (2007). ''The accessibility of substance abuse treatment facilities in the United States for persons with disabilities.'' Journal of Substance Abuse Treatment, 33(1), 1–5. *https://doi.org/10.1016/j.jsat.2006.11.001.*

CY 2025 PFS proposed rule. Specifically, we proposed to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone, to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished. We noted that under this proposal, the initiation of treatment with methadone using telecommunications technology would be considered an intake activity for purposes of paragraph (vi) of the definition of ''Opioid use disorder treatment services'' at § 410.67(b) only to the extent that the use of such telecommunications technology is permitted under the applicable DEA and SAMHSA regulations and guidance at the time the services are furnished. However, we did not propose to extend the flexibility to allow the use of audio-only telecommunications for intake activities described in paragraph (vi) of the definition of ''Opioid use disorder treatment services'' at § 410.67(b) for initiation of treatment with methadone, as these flexibilities are not currently permitted by SAMHSA and the DEA. We recognized that methadone is characterized as a schedule II controlled substance, which means that it still has higher potential for misuse with potential physical dependence.[423] Unlike buprenorphine that is a schedule III controlled substance, methadone is a full agonist and does not have a ''ceiling effect,'' which provides more protective overdose factors when taking additional doses of the drug.[424] Thus, use of audio-visual telecommunications for initiation of treatment with methadone would balance potential safety concerns associated with methadone, such as its higher potential for misuse and risk for sedation in patients presenting with mild somnolence which may be easier to identify via a audio-visual telehealth platform, while still allowing patients the flexibility of initiating treatment via (audio-visual) telehealth at an OTP. However, CMS continues to defer to SAMHSA guidance on the use of audio-only telecommunications for initiation of treatment with methadone pursuant to § 8.12(f)(2)(v)(A), which allows a specific exception to allow for the use of audio-only devices when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications, and when audio-visual technologies are not available or their use is not feasible for a patient (89 FR 7539). Accordingly, we proposed to allow the intake add-on code to be billed for audio-only telecommunications for initiation of treatment with methadone if these specific exceptions are met, consistent with SAMHSA guidance at § 8.12(f)(2)(v)(A).

We believed that this proposal would meaningfully improve access to care, promote positive health outcomes, and advance health equity among Medicare beneficiaries. Data indicate that expanded use of telehealth and flexibilities for the provision of MOUD during the COVID–19 pandemic was associated with improved care retention and a reduction in medically treated overdoses among Medicare beneficiaries.[425] Similarly, telehealth initiation for buprenorphine to treat OUD was associated with improved treatment retention in a subset of U.S States.[426] Other research has not found significant differences in clinical severity and complexity markers (for example, OUD-related emergency department visits) between patients receiving telemedicine inductions into treatment versus in-person examinations,[427] suggesting that quality of care can be maintained through initiation of treatments via telehealth. Thus, many of these benefits associated with telehealth flexibilities for initiating treatment with other MOUDs can be potentially replicated by allowing initiation of treatment with methadone via audio-visual telecommunications. Additionally, we believed this proposal would meaningfully impact health equity. Individuals from Black, American Indian and Alaska Native, and Hispanic populations are significantly less likely to initiate treatment for a SUD, as well as individuals from economically disadvantaged communities.[428] Despite these disparities, during the COVID–19 pandemic, the odds of initiating treatment for a SUD increased for most age, race, ethnicity, and socioeconomic status subgroups, which may have been explained by increases in treatment initiation occurring through telehealth.[429] Thus, promoting flexibilities for telecommunication modalities of treatment initiation in regards to methadone may provide additional options for accessing treatment, especially for populations who often experience barriers in beginning treatment. Lastly, we believed this proposal was in alignment with the HHS Overdose Prevention Strategy, which aims to broaden access to evidence-based care that increases willingness to engage and remain in treatment.[430] Similarly, we believed this proposal would further the goals of the National Drug Control Strategy, which strives to expand policies that improve SUD treatment engagement by lowering various barriers to enter and participate in treatment, such as through telemedicine treatment initiation.[431]

Accordingly, we proposed to revise the regulations for intake activities at paragraph (vi) within the definition of ''Opioid use disorder treatment service'' at § 410.67(b). We proposed to add a new paragraph (vi)(A) within the description of intake activities to separately list flexibilities for intake activities furnished via communications technology, and we proposed to add and reserve a new paragraph (vi)(B). We proposed to move the language related to the existing flexibilities for the initiation of treatment with buprenorphine to paragraph (vi)(A)(*1*). Additionally, in the definition of ''Opioid use disorder treatment service''

[423] *https://www.dea.gov/drug-information/drug-scheduling.*

[424] Whelan, P.J., & Remski, K. (2012). ''Buprenorphine vs methadone treatment: A review of evidence in both developed and developing worlds.'' Journal of Neurosciences in Rural Practice, 3(1), 45–50. *https://doi.org/10.4103/0976-3147.91934.*

[425] Jones, C.M., Shoff, C., Hodges, K., Blanco, C., Losby, J.L., Ling, S.M., & Compton, W.M. (2022). ''Receipt of telehealth services, receipt and retention of medications for opioid use disorder, and medically treated overdose among Medicare beneficiaries before and during the covid–19 pandemic.'' JAMA Psychiatry, 79(10), 981–992. *https://doi.org/10.1001/jamapsychiatry.2022.2284.*

[426] Hammerslag, L.R., Mack, A., Chandler, R.K., Fanucchi, L.C., Feaster, D.J., LaRochelle, M.R., Lofwall, M.R., Nau, M., Villani, J., Walsh, S.L., Westgate, P.M., Slavova, S., & Talbert, J.C. (2023). ''Telemedicine buprenorphine initiation and retention in opioid use disorder treatment for Medicaid enrollees.'' JAMA Network Open, 6(10), e2336914. *https://doi.org/10.1001/jamanetworkopen.2023.36914.*

[427] Barsky, B.A., Busch, A.B., Patel, S.Y., Mehrotra, A., & Huskamp, H.A. (2022). ''Use of telemedicine for buprenorphine inductions in patients with commercial insurance or Medicare advantage.'' JAMA Network Open, 5(1), e2142531. *https://doi.org/10.1001/jamanetworkopen.2021.42531.*

[428] Acevedo, A., Panas, L., Garnick, D., Acevedo-Garcia, D., Miles, J., Ritter, G., & Campbell, K. (2018). ''Disparities in the treatment of substance use disorders: Does where you live matter?'' The Journal of Behavioral Health Services & Research, 45(4), 533–549. *https://doi.org/10.1007/s11414-018-9586-y.*

[429] Palzes, V.A., Chi, F.W., Metz, V.E., Sterling, S., Asyyed, A., Ridout, K.K., & Campbell, C.I. (2023). ''Overall and telehealth addiction treatment utilization by age, race, ethnicity, and socioeconomic status in California after covid–19 policy changes.'' JAMA Health Forum, 4(5), e231018. *https://doi.org/10.1001/jamahealthforum.2023.1018.*

[430] *https://www.hhs.gov/overdose-prevention/.*

[431] *https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.*

at § 410.67(b), we proposed to codify telecommunications flexibilities for initiation of treatment with methadone at paragraph (vi)(A)(*2*). Specifically, we proposed that services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if an OTP determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology. We received public comments on our proposal to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone if the OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform.

The following is a summary of the comments we received and our responses.

Comment: We received many comments in strong support of this proposal. Commenters expressed that providing the flexibility to initiate methadone treatment via audio-video telecommunications would improve access to care, advance health equity, and encourage positive health outcomes. Commenters shared that many individuals face geographic or social challenges to engaging in OUD treatment, and others may have an immediate need for treatment with methadone but face barriers to initiating treatment due to the need to coordinate transportation, childcare, work schedules, or other complicating factors. Commenters further added that this flexibility would assist in reducing barriers to care since it would limit the need for patients to travel to and from appointments when initiating treatment with methadone, which is a difficulty faced by many individuals from rural communities and other underserved populations. A few commenters noted that this telecommunications flexibility is needed, as OTPs are one of the few settings where beneficiaries can receive this medication. Multiple commenters agreed with CMS on the necessity of requiring audio-video telecommunications when initiating treatment with methadone. Specifically, commenters concurred that methadone is distinct from buprenorphine, given both its risk for sedation and complex pharmacokinetics. For these reasons, commenters stated that utilizing audio-visual telecommunications for methadone treatment initiation would address potential safety concerns by allowing the OTP to monitor the patients via audio-video telecommunications technology, while still increasing access to care and maintaining care quality.

Response: We thank commenters for their support of this proposal.

Comment: One commenter stated that while they believe extending the COVID–19 PHE telecommunications flexibilities is important as they are approaching expiration, they do not believe that controlled substances should be prescribed without an initial in-person visit.

Response: We agree that there could be limited instances where it may not be appropriate for an OTP to initiate treatment with methadone via audio-visual communication technology for a particular patient without an in-person visit. However, as we stated in the proposed rule, existing evidence has demonstrated that initiating OUD treatment via audio-visual communications technology can be done in a manner that maintains quality of care and safety for patients. For example, some research has not found significant differences in clinical outcomes (for example, OUD-related emergency department visits or severity of an OUD) between patients receiving telemedicine inductions into treatment versus in-person examinations, suggesting that telemedicine inductions to OUD treatment can serve as an appropriate substitute for in-person visits in many cases.[432] Furthermore, we believe limiting the use of audio-video telecommunication technology to instances where an OTP determines that an adequate evaluation of the patient can be accomplished via an audio-video platform requires the OTP to evaluate on an individual basis if audio-video communication technology is an appropriate modality for initiating methadone treatment. We note that our proposal to allow OTPs to initiate methadone treatment via audio-video communication technology was meant to be a flexibility and not a requirement, meaning that we intended OTPs could still choose to see the patient in person instead. Lastly, CMS defers to program requirements established by SAMHSA and the DEA concerning when these communication technology services can be furnished before they can be billed for under the Medicare OTP benefit, including program requirements relating to initiation of MOUD through various forms of telecommunications and in-person visit requirements.

Comment: A few commenters, including some representing tribal populations, requested that CMS consider extending flexibilities to allow initiation of treatment with methadone via audio-only telecommunications. One commenter asked the agency to evaluate the evidence and appropriateness of enabling audio-only treatment initiation of methadone, including by partnering with external research organizations to assess this topic, improve parity in flexibilities for buprenorphine and methadone, and reduce stigma around methadone. This same commenter suggested that CMS should consider in the interim, implementing waivers for individual cases where an audio-only telecommunications evaluation of the patient is the only means that a patient can access services, or where there is an insufficient supply of OTP providers in the area to prescribe or dispense methadone.

Response: We appreciate the feedback shared by commenters. We agree that it is important to continue to monitor and evaluate the evidence of the appropriateness of various telecommunication flexibilities furnished in the OTP setting. In proposing to allow initiation of treatment with methadone utilizing audio-video telecommunications if an OTP determines that an adequate evaluation of the patient can be accomplished via an audio-video platform, we considered the existing evidence based on safety and quality of these assessments conducted via telecommunications platforms, including potentially via audio-only telecommunications. As we stated in the proposed rule (89 FR 61822), methadone is characterized as a schedule II-controlled substance, which means that it has higher potential for misuse with potential physical dependence, thus there are potential safety concerns associated with conducting these type of assessments through audio-only platforms.[433] Additionally, CMS believes it is important to ensure telecommunication flexibilities allowed in OTP settings are consistent with existing guidance by SAMHSA and the DEA to ensure the health and safety of Medicare beneficiaries. As we stated in the discussion above, SAMHSA allows a specific exception to the use of audio-only initiation of treatment with

[432] Barsky, B.A., Busch, A.B., Patel, S.Y., Mehrotra, A., & Huskamp, H.A. (2022). ''Use of telemedicine for buprenorphine inductions in patients with commercial insurance or Medicare advantage.'' JAMA Network Open, 5(1), e2142531. *https://doi.org/10.1001/jamanetworkopen.2021.42531.*

[433] *4https://www.dea.gov/drug-information/drug-scheduling.*

methadone pursuant to § 8.12(f)(2)(v)(A), which allows for the use of audio-only devices when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications, and when audio-visual technologies are not available or their use is not feasible for a patient (89 FR 7539). If these specific exceptions are met, CMS will allow the intake add-on code to be billed for audio-only telecommunications for initiation of treatment with methadone consistent with SAMHSA requirements at § 8.12(f)(2)(v)(A). CMS believes in the importance of expanding access to services under the OTP benefit and will continue to collaborate with Federal partners to continually monitor these various telecommunication flexibilities and propose updates in future rulemaking as appropriate.

After consideration of public comments, we are finalizing our proposal to allow the OTP intake add-on code (HCPCS code G2076) to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone, to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished, and if the OTP determines that an adequate evaluation of the patient can be accomplished via audio-video communication technology. We are finalizing our revisions to intake activities within the definition of ''opioid use disorder treatment service'' at § 410.67(b) by adding new paragraphs (vi)(A) and (vi)(B) within the description of intake activities at paragraph (vi). We are moving the language related to the existing flexibilities for the initiation of treatment with buprenorphine to paragraph (vi)(A)(1) to separately list flexibilities for intake activities furnished via communications technology. In the definition of ''opioid use disorder treatment service'' at § 410.67(b), we are codifying telecommunications flexibilities for initiation of treatment with methadone at paragraph (vi)(A)(2). Specifically, we are codifying that services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if an OTP determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology. We are reserving new paragraph (vi)(B).

3. Reforms to 42 CFR Part 8

In the CY 2020 PFS final rule, we implemented payment and coverage for opioid use disorder treatment services, including services such as substance use counseling by a professional to the extent authorized under State law to furnish such services, individual and group therapy with a physician, psychologist (or other mental health professional to the extent authorized under State law), and other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation), as authorized by section 1861 of the Act (84 FR 62630 through 62677 and 84 FR 62919 through 62926). Consequently, we included these services within the definition of OUD treatment services at § 410.67(b) and incorporated payment for these services as part of the non-drug component at § 410.67(d)(2)(ii). We also created an add-on code described by HCPCS code G2080 to reflect an additional 30 minutes of counseling or individual or group therapy provided in a week. We further finalized additional adjustments to the bundled payment for an episode of care, such as intake activities and periodic assessments. At the time, we noted that both initial and periodic assessments are required under SAMHSA regulations, and that they were integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP (84 FR 62634). We codified definitions of these services within the definition of *OUD treatment services* at § 410.67(b); at paragraph (vi), we stated that intake activities include initial medical examination services required under § 8.12(f)(2), and initial assessment services required under § 8.12(f)(4); at paragraph (vii) we stated that periodic assessment services include those required under § 8.12(f)(4). Services under § 8.12(f) are required services as part of Federal opioid treatment standards for OTPs, as regulated by SAMHSA. Accordingly, we created HCPCS code G2076 [*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*], and code G2077 [*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*] in order to have a mechanism to make payment under Medicare to OTPs for these required services. In the CY 2021 and CY 2022 PFS final rules (85 FR 84682 through 84690; 86 FR 65338 through 65341), we also established payment for take-home supplies of naloxone and overdose education furnished in conjunction with providing an opioid antagonist medication.

Additionally, in the CY 2020 PFS final rule, we codified requirements specified in the section 1861(jjj)(2) of the Act for OTPs. Specifically, we defined an ''opioid treatment program'' at § 410.67(b) as an entity that is an OTP as defined in § 8.2 (or any successor regulation) that meets the applicable requirements for an OTP. For an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled in Medicare under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. Lastly, an OTP must meet additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

Recently, SAMHSA issued a new final rule (89 FR 7528), which made significant reforms to 42 CFR part 8, governing requirements for OTPs in providing medications for the treatment of OUD and many other services. The rule provides significant refinements, as 42 CFR part 8 was originally published over 21 years ago, by reflecting new paradigms of care for OUD that have become increasingly patient-centered and evidence-based. The regulatory reforms for opioid treatment standards reflect an understanding that OUD is a chronic disease that necessitates respective patient-centered care, and to be successful, treatment interventions should be individualized and include harm reduction and recovery support

services, among other services.[434] Consequently, SAMHSA redefined comprehensive treatment at § 8.2 to specify that comprehensive treatment at OTPs includes ''the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.'' At the same time, SAMHSA constructed a new definition of harm reduction services at § 8.2 to specify that harm reduction ''refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.'' Harm reduction approaches are especially important to reduce certain health and safety issues associated with drug use through care that is intended to be free of stigma and centered on the needs of people who use drugs. Decades of research have shown that harm reduction strategies provide significant benefits in preventing drug overdose deaths and transmission of infectious diseases among those who use drugs, educate individuals and community members about reducing the negative consequences associated with drug use, and link individuals to SUD treatment and other recovery resources.[435] Harm reduction is also a crucial component of the HHS Overdose Prevention Strategy, which aims to promote evidence-based harm reduction services, including those that are integrated within healthcare delivery, and to expand sustainable funding strategies for harm reduction services.[436] Besides defining harm reduction, SAMHSA also finalized a new definition for ''recovery support services'' at § 8.2, which includes definitions for ''recovery,'' and ''recovery support services.'' Specifically, ''recovery'' is defined as ''the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.'' ''Recovery support services'' ''can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages.'' Recovery support services are a vital part SUD treatment, as they take into account the relapsing and chronic nature of SUD, and emphasize the need for continuous care to keep individuals engaged in treatment, especially along different stages of recovery.[437] Recovery support services are also a component of the HHS Overdose Prevention Strategy, which recognizes that treatment alone may not be enough to support long-term recovery, and that enabling access to quality integrated and coordinated recovery support services is important to prevent drug overdoses.[438]

Furthermore, SAMHSA made updates to existing definitions that include some of the services currently covered under the Medicare OTP benefit. For example, a psychoeducational service element was added to the definition of counseling services at § 8.12(f)(5), so that both counseling and psychoeducational services would also include harm reduction education and recovery-oriented counseling. New guidelines on counseling related to preventing exposure to and transmission of various infectious diseases were also added. As part of these services, at § 8.12(f)(5)(iii), OTPs also must continue to provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff. Notably, SAMHSA also made updates to their descriptions of initial and periodic assessment activities at § 8.12(f)(4), which initially informed the definitions of intake activities and periodic assessments in the definition of ''OUD treatment services'' at § 410.67(b) and the creation of codes describing these services (HCPCS codes G2076 and G2077) when CMS first implemented the Medicare OTP benefit in the CY 2020 PFS final rule. When introducing these changes in their proposed rule in December 2022 (87 FR 77330), SAMHSA noted that ''changes to the initial and periodic medical services sections are intended to promote key issues for OTP medical practitioners and the OTP multi-disciplinary team to address with a patient as part of treatment. This includes areas that may increase the risk of a patient leaving care prematurely, such as unmet mental health or other disability, medical and oral health needs, the need for culturally supportive care that addresses race, ethnicity, sexual orientation, religion or gender identity, and social determinants of health, such as housing and transportation, that may pose barriers to treatment engagement, or harm reduction and recovery support service needs.'' SAMHSA's new changes to the definition of initial assessments now include more patient-centered language to ensure that care provided is consistent with the patient's needs and self-identified goals for treatment and recovery, while promoting shared decision making between the OTP practitioner and patient to create individualized care plans. SAMHSA's revisions to initial assessments reflect the need for care plans to include the patient's goals and mutually agreed-upon actions for the patient to meet those goals, and new references are added for harm reduction interventions and recovery support services to be included as components of care plans if a patient needs and wishes to pursue these services. For example, patient-centered care plans developed during initial assessments may reflect a ''patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue (89 FR 7558).'' Lastly, regarding periodic assessment services at § 8.12(f)(4)(ii), SAMHSA requires that these examinations should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing,

[434] 89 FR 7528, February 2, 2024 (*https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder*).

[435] *https://www.cdc.gov/overdose-prevention/php/od2a/harm-reduction.html. https://nida.nih.gov/research-topics/harm-reduction.*

[436] *https://www.hhs.gov/overdose-prevention/harm-reduction.*

[437] Stanojlović, M., & Davidson, L. (2021). ''Targeting the barriers in the substance use disorder continuum of care with peer recovery support.'' Substance Abuse: Research and Treatment, 15, 117822182097698. *https://doi.org/10.1177/1178221820976988; https://www.samhsa.gov/find-help/recovery.*

[438] *https://www.hhs.gov/overdose-prevention/recovery-support.*

treatment response, other SUD treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

As a whole, SAMHSA'S regulatory changes largely reflect significant changes in evidence-based practice and towards patient-centered care in the treatment of OUD that have occurred in the past couple of decades, including considerations of the need to address unmet health related social needs (HRSN) that impose barriers on a patient's ability to initiate, engage, and remain in treatment, including in areas of education, employment, and housing as well as in harm reduction strategies that decrease the negative consequences associated with a patient's use or abuse of opioids, and recovery support services that address the chronic nature of OUD and the need for supports across the full continuum of care.

In addition to these reforms to opioid treatment standards at 42 CFR part 8 codified by SAMHSA, there have been recent activities under the Medicare in the PFS, and through other CMS programs, that have addressed the social determinants of health (SDOH), which often affect the diagnosis and treatment of a patient's medical problem. Healthy People 2030, which is a 10-year HHS initiative to identify public health priorities that help individuals, organizations, and communities across the U.S improve health and well-being,[439] defines the SDOH, as the ''conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' [440] SDOH include many domains that largely impact health, including economic stability, education, healthcare, the neighborhood and built environment, and social and community context. Some studies have estimated that SDOH can affect as much as 50 percent of the variation in health outcomes compared to clinical care impacting only 20 percent.[441] For example, individuals with a higher income have been found to exhibit lower mortality, higher life expectancy, and slower declines in physical mobility; individuals who lack insurance are less likely to obtain necessary medical care and prescription medications; and, food insecurity is associated with higher rates of birth defects, cognitive problems, hospitalization rates, asthma, and behavioral health problems.[442] Moreover, SDOH act as structural and contextual factors that shape the conditions impacting health, and their unequal distribution impacts the development of HRSNs at the individual level, which refer to an individual's needs that might include housing, healthy foods, transportation, financial assistance, etc. An inability to address these HRSNs put individuals at a higher risk for exacerbating health conditions, and it is a major driver of health inequities.[443] Health equity is the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes, which is complicated by SDOH such as poverty, unequal access to healthcare, lack of education or employment, stigma, and discrimination.[444] Therefore, in light of decades of research showing that these upstream factors drive health outcomes, and evidence suggesting interventions in healthcare settings that address social needs can improve the treatment of an individual's condition, CMS recently finalized coding and payment for SDOH risk assessments in the CY 2024 PFS final rule (88 FR 78932). HCPCS code G0136 describes SDOH risk assessments (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*) that may be billed when practitioners spend time and resources assessing HRSNs that interfere with the practitioner's ability to diagnose or treat the patient. These assessments, which may also be provided during a behavioral health visit, are often administered as part of an assessment of patient histories, risk, and in informing medical decision-making around the care and treatment of the disease or illness. They are often accomplished through the use of a standardized evidence-based tool that include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties. Besides establishing standalone payment for SDOH risk assessments, in the CY 2024 PFS final rule, CMS also created coding and payment for community health integration (CHI) (HCPCS codes G0019 & G0022) and principal illness navigation services (PIN) (HCPCS codes G0023, G0024, G0140, and G0146). Both CHI and PIN services include: performing a person-centered assessment to better understand the patient's life story, coordinating care coordination between different providers and care settings, contextualizing health education, building patient self-advocacy skills, assisting the patient with health system navigation, facilitating behavioral change, providing social and emotional support, and facilitating access to community-based social services (for example, housing, utilities, transportation, food assistance) to address unmet SDOH needs. The services described by the CHI codes address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems. PIN services focus on Medicare beneficiaries diagnosed with high-risk conditions (for example, dementia, HIV/AIDS, and cancer) in order to identify and connect them with appropriate clinical and support resources.

Moreover, many of these aforementioned services, including harm reduction interventions, recovery support services, addressing HRSN, and facilitating access to community-based social services to address these needs, ordinarily occur in OTP settings. In 2022, approximately 92 percent of OTP facilities offered various recovery support services, including peer support (59.6 percent), assistance locating housing for clients (75.0 percent), employment counseling (49.5 percent),

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[439] *https://health.gov/healthypeople/about#:~:text=What%20is%20Healthy%20People%202030,over%20the%20first%204%20decades.*

[440] *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[441] Whitman, A., Chapell, A., Aysola, V., Zuckerman, R., & Sommers, B. (2022). ''Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts'' (ASPE, Office of Health Policy HP–2022–12). *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf;* Hood, C.M., Gennuso, K.P., Swain, G.R., & Catlin, B.B. (2016). ''County health rankings: Relationships between determinant factors and health outcomes.'' American Journal of Preventive Medicine, 50(2), 129–135. *https://doi.org/10.1016/j.amepre.2015.08.024.*

[442] National Academies of Sciences, E., Medicine, N.A. of, Nursing 2020–2030, C. on the F. of, Flaubert, J.L., Menestrel, S.L., Williams, D.R., & Wakefield, M.K. (2021). ''Social determinants of health and health equity. In The Future of Nursing 2020–2030: Charting a Path to Achieve Health Equity.'' National Academies Press (U.S.). *https://www.ncbi.nlm.nih.gov/books/NBK573923/.*

[443] Whitman, A., Chapell, A., Aysola, V., Zuckerman, R., & Sommers, B. (2022). ''Addressing Social Determinants of Health: Examples of Successful Evidence-Based Strategies and Current Federal Efforts'' (ASPE, Office of Health Policy HP–2022–12). *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf; https://www.whitehouse.gov/wp-content/uploads/2023/11/SDOH-Playbook-3.pdf.*

[444] *https://www.cms.gov/pillar/health-equity.*

and assistance helping patients obtain social services (81.2 percent). The majority of OTPs also offered various types of harm reduction services, including testing for various types of infectious diseases (>55 percent), health education (>77 percent), and naloxone and overdose education (92.3 percent). Many OTPs also conduct community outreach services to those in need of OUD treatment (76.1 percent) and case management services (87.8 percent).[445] Additionally, as part of initial and periodic assessment services at § 8.12(f)(4), OTPs must designate in the care plan a patient's needs and goals in the areas of harm reduction interventions, education, vocational training, and employment, along with the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, which all reflect consideration to various HRSN. The new definitions of harm reduction and recovery support services at § 8.2 are also inclusive of activities that involve linkage to and coordination with providers that address a full range of human and public health services to facilitate recovery and wellness for a SUD. Lastly, in the CY 2020 PFS final rule we responded to public comments pertaining to the above-mentioned activities. Specifically, several commenters stated that OTPs often provide case management and/or care management services and requested that CMS consider reimbursing for these services either as part of the standard bundle or as an adjustment to the bundled payment, as applicable. A few commenters stated that OTPs serve as a fixed point of responsibility in the provision of whole person-centered care and improving health outcomes through collaborative arrangements with health care providers outside of the OTP and that the goal of care management is to reduce health care costs, specifically preventable hospital admissions, readmissions, and avoidable emergency room visits. The commenters also stated in the CY 2020 final rule that OTP staff also help patients with accessing food benefits, housing, and employment searches, which are critical components for sustained recovery, as part of the goal of complete case management (84 FR 62648). At the time, CMS stated that we would consider making payment for these types of care management activities in future rulemaking, including activities whereby OTPs collaborate with providers outside the OTPs to help patients access social services. We believed it was appropriate to work with OTPs to better understand how these services are furnished in an OTP setting, as well as to continue to look at data on specific items and services that may fit within the scope of OUD treatment services.

a. Payment for Social Determinants of Health Risk Assessments

The recent refinements to initial assessments under § 8.12(f)(4)(i) likely necessitate additional resource costs for OTPs to comply with the opioid treatment standards for assessing various SDOHs (for example, education, vocational training, employment, economic, legal, housing, etc.) that impact a patient's HRSNs, and to identify a patient's goals for harm reduction interventions and needs for recovery support services as they relate to the treatment of an OUD. We recognize that the paradigm for OUD treatment and care has evolved rapidly since the implementation of the Medicare OTP benefit in CY 2020, and that providers have increasingly incorporated interventions to address HRSNs that increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement. We additionally acknowledge that coding already exists under the PFS that accounts for the resources involved in conducting these types of assessments. For these reasons, in the CY 2025 PFS proposed rule we proposed to establish payment for SDOH risk assessments as part of intake activities within OUD treatment services, as long as these assessments are medically reasonable and necessary for the diagnosis or treatment of an OUD, and OTPs have a reason to believe unmet HRSNs or the need for harm reduction intervention or recovery support services identified during such an assessment could interfere with the OTP's ability to diagnose or treat the patient's OUD. As previously stated, the SDOH include broad structural and contextual domains that may impact health (for example, economic stability, education, healthcare, neighborhood and built environment, and social and community context) and the development of HRSNs at the individual-level (for example, housing and utilities assistance, transportation assistance, financial assistance, healthy foods, personal safety, employment, recovery support and harm reduction services). We understand that there are multiple standardized, evidence-based SDOH risk-assessment tools utilized across the healthcare system that are structured to assess a patient across various SDOH domains.[446] If an OTP furnishes SDOH risk assessments as part of initial assessments under § 8.12(f)(4)(i), we would expect that the assessment tools used would allow the OTP to identify more specific individual-level HRSNs as part of the care plan, including giving consideration to potential harm reduction and recovery support services needs.

Specifically, we proposed to update the payment rate for intake activities described by HCPCS code G2076 by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code (G0136). We believe HCPCS code G0136 may serve as a reasonable proxy to reflect the value and resources required for the type of assessment service activities that OTPs are required to provide according to SAMHSA requirements under § 8.12(f)(4)(i), including an assessment to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services that are critical to the treatment of an OUD. We understand that OTPs have been involved in collaborative agreements with organizations who address HRSNs and offer various recovery support services (84 FR 62648), and we believe that for OTPs to appropriately identify these types of organizations that target a specific need, identifying these HRSNs as part of SDOH risk assessments is likely needed prior to engaging in activities to coordinate service delivery. However, we solicited comment on whether these types of SDOH assessments ordinarily complement the type of community coordination activities that OTPs perform.

Establishing payment to account for SDOH risk assessments as part of intake activities under the OTP benefit is important, as unmet HRSNs identified as part of such assessments significantly impact outcomes for OUD treatment. Evidence shows that healthcare providers who screen for SDOH in their settings have found that patients who screen positive for a HRSN were significantly more likely to have a history of substance use or mental illness compared to patients who did not have an HRSN.[447] For example, one

[445] Table SU17b: Substance use treatment facilities, by services provided and facility type: Number and column percent, 2022: *https://www.samhsa.gov/data/sites/default/files/reports/rpt42714/NSUMHSS-Annual-Detailed-Tables-22.pdf*.

[446] *https://prapare.org/wp-content/uploads/2021/10/What-is-PRAPARE_2.1.21-1.pdf; https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion*.

[447] Chukmaitov, A., Dahman, B., Garland, S.L., Dow, A., Parsons, P.L., Harris, K.A., & Sheppard, Continued

review found that between 50 to 90 percent of patients in publicly funded OTPs were unemployed, and that older adults identified to have misused opioids were 22-percent less likely to be employed.[448] Patients with an OUD are also more likely to have a lower educational attainment, encounter financial hardship, and housing instability.[449] Even more, food insecurity has been indicated to be a strong predictor of prescription opioid misuse and abuse.[450] The SDOH and their contribution to unmet HRSNs have also heavily impacted the rates of drug overdoses. For example, one study examined 28 different SDOH measures that collectively explained 89-percent of the variance in drug-overdose mortality across States.[451] Housing insecurity, in particular, negatively affects the population with an OUD, as this risk factor has been increasing over time among those seeking treatment with an OUD.[452] One analysis conducted by the State of Massachusetts has revealed alarming evidence that the risk of death from an opioid overdose is 30-times higher for those who have experienced homelessness.[453] Lower median household income and unemployment have also been associated with an increase in opioid death rates.[454] Moreover, unmet HRSNs have also hampered access to treatment among Medicare beneficiaries with a SUD, as evidence has shown that among Medicare beneficiaries with an SUD who were not receiving treatment, one-third reported financial barriers and one-fifth reported logistical barriers such as lack of access to transportation as rationales for not receiving treatment.[455] Lastly, many of these SDOH factors have impaired treatment retention and completion rates. Those with lower levels of educational attainment and who are unemployed are less likely to complete SUD treatment, and individuals who are experiencing homelessness are significantly less likely to remain in treatment.[456] Therefore, screening for the SDOH and identifying these unmet HRSNs as part of intake assessments may help OTPs link patients with an identified social need to appropriate resources that can impact the diagnosis of an OUD or address barriers to treating an OUD.

As previously stated, we proposed to update the adjustment to the bundled payment for an episode of care for intake activities (G2076) by adding in the value of the non-facility rate for SDOH risk assessments (G0136: *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*), which is currently assigned a non-facility rate of $18.66 under the PFS. At the time of ratesetting during the CY 2025 PFS proposed rule, the CY 2024 payment rate for the intake add-on code (G0276) was $201.73 and adding the value of a crosswalk to the CY 2024 non-facility rate of $18.66 resulted in a payment rate of approximately $220.39. We stated that we believed that incorporating the value of G0136 into the intake activities adjustment would be the most appropriate, as we believe assessment activities related to SDOH are more likely to occur during intake assessments when a new patient is admitted to an OTP. SAMHSA treatment guidelines recommend that during initial screenings, OTPs should identify barriers and medical and psychosocial risk-factors that may hinder a patient's ability to meet treatment requirements, including co-occurring health conditions, and vocational, legal, financial, transportation, and family concerns.[457] We noted that intake activities (G2076) should only be billed for new patients (that is, patients starting treatment at the OTP), and since SDOH risk assessments would be bundled into the code describing intake activities, this billing requirement would similarly apply. However, we solicited comment on the frequency with which these SDOH risk assessments occur, and whether it would be more appropriate if these assessments occur when OTPs furnish periodic assessments described by HCPCS code G2077.

When OTPs bill the intake add-on code (G2076), we did not propose to require that OTPs performed SDOH risk assessments in a specific manner, but rather that OTPs continued to perform initial assessment services consistent with SAMHSA certification requirements at § 8.12(f)(4)(i) that already largely reflect these type of SDOH risk assessment activities; and, that OTPs abided by other applicable requirements under the Medicare OTP benefit at § 410.67, including those listed in the definition of intake activities at paragraph (vi) within the definition of ''OUD treatment service'' at § 410.67(b). This also means that for the purposes of Medicare payment, if SDOH risk assessments are furnished, they must be related to the diagnosis or treatment of OUD, and any HRSNs identified through SDOH risk assessments performed should be documented in the patient's medical

V.B. (2022). ''Addressing social risk factors in the inpatient setting: Initial findings from a screening and referral pilot at an urban safety-net academic medical center in Virginia, USA.'' Preventive Medicine Reports, 29, 101935. *https://doi.org/10.1016/j.pmedr.2022.101935*.

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[453] *https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf*.

[454] Rangachari, P., Govindarajan, A., Mehta, R., Seehusen, D., & Rethemeyer, R.K. (2022). ''The relationship between Social Determinants of Health (Sdoh) and death from cardiovascular disease or opioid use in counties across the United States (2009–2018).'' BMC Public Health, 22(1), 236. *https://doi.org/10.1186/s12889-022-12653-8;* Hollingsworth, A., Ruhm, C.J., & Simon, K. (2017). Macroeconomic conditions and opioid abuse (Working Paper 23192). National Bureau of Economic Research. *https://doi.org/10.3386/w23192*.

[455] Parish, W.J., Mark, T.L., Weber, E.M., & Steinberg, D.G. (2022). ''Substance use disorders among Medicare beneficiaries: Prevalence, mental and physical comorbidities, and treatment barriers.'' American Journal of Preventive Medicine, 63(2), 225–232. *https://doi.org/10.1016/j.amepre.2022.01.021*.

[456] Mennis, J., & Stahler, G.J. (2016). Racial and ethnic disparities in outpatient substance use disorder treatment episode completion for different substances. Journal of Substance Abuse Treatment, 63, 25–33. *https://doi.org/10.1016/j.jsat.2015.12.007;* Gaeta Gazzola, M., Carmichael, I.D., Christian, N.J., Zheng, X., Madden, L.M., & Barry, D.T. (2023). ''A national study of homelessness, social determinants of health, and treatment engagement among outpatient medication for opioid use disorder-seeking individuals in the United States.'' Substance Abuse, 44(1–2), 62–72. *https://doi.org/10.1177/0889707723116729*.

[457] SAMHSA. (2012). Medication-assisted treatment for opioid addiction in opioid treatment programs. *https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf_NBK64164.pdf*.

record to indicate how assessing and addressing the HRSN relates to the treatment and diagnosis of an OUD. We reiterate that our proposal to incorporate the value of HCPCS code G0136 into the OTP intake add-on code (G2076) is meant to serve as a reasonable proxy to reflect the value and resources of the type of initial assessment service activities that OTPs are required to provide under SAMHSA requirements, which now include more specific updates to a patient's care plan with considerations of a patient's goals related to harm reduction interventions, needs for recovery support services, and other HRSNs. However, if OTPs utilize SDOH risk assessments during intake activities, CMS did not propose to require OTPs to utilize a specific type of SDOH risk assessment tool, consistent with similar existing requirements under the PFS for these services. If OTPs do furnish these assessment services, CMS encourages OTPs to adopt evidence-based, validated tools that are already available (such as the CMS Accountable Health Communities tool, the Protocol for Responding to and Assessing Patients Assets, Risks and Experiences (PRAPARE), and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment);[458] that include the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties, and that can be furnished in a manner appropriate for the patient's educational, developmental, and health literacy level, and that are culturally and linguistically appropriate. We understand that there is not a national consensus around one specific tool, and OTPs should choose the tool that fits their needs and allows them to appropriately detect unmet HRSNs, as well as other needs for harm reduction interventions and recovery support services that are integral to the treatment of an OUD.

Lastly, in light of these proposed changes, we proposed to revise the current descriptor for the intake add-on code for consistency with revisions to § 8.12(f)(4)(i) and to reflect furnishing an SDOH risk assessment: G2076 (*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a care plan, which may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, and that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*).

We received many public comments from a variety of interested parties on this proposal to establish payment for SDOH risk assessments as part of intake activities within OUD treatment services to support activities at an OTP that identify a patient's unmet HRSNs or the need and interest for harm reduction interventions and recovery support services that are critical to the treatment of an OUD. The following is a summary of the comments we received and our responses.

Comment: We received many comments that supported our proposal to establish payment for intake activities to account for SDOH risk assessments that allow an OTP to identify unmet HRSNs that could interfere with the OTP's ability to diagnose or treat the patient's OUD. Commenters agreed that recent regulatory reforms to OUD treatment finalized by SAMHSA necessitate additional resources for OTPs to implement the new changes. Commenters stated that improving the valuation of intake activities by accounting for SDOH risk assessments would align with new paradigms of whole-person-centered care for OUD treatment. Commenters noted that the proposed update would help OTPs address key issues during intake activities that increase the risk of a patient leaving OUD treatment prematurely or that pose barriers to treatment engagement and allow an OTP to identify appropriate harm reduction interventions, recovery support service needs, or other supports to address unmet HRSNs. Commenters also noted that some accrediting organizations require HRSNs to be assessed as part of a patient's initial assessment, and that establishing payment for intake activities to account for these assessments may further incentivize these assessments as a standard practice at OTP intakes. One commenter agreed with CMS' proposal not to require a specific SDOH risk assessment screening tool if an OTP conducts these assessments during intake activities, but rather to provide OTPs the discretion to select the most appropriate and evidence-based, validated tool.

Furthermore, commenters believe that these proposed updates would help promote health equity while improving the quality of treatment provided at OTPs. Commenters shared that beneficiaries with an OUD may experience greater disparities in accessing safe housing, transportation, education, and job training, and are more likely to have limited financial resources, difficulty accessing medical care, underemployment, and underinsurance. Thus, interventions designed to address these needs could reduce barriers to seeking care, improving health outcomes, and increasing the likelihood of treatment success.

Response: We appreciate these comments that validate the need to update intake activities to account for SDOH risk assessments to promote new paradigms of care for OUD treatment, as well as to allow OTPs to effectively address key issues that increase the risk of a patient prematurely leaving OUD treatment or that create barriers to engaging in OUD treatment.

Comment: One commenter encouraged CMS to make SDOH risk assessments optional as part of intake activities for both the OTP and beneficiary. The commenter reasoned that there may be some circumstances that prevent OTPs from being able to administer an SDOH risk assessment during intake activities, such as a patient being under the influence or unable to answer questions.

Response: We agree with the commenter that there could be circumstances that impact OTPs being able to effectively assess the patient and perform an SDOH risk assessment. However, OTPs must perform initial assessment services consistent with SAMHSA certification requirements at § 8.12(f)(4)(i) that already largely reflect these types of SDOH risk assessment activities. In the proposed rule, we did not propose to require that OTPs perform SDOH risk assessments in a specific manner. (89 FR 61828) We understand that there are various types of validated SDOH risk assessment tools available that OTPs may use to conduct these assessments, and OTPs are best suited to evaluate when and how to appropriately conduct these assessments after considering clinical

[458] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf; https://www.nachc.org/research-and-data/prapare/;* CMS–10825.

and situational circumstances of the patient.

Comment: One commenter mentioned that the code descriptor for the current SDOH risk assessment code (G0136) is based on assessments between 5–15 minutes that are not more often than every 6 months (G0136: *Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*). This commenter requested that we confirm the frequency for which this type of SDOH risk assessment could be billed in OTP settings, including whether it is permissible to bill for intake activities each time these SDOH risk assessments are furnished.

Response: We appreciate this question. Intake activities (HCPCS code G2076) may only be billed for new patients (that is, patients starting treatment at the OTP), and since SDOH risk assessments would be bundled into the code describing intake activities, this billing requirement would similarly apply. Thus, an OTP is not permitted to bill multiple intake activities via HCPCS code G2076 for existing patients.

Comment: One commenter stated that they did not believe CMS' proposed revision to the code descriptor for intake activities was appropriate, that is, HCPCS code G2076 (*Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a care plan, which may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, and that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*). The commenter highlighted that the language in the descriptor referring to initial medical examination and initial assessments specifies that these services are conducted by ''a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel.'' The commenter added that this specific language has been removed in SAMHSA's regulations at § 8.12(f)(2)(i) after the recent final rule, so the current code descriptor language is not in alignment with new regulatory requirements. Instead, the commenter requested that CMS update the code descriptor with current regulatory language that utilizes an ''appropriately licensed practitioner.''

Response: We appreciate the comment raising this important discrepancy. We agree that it is important for the code descriptor language to reflect current regulatory requirements for OTPs under 42 CFR part 8. Accordingly, we are finalizing a revision to the code descriptor of HCPCS code G2076 to be more inclusive to other types of professionals who may conduct these assessments in an OTP setting, as follows: (*Intake activities, including initial medical examination that is conducted by an appropriately licensed practitioner and preparation of a care plan, which may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, and that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue, conducted by an appropriately licensed/credentialed personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*).

Comment: A few commenters requested that CMS clarify the types of healthcare professionals who may receive payment for furnishing SDOH risk assessments during intake activities at OTPs. For example, commenters noted that clinical social workers, counselors, and nurses are often involved in assessment processes for identifying SDOH needs.

Response: In the CY 2025 PFS proposed rule, we did not propose to limit the types of professionals that can provide these aforementioned services. If OTPs furnish SDOH risk assessments during intake activities, they must continue to furnish these services consistent with SAMHSA certification requirements at § 8.12(f)(4)(i), which currently reflect that these initial assessment services may be furnished by ''appropriately licensed/credentialed personnel.''

Comment: One commenter requested that CMS clarify if SDOH risk assessment services can be billed in connection with discharge in OTP programs.

Response: There is no current coding under the Medicare OTP benefit that describes discharge planning or services, and we did not propose to include payment for SDOH risk assessments in connection with these types of services. We appreciate the commenter's question and may consider this topic for future rulemaking.

Comment: One commenter asked CMS to clarify whether these payment updates will have an impact on budget neutrality and urged CMS to not subject these payment updates to budget neutrality limitations to avoid potential financial impacts on the broader healthcare system.

Response: Although CMS typically includes proposals for modifications related to Medicare coverage for OUD treatment services furnished by OTPs within annual PFS rules, we note that the Medicare OTP benefit is wholly separate from services paid under the PFS and physician services, and for which payment is made under section 1848 of the Act, and is not subject to budget neutrality rules or limitations.

Comment: One commenter requested that the agency avoid payment conditions that require services to be medically reasonable and necessary prior to billing under the Medicare program, and to instead defer to the judgment of healthcare professionals.

Response: In general, the Medicare statute at section 1862(a)(1)(A) prohibits payment for items and services under Part A and Part B that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Although Congress has made some exceptions for some services, Congress has not made an exception for OUD treatment services. Thus, while we appreciate the commenter's suggestion, we are not adopting it. OUD treatment services furnished under the OTP benefit must be medically reasonable and necessary for the treatment of an OUD in order to be paid under Medicare Part B.

Comment: Multiple commenters stated that establishing payment for SDOH risk assessments should not just be limited to intake activities. Commenters highlighted several concerns, including: there may be

circumstances preventing OTPs from administering SDOH screenings at intake; patients may not be willing to answer sensitive SDOH questions at the time of intake since it takes time for patients to establish trust with their providers before sharing any treatment barriers they may face; intake activities in OTP settings involve a mix of multiple assessments and medical evaluations that are time-intensive, so additional assessments furnished may require multiple treatment sessions to complete; and the recovery process for patients with an OUD is rarely linear, and patients with an OUD often face changes in their SDOHs throughout treatment, including in economic circumstances, housing, and employment, which require the OTP to continuously reassess unmet HRSNs and update care plans. In raising these concerns, commenters recommended that CMS modify the frequency for which SDOH risk assessments could be billed. One commenter requested that CMS create separate coding to allow billing for additional SDOH reassessments if needed. Other commenters specifically asked that CMS also add the value of the SDOH risk assessment code (HCPCS code G0136) to the existing periodic assessments code (HCPCS code G2077) under the Medicare OTP benefit.

Response: We thank the commenters for these comments. CMS understands that OUD is a chronic condition, and that recovery is an ongoing, long-term process that may necessitate various supports across different stages of the continuum of care. While we proposed that OTPs would account for SDOH risk assessments as part of intake activities, we specifically sought comments on the frequency with which SDOH risk assessments occur and whether it would be more appropriate if those assessments occurred when OTPs furnish periodic assessments described by HCPCS code G2077 (89 FR 61827 through 61828). At the time of drafting the proposed rule, CMS did not have enough information to understand the extent to which SDOH risk assessments are performed following intake activities. However, we recognized that patients with an OUD are at a higher risk for having unmet HRSNs, including housing instability, financial hardship, food insecurity, unemployment, and lack of access to transportation.[459] In response to the proposed rule, commenters affirmed that these unmet HRSNs often require OTPs to continuously reassess a patient's unmet HRSNs and the needs for various harm reduction interventions and peer recovery supports throughout the duration of treatment in order to reduce potential barriers that may limit the likelihood of a patient's treatment success. Additionally, in the proposed rule, CMS did not initially consider various circumstances that may prevent an OTP from being able to perform SDOH risk assessments at intake, which commenters highlighted. These various circumstances include a patient not being able to answer sensitive SDOH questions at the beginning of treatment due to a lack of trust with their provider, or an OTP not being able to assess a patient who is under the influence. CMS was also made aware by commenters that these types of assessments take additional time and, in some cases, cannot be completed in full at the time of intake. Thus, we are persuaded by commenters that multiple SDOH risk assessments may be needed to address unmet HRSNs that impact OUD treatment outcomes when a patient is being treated at an OTP, so these types of assessments should not be limited to only intake activities that are payable under the Medicare OTP benefit for new patients. Therefore, we believe it is appropriate to finalize payment for SDOH risk assessments during periodic assessments in addition to intake activities. We note that when SAMHSA introduced changes to 42 CFR part 8, they intended also for changes to periodic assessments to promote key issues for OTPs to address with a patient as part of treatment, including ''areas that may increase the risk of a patient leaving care prematurely, such as unmet mental health or other disability, medical and oral health needs, the need for culturally supportive care that addresses race, ethnicity, sexual orientation, religion or gender identity, and social determinants of health, such as housing and transportation, that may pose barriers to treatment engagement, or harm reduction and recovery support service needs.'' (87 FR 77341) SAMHSA requires that periodic assessment services at § 8.12(f)(4)(ii) ''should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include a review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals.'' CMS understands that periodic assessments often build upon and adjust the care plan initially developed during intake activities, which may reflect various SDOH, harm reduction, and recovery support service needs. Therefore, consistent with the feedback shared by commenters, we believe it is appropriate to also update payment for periodic assessments (HCPCS code G2077) by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code (G0136). We believe that this update will reflect additional activities undertaken by OTPs to continuously reassess unmet HRSNs or the need for harm reduction interventions and recovery support services throughout various lengths of treatment and that are critical to the treatment of an OUD. Accordingly, we are also finalizing a revision to the code descriptor for periodic assessments to reflect furnishing an SDOH risk assessment and to reflect current regulatory requirements for periodic assessments furnished by OTPs under § 8.12(f)(4)(ii): G2076 (*Periodic assessment; assessing periodically by an OTP practitioner and includes a review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals; assessment may be informed by administration of a standardized, evidence-based Social Determinants of Health Risk Assessment to identify unmet health-related social needs, or the need and interest for harm reduction interventions and recovery support services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*). By adding the valuation of SDOH risk assessments into the code for periodic assessments, we are clarifying that this does not require OTPs to perform SDOH risk assessments during periodic assessments or in a specific manner or duration. Rather, as with intake activities, this valuation is similarly intended to serve as a proxy to reflect the additional effort needed by OTPs in line with new SAMHSA reforms. We continue to expect that OTPs perform periodic assessments consistent with SAMHSA certification requirements at § 8.12(f)(4)(ii).

After consideration of public comments, we are finalizing our proposal to update the payment rate for intake activities (HCPCS code G2076) by adding in the value of the non-facility rate for SDOH risk assessments (G0136). We are also updating the payment rate for periodic assessments (HCPCS code G2077) by adding in the value of the

[459] *https://doi.org/10.1016/j.pmedr.2022.101935; https://doi.org/10.1080/19371918.2021.1939831; https://doi.org/10.1016/j.japh.2023.02.016; https://doi.org/10.1016/j.ssmph.2021.100768.*

non-facility rate for SDOH risk assessments (G0136). We believe these updates are needed to reflect the value and resources of initial and periodic assessment activities required by OTPs to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services while remaining consistent with SAMHSA requirements at § 8.12(f)(4). The current CY 2024 non-facility rate for G0136 is $18.97, and this amount will be added to the current CY 2024 payment rates for the intake add-on code ($201.73) and periodic assessments add-on code ($123.96) for approximate final payment rates of $220.70 (HCPCS code G2076) and $142.93 (HCPCS code G2077), respectively, and updated by the MEI and GAF. The final CY 2025 OTP payment rates will be posted on the CMS website after publication of this final rule.[460] We reiterate that intake activities, periodic assessments, and SDOH risk assessments conducted during intake and periodic assessments must continue to relate to the diagnosis or treatment of an OUD and be consistent with SAMHSA requirements under § 8.12(f)(4). In addition, we expect that any unmet HRSNs identified through SDOH risk assessments performed should be documented in the patient's medical record to indicate how assessing and addressing the HRSN relates to the treatment and diagnosis of an OUD.

b. Request for Information on Payment for Coordinated Care and Referrals to Community-Based Organizations That Address Unmet Health-Related Social Needs, Provide Harm Reduction Services, and/or Provide Recovery Support Services

In the discussion above, we noted that SAMHSA's recent reforms to 42 CFR part 8 finalized new definitions for harm reduction and recovery support services, which are included as components of the type of services that OTPs may provide. Some examples of harm reduction strategies include overdose education, distribution of opioid overdose reversal medications, and linkage to other public health services. Recovery support services can include, but are not limited to, community-based recovery housing, social support, and linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness. Under the Medicare OTP benefit, we have already established payment for some of these services, including take-home supplies of opioid antagonist medications for emergency treatment of known or suspected opioid overdose (for example, naloxone), overdose education furnished in conjunction with opioid antagonist medications, and social support via group therapy. However, we do not currently have specific coding for activities that OTPs may conduct to coordinate care and make referrals or ''link'' to community-based organizations (CBOs) that help facilitate a patient's needs and goals related to harm reduction and recovery support services, as well as to address unmet HRSNs. We understand that a referral is an important aspect of following up on unmet HRSNs identified during an initial assessment service and/or SDOH risk assessment so that a patient can be connected to resources or services that may help address their unmet HRSN that interferes with treatment of their OUD. Additionally, we have received previous comments that OTPs often have collaborative agreements with providers outside of the OTP. For these reasons, we solicited comment to understand how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, and/or provide recovery support services.

Some evidence has indicated that providers who coordinate care with CBOs to address HRSNs (for example, housing, transportation, care management, etc.) can positively influence health outcomes,[461] and that SUD treatment facilities establishing relationships with community-based peer support services, educational and employment agencies, housing agencies, and other organizations have been able to better support a patient's engagement in SUD treatment.[462] Additionally, harm reduction organizations, including syringe service programs, function as important facilitators of entry to treatment, as individuals who partake in these programs are five times more likely to enter treatment, more likely to remain engaged in treatment, and more likely to reduce their injection drug use.[463] Additionally, recovery support services, such as those linking individuals in SUD treatment who are also experiencing homelessness with supportive or transitional housing, have resulted in improved uptake of behavioral health visits;[464] and, recovery support services facilitated by peers who have recovered from a SUD have been shown to reduce relapse rates, improve treatment retention, enhance the provider and patient relationship, and boost overall treatment experience.[465] Therefore, there is evidence to suggest that linkage to these types of community-based resources may contribute to improved outcomes related to OUD treatment; however, we solicited comment on additional evidence that demonstrates how this type of services would directly help OTPs address the diagnosis or treatment of an OUD. CMS would also be interested in additional evidence describing how these community-based resources and coordination of these services with MOUD provided by OTPs would impact access to treatment for Medicare beneficiaries who may face barriers in accessing treatment, such as those who are residents of rural areas, racial/ethnic minorities, living with a disability, dual-enrollees in Medicare and Medicaid, and low-income, or other populations who may face barriers in accessing treatment. Additionally, we sought information on the types of entities, service providers, and organizations that OTPs may interact with on a regular basis to address a patient's unmet HRSNs and needs or goals related to harm reduction and recovery support services. For example, we sought to understand if these entities would typically include housing or transportation agencies, local support groups, syringe service programs, non-profits that provide financial assistance, etc. We sought information on the types

[460] *https://www.cms.gov/medicare/payment/opioid-treatment-program/billing-payment.*

[461] McCarthy, D., Lewis, C., Horstman, C., Bryan, A., & Shah, T. (2022). ''Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update'' [ROI Calculator for Partnerships to Address the Social Determinants of Health]. The Commonwealth Fund. *https://www.commonwealthfund.org/sites/default/files/2022-09/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.*

[462] O'Brien, P., Crable, E., Fullerton, C., & Hughey, L. (2019). ''Best Practices and Barriers to Engaging People with Substance Use Disorders in Treatment.'' ASPE. *https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf f.*

[463] Hagan, H., McGough, J.P., Thiede, H., Hopkins, S., Duchin, J., & Alexander, E.R. (2000). ''Reduced injection frequency and increased entry and retention in drug treatment associated with needle-exchange participation in Seattle drug injectors.'' Journal of Substance Abuse Treatment, 19(3), 247–252. *https://doi.org/10.1016/s0740-5472(00)00104-5.*

[464] Brennan, K., Buggs, K., Zuckerman, P., Muyeba, S., Henry, A., Gettens, J., & Kunte, P. (2020). ''The Preventive Effect of Housing First on Health Care Utilization and Costs among Chronically Homeless Individuals.'' *https://www.bluecrossmafoundation.org/sites/g/files/csphws2101/files/2020-12/Housing%20First_summary_Final.pdf.*

[465] Reif, S., Braude, L., Lyman, D.R., Dougherty, R.H., Daniels, A.S., Ghose, S.S., Salim, O., & Delphin-Rittmon, M.E. (2014). ''Peer recovery support for individuals with substance use disorders: Assessing the evidence.'' Psychiatric Services, 65(7), 853–861. *https://doi.org/10.1176/appi.ps.201400047.*

of collaborative arrangements that OTPs typically have with these CBOs, including how frequently (for example, weekly, monthly, annually, etc.) OTPs coordinate care or make referrals to these CBOs for patients with an OUD, the types of circumstances that warrant an OTP interacting with these CBOs, and the workflows originating from the initial SDOH assessment to identify these HRSNs to a beneficiary successfully receiving referred services. We also expressed interest in learning to what extent some of these programs are already integrated into OTP settings.

Moreover, we stated we were also interested in learning when these coordinated activities and/or referrals occur in the process of furnishing care to a beneficiary. For example, a component of SAMHSA's new revised standards for MOUD treatment under counseling and psychoeducational services at § 8.12(f)(5)(iii) suggests that OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed upon as beneficial by the patient and program staff. Thus, we solicited comment on whether these coordination and referral services typically occur during SUD counseling session services, or if they may occur during initial or periodic assessments, therapy sessions, or as part of other services. We also expressed interest in understanding if, when billing for intake activities (G2076), periodic assessments (G2077), additional therapy/counseling (G2080), and/or the non-drug component code (G2074) under the Medicare OTP benefit, OTPs are already accounting for these coordinated care and referral services as part of those codes.

We also stated that we are interested in additional information related to payment for these types of coordinated care or referral services. Specifically, we solicited comment on the resource costs that OTPs must expend to coordinate or make referrals to community-based services that address HRSNs, harm reduction, or recovery support needs. We mentioned that we were also interested in learning whether there is existing coding that properly describes these types of coordinated care or referral services, or whether there are elements to these types of services that are unique to OTPs and require new coding. We solicited comment on if any of the following codes below may describe the type of coordinated care or referral activities that OTPs may provide, or if there are other codes that more precisely match the type of coordinated care or referral activities at OTPs: community health integration (G0019 & G0022), principal illness navigation (G0023, G0024, G0140, G0146), chronic care management (99437, 99439, 99490, 99491), complex chronic care management (99487, 99489), principal care management (99424, 99425, 99426, 99427), or other codes, including any other relevant codes used by other payers.

Lastly, we sought information on whether OTPs already receive funding for these types of coordinated care or referral services from other public or private sources, and if additional payment would be duplicative or unnecessary. We mentioned we were interested in learning, for example, if OTPs already receive State or Federal grants for these types of activities (for example, the SAMHSA Harm Reduction Grant Program, Rural Communities Opioid Response Program, State Opioid Response Grants, Building Communities of Recovery, Substance Use Prevention, Treatment, and Recovery Services Block Grant, etc.).[466] Additionally, we stated that we would like to understand if OTPs already receive payment from States who might already cover these services under State Medicaid programs, including through section 1115 waiver demonstrations and delivery system reform incentive payments, State plan amendments, managed care contracts, or other service benefits and payment arrangements,[467] and if new coding under the Medicare OTP benefit may unintentionally supplant coverage for dually eligible beneficiaries. We solicited comment by the public on these questions and issues to better understand activities that OTPs conduct to coordinate care and make referrals to CBOs that address unmet health-related social needs, provide harm reduction services, and/or provide recovery support services.

We received many public comments on this request for information to understand how OTPs are currently coordinating care and making referrals to CBOs that address unmet HRSNs, provide harm reduction services, and/or provide recovery support services. The section below includes a summary of the comments we received related to this topic and our responses.

Comment: Commenters submitted an abundance of information on coordinated care and referral services within OTP settings, including the types of service provider entities in the community OTPs interact with, examples of operational processes in OTP settings related to these activities, the types of referral services OTPs refer patients to, potential resource costs associated with rendering coordinated care and referral services, current public and private funding mechanisms for these activities, and existing coding that may appropriately describe these activities in OTP settings.

Commenters shared that providing services and supports to address unmet HRSNs, harm reduction intervention needs and/or recovery support services needs are vital elements of treatment and recovery, and that these integral activities should be meaningfully incorporated into the Medicare OTP benefit. One commenter encouraged CMS to work with other HHS agencies, community organizations, and patients with an OUD to implement more payment and coverage policies, consistent with the HHS Overdose Prevention Strategy, SAMHSA's Harm Reduction Framework, and the National Drug Control Strategy.[468]

Commenters described the various types of entities OTPs typically coordinate with or provide referrals to such as local recovery community organizations, State and residential programs, recovery houses, certified community behavioral health centers (CCBHCs), food pantries and distribution programs, job training programs, community support specialists, and peer recovery support specialists. Commenters mentioned that OTPs often have memorandums of understanding with these types of service providers. For example, a few commenters noted that Missouri requires OTPs to hire or coordinate with community support specialists who function as system navigators, care coordinators, or case managers to ensure patients receive services they are referred to. Additional commenters communicated that by licensing regulations, Massachusetts requires OTPs to maintain qualified service

[466] *https://www.samhsa.gov/grants/grant-announcements/sp-22-001; https://grants.hrsa.gov/2010/Web2External/Interface/FundingCycle/ExternalView.aspx?fCycleID=af0c3bac-6d99-4314-ab7b-c1602e6c471c; https://www.samhsa.gov/grants/grants-dashboard; https://nashp.org/funding-options-for-states/.*

[467] Artiga, S., & Published, E.H. (2018, May 10). ''Beyond health care: The role of social determinants in promoting health and health equity.'' KFF. *https://www.kff.org/racial-equity-and-health-policy/issue-brief/beyond-health-care-the-role-of-social-determinants-in-promoting-health-and-health-equity/; https://www.health.ny.gov/diseases/aids/consumers/prevention/medicaid_harm_reduction.htm.*

[468] *https://www.hhs.gov/overdose-prevention/; https://www.samhsa.gov/sites/default/files/harm-reduction-framework.pdf; www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.*

organization agreements with a wide variety of healthcare and social service providers, and to outline referral pathways in these agreements to ensure SDOH needs identified by the OTP can be addressed by the appropriate community-based organization. One commenter stated that for over 8 years, OTPs in South Carolina have leveraged a Screening, Brief Intervention, and Referral to Treatment (SBIRT) online system where community-based referrals are regularly tracked and monitored. A few commenters added that beginning July 1, 2024, CCBHCs are required to partner with OTPs in their service areas, and often these healthcare organizations help facilitate access to supportive housing programs for patients. Many commenters also shared that in some cases, OTPs may refer patients who both are receiving treatment with methadone and require higher levels of care to recovery centers, which may offer additional supports including if a patient has additional SUD diagnoses. Some commenters also raised that peer recovery specialists often interact with OTPs and assist patients on their treatment journeys by providing peer support, connecting the patient with resources in the community, or helping the patient navigate various care options.

Commenters furthered shared when coordination and referral services occur in OTP settings. Specifically, OTPs routinely perform coordination of care and referral and linkage services, and these activities could occur when an unmet HRSN is identified during an initial assessment, individual counseling session, case management visit, or medical examination. Commenters shared the types of frequent services that OTPs refer patients to: overdose prevention education, legal assistance, housing, nutrition, primary care, vocational, education, employment, and services to address or treat co-occurring HIV, viral hepatitis, and STIs.

Furthermore, regarding payment and funding for these coordinated care and referral services, commenters mentioned that many OTPs don't necessarily have all the resources to implement these services to their full extent due to lack of infrastructure and relevant information technologies, administrative burden, and the availability of community resources. Commenters stated that some OTPs have used grant funds or opioid settlement money to fund these types of activities, but that these funding sources are not as stable as direct payment for OUD treatment services under the Medicare program. Other commenters noted that some underserved communities may not have easy access to private (for example, private health insurers, charitable foundations, etc.) or public funding sources (for example, State or Federal grants, State Medicaid programs, etc.) to fill this gap in payment for coordinated care and referral services. A few commenters also stated that although some State Medicaid programs may offer coverage for case management services, in most cases OTPs are not reimbursed for these types of coordination or referral services they furnish to Medicare beneficiaries. Commenters further added that if OTPs received payment through Medicare, they would have the capacity to expand the breadth of these services and hire additional full-time staff. Many commenters specified the types of coding that would be appropriate to characterize coordinated care or referral activities in OTP settings, including community health integration (CHI) services (HCPCS codes G0019 and G0022) and/or Principal Illness Navigation (PIN) services (HCPCS codes G0023, G0024, G0140, and G0146). A few commenters encouraged CMS to focus on payment for case management services or peer recovery support services.

Response: We appreciate information submitted by commenters, which offered an abundance of detail as to how coordinated care and referral services are provided in OTP settings. We are persuaded by commenters that these types of services have been integrated into OTP settings for a long period of time, are critical to the treatment of an OUD and a patient's recovery and warrant additional payment under the Medicare OTP benefit. As we stated in the proposed rule (89 FR 61826), we recognize that OTPs often directly provide, or provide referrals to, services related to harm reduction interventions, recovery support services, addressing HRSNs, and facilitate access to community-based social services. For example, data collected by SAMHSA in 2022 indicated approximately 92 percent of OTP facilities offered various recovery support services, including peer support (59.6 percent), assistance locating housing for clients (75.0 percent), employment counseling (49.5 percent), and assistance helping patients obtain social services (81.2 percent).[469] Public comments in response to the implementing final rule (CY 2020 PFS final rule) stated OTPs often provide various coordinated care services, possess collaborative arrangements with healthcare providers outside of the OTP, and help patients with accessing food benefits, housing, and employment searches, which are critical components for sustained recovery (84 FR 62648). Altogether, CMS believes that we now have enough information to establish coding and payment for coordinated care and referral activities as well as for patient navigational and peer recovery support services in this final rule. We believe establishing payment for these services will further efforts to enhance access to MOUD treatment and recovery services among Medicare beneficiaries with an OUD, and align services covered under the Medicare OTP benefit with current paradigms of whole-person centered care for MOUD treatment. We also believe expansion of these services is important to ensure consistency across the Medicare program in the types of benefits that are accessible to Medicare beneficiaries in different care settings and allow OTPs to receive additional payment to implement new SAMHSA reforms to MOUD treatment.

Based on the comments received, we believe that community health integration services (CHI), principal illness navigation services (PIN), and principal illness navigation services—peer support (PIN–PS) are consistent with services ordinarily provided in OTP settings to coordinate care or referrals to community-based organizations, in addition to navigational or peer recovery support services. CHI services, described by HCPCS G-codes G0019 and G0022, focus on providing tailored support to help address unmet HRSNs that significantly limit a provider's ability to diagnose or treat the patient. Some of these services include: coordinating receipt of needed services from health care providers, health care facilities, and community-based service providers; coordination of care transitions between and among other health care providers and settings; following up with a patient after an emergency department visit or discharge from a health care facility; and facilitating access to community-based social services to address unmet HRSN (for example, housing, utilities, transportation, food assistance) to address the SDOH need(s). We are finalizing creation of a new code for coordinated care and/or referral services (G0534) that is based on a crosswalk to the CY 2024 PFS non-facility rate of the community health integration base HCPCS code G0019 (*Community health integration services performed by*

[469] Table SU17b: Substance use treatment facilities, by services provided and facility type: Number and column percent, 2022: *https://www.samhsa.gov/data/sites/default/files/reports/rpt42714/NSUMHSS-Annual-Detailed-Tables-22.pdf.*

certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that significantly limit the ability to diagnose or treat problem(s) addressed in an initiating visit), but divided by two to represent each additional 30 minutes of services furnished (CY 2024 PFS non-facility rate of G0019 = $80.56 and divided by two = $40.28). We believe that basing HCPCS code G0534 on each additional 30 minutes of services furnished would allow for a smaller unit of billing (30 minutes versus 60 minutes per calendar month for HCPCS code G0019), which would lower the time threshold needed to bill for coordinated care and/or referral services as CMS learns how often these services are furnished in OTP settings. Additionally, basing HCPCS code G0534 on each additional 30 minutes of services for coordinated care and/or referral activities may allow these services to be more easily billed alongside the weekly bundled payments for an episode of care due to the smaller time increments. It may further reduce administrative burden through billing simplification via one HCPCS G-code, rather than creating two separate codes for coordinated care and referral activities based on the two CHI codes under the PFS for 60 minutes per calendar month (G0019) and each additional 30 minutes thereafter (G0022). Moreover, we expect OTPs to furnish services coded with G0534 (*Coordinated care and/or referral services, such as to adequate and accessible community resources to address unmet health-related social needs, including harm reduction interventions and recovery support services a patient needs and wishes to pursue, which significantly limit the ability to diagnose or treat an opioid use disorder; each additional 30 minutes of services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*) when an OTP coordinates care or provides referral or linkage services to adequate and accessible community resources or community-based organizations that address a patient's identified unmet HRSN, or need and interest for harm reduction interventions and recovery support services, which may limit the ability of an OTP to diagnose or treat a patient's OUD. These community-based organizations may include, but are not limited to, harm reduction organizations, peer support organizations, housing agencies, job training programs, recovery centers, food assistance or distribution programs, residential programs, and educational services. Accordingly, we are finalizing a revision to the definition of an opioid use disorder treatment service at § 410.67(b) by adding paragraph (x) to account for these type of ''coordinated care and/or referral services, provided by an OTP to link a beneficiary with community resources to address unmet health-related social needs or the need and interest for harm reduction interventions and recovery support services that significantly limit the ability to diagnose or treat a patient's opioid use disorder.'' We are also revising § 410.67(d)(4)(i) by adding paragraph (G) to specify that for the ''coordinated care and/or referral services described in paragraph (x) of the definition of OUD treatment service at § 410.67(b), an adjustment will be made when each additional 30 minutes of these services are furnished,'' to the bundled payment.

Moreover, PIN services, described by HCPCS G-codes G0023 and G0024, and PIN–PS services, described by G0140 and G0146, are similar to CHI, but do not necessarily require a patient to have an unmet HRSN before services are furnished. PIN and PIN–PS are more focused on helping patients with a serious high-risk condition (for example, substance use disorder) navigate the health care system and guiding them through their course of care. PIN–PS services are slightly distinct from PIN services in that these services are often facilitated by peer support specialists who directly assist patients in helping to navigate various health system and social sector interactions, whereas navigators may serve as a more direct point of contact on behalf of the patient. We are finalizing the creation of a new code for patient navigational services (HCPCS code G0535) that is based on a crosswalk to the CY 2024 PFS non-facility rate of the principal illness navigation base HCPCS code G0023 (*Principal illness navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator; 60 minutes per calendar month, in the following activities*), but divided by two to represent each additional 30 minutes of services furnished (CY 2024 PFS non-facility rate of HCPCS code G0023 = $80.56 and divided by two = $40.28). We are basing HCPCS code G0535 on each additional 30 minutes of services for similar reasons to why we are finalizing each additional 30 minutes of service for HCPCS code G0534, that is, administrative simplification for providers, to lower the billing threshold, to more easily be billed alongside the weekly bundled payment for an episode of care, and to be consistent with the payment approach for HCPCS code G0534.) We expect OTPs to bill for HCPCS code G0535 (*Patient navigational services, provided directly or by referral; including helping the patient to navigate health systems and identify care providers and supportive services, to build patient self-advocacy and communication skills with care providers, and to promote patient-driven action plans and goals; each additional 30 minutes of services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code*) when an OTP provides directly or by referral to patient navigational services that help the patient with an OUD navigate multiple settings of care, including by identifying care providers or recovery supportive services, communicating with other health care or social service providers and securing appointments for patients, building patient self-advocacy and communication skills, and facilitating patient-driven goal-setting and action plans for MOUD treatment and recovery. We believe patient navigational services may be best suited for situations in which the navigator may serve as a more direct point of contact for the patient. Additionally, we are finalizing the creation of a new code for peer recovery support services (HCPCS code G0536) that is based on a crosswalk to the CY 2024 PFS non-facility rate of the principal illness navigation—peer support base code HCPCS code G0140 (*Principal illness navigation—peer support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities*) but divided by two to represent each additional 30 minutes of services furnished (CY 2024 PFS non-facility rate of HCPCS code G0140 = $80.56 and divided by two = $40.28). We are basing HCPCS code G0536 on each additional 30 minutes of services for similar reasons to why we are finalizing each additional 30 minutes of service for G0534 and G0535, that is, administrative simplification for providers, to lower the billing threshold, to more easily be billed alongside the weekly bundled payment for an episode of care, and to be consistent with the

payment approach for HCPCS codes G0534 and G0535. We expect OTPs to bill for HCPCS code G0536 (*Peer recovery support services, provided directly or by referral; including leveraging knowledge of condition or lived experience to provide support, mentorship, or inspiration to meet OUD treatment and recovery goals; conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes; developing and proposing strategies to help meet person-centered treatment goals; assisting the patient in locating or navigating recovery support services; each additional 30 minutes of services (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to each primary code)* when individuals either with knowledge of an OUD, or with lived experience of an OUD, provide support, coaching, mentorship, or inspiration to patients with an OUD to meet various MOUD treatment and recovery goals. Peer recovery support specialists may help: Medicare beneficiaries with an OUD to stay engaged in treatment at an OTP; connect patients with other peer support networks or recovery services in the community; conduct interviews of the patient to understand their background, needs, and goals, and then propose or strategize means for accomplishing such treatment and recovery goals; and more. Accordingly, we are finalizing a revision to the definition of opioid use disorder treatment service at § 410.67(b) by adding paragraph (xi) to account for ''patient navigational services and/or peer recovery support services, when provided directly by an OTP or through referral, in order to assist patients with an OUD in navigating the health system and accessing supportive services, and/or to provide support in meeting patient-driven OUD treatment and recovery goals.'' We are also adding new paragraph (H) to § 410.67(d)(4)(i) to specify that we are making an adjustment to the bundled payment for patient navigational services and/or peer recovery support services when each additional 30 minutes of these services are furnished.

Furthermore, we are revising § 410.67(d)(4)(ii) and (iii) to update the adjustment to the bundled payment for coordinated care and/or referral services (G0534), and patient navigational services (G0535) and/or peer recovery support services (G0536) by the GAF and MEI, respectively, consistent with other adjustments to the bundled payment.

Moreover, we encourage OTPs to engage in discussions with patients regarding coordinated care and/or referral services, patient navigational services, and/or peer recovery support services prior to furnishing and billing for these services under the Medicare OTP benefit. We believe these discussions are important to ensure patients are aware of and agree with these services being furnished, to provide information to patients regarding these services and their benefits, and so that these services are furnished in a manner that is patient-centered and consistent with a patient's OUD treatment and recovery goals. We expect OTPs to document in the patient's medical record how coordinated care and/or referral services, patient navigational services, and/or peer recovery support services relate to the treatment and diagnosis of an OUD. Like other services provided under the Medicare OTP benefit, we are not limiting the types of professionals that can provide these services to those professionals who are able to bill Medicare directly. However, professionals who render these services (coordinated care/referral services, patient navigational services, and peer recovery support services) within or external to OTP settings must be authorized under State law, including by licensure, certification, and/or training, for these services prior to furnishing them to Medicare beneficiaries. We further note that only OTPs may continue to bill directly for OUD treatment services furnished via the bundled payment and adjustments to the bundled payment, including these new codes (HCPCS codes G0534, G0535, and G0536). Additionally, all services provided to Medicare beneficiaries under the OTP benefit must be medically reasonable and necessary and related to the treatment of an OUD. We similarly expect for coordinated care and/or referral services, patient navigational services, and/or peer recovery support services to be medically reasonable and necessary and related to the treatment of an OUD. Thus, OTPs should document in the patient's care plan how these services relate to the diagnosis or treatment of an OUD prior to billing Medicare for these services. At this time, we are not finalizing limitations to how frequently these services may be furnished, so as to not hinder access as we gather more information on how these services will be utilized under the OTP benefit. We understand that the number of minutes needed for these services may vary greatly depending on the needs and condition of the patient with an OUD. Given the addition of these new codes under the Medicare OTP benefit, CMS remains open to feedback from the public on the implementation and utilization of these codes; therefore, we will continue to consider additional refinements as needed via future rulemaking to ensure Medicare beneficiaries have appropriate access to these services to meet MOUD treatment and recovery needs.

4. Payment for New FDA-Approved Opioid Agonist and Antagonist Medications

Section 1861(jjj)(1)(A) of the Act establishes Medicare payment for opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for use in the treatment of OUD and as part of OUD treatment services under the OTP benefit. Additionally, section 1834(w)(2) of the Act granted CMS the authority to establish multiple bundled payments in stating that the Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In the CY 2020 PFS final rule, we finalized basing the OTP bundled payments, in part, on the type of medication used for treatment that reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD. Accordingly, at § 410.67(d)(1) we specified that CMS would establish categories of bundled payments for OTPs for an episode of care, including categories for each type of opioid agonist and antagonist treatment medication, a category for medications not otherwise specified, and a category for episodes of care in which no medication is provided. At § 410.67(d)(2) we finalized that the bundled payment amounts for an episode of care would be based on both a drug and non-drug component, and we codified the payment methodology for determining these components. At § 410.67(d)(4), we described various adjustments that could be made to the bundled payment. Since the implementation of the Medicare OTP benefit on January 1, 2020, we have established bundled payments and/or add-on codes for the following

medications: methadone (HCPCS codes G2067 & G2078), oral buprenorphine (HCPCS codes G2068 & G2079), injectable buprenorphine (HCPCS code G2069), buprenorphine implants (HCPCS codes G2070 through G2072), naltrexone (HCPCS code G2073), nasal naloxone (HCPCS codes G2215 & G1028), injectable naloxone (HCPCS code G2216), and medication not otherwise specified (HCPCS code G2075) (for new FDA-approved opioid agonist or antagonist medications for OUD treatment that is not specified in one of our existing codes). In the CY 2025 PFS proposed rule, we proposed new payment for injectable buprenorphine and nalmefene hydrochloride products furnished by OTPs.

a. Coding and Payment for a New Nalmefene Hydrochloride Product

In May of 2023, the FDA approved the first nalmefene hydrochloride (nalmefene) nasal spray (under the brand name Opvee®), which is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids. This is the first FDA approval of a nasal spray for nalmefene hydrochloride for health care and community use, and it is intended for immediate administration as emergency therapy in settings where opioids may be present. Nalmefene acts as an opioid receptor antagonist and when administered quickly, it can reverse the effects of an opioid overdose including respiratory depression, sedation, and low blood pressure.[470] Newly approved Opvee® delivers 2.7 milligrams (mg) of nalmefene in a single spray into the nasal cavity. After the first dose is administered, if the patient does not respond, or responds and there is a recurrence of respiratory depression, additional doses of the Opvee® nasal spray may be administered with an additional spray every 2 to 5 minutes until emergency medical assistance arrives.[471] Compared to naloxone which has a half-life of approximately 2 hours and also rapidly reverses the effects of an opioid overdose, nalmefene has a half-life of 11 hours which means that it remains in the body much longer than other overdose reversal drugs.[472] The rise of dangerous synthetic opioids, such as fentanyl and its analogs (for example, carfentanil, acetylfentanyl, furanylfentanyl) have made it increasingly important to increase the types of opioid overdose reversal agents available to respond to the possibility of an opioid overdose.

In the CY 2021 PFS final rule (85 FR 84683 through 84692), we adopted new add-on codes for take-home supplies of nasal naloxone (HCPCS code G2215) and injectable naloxone (HCPCS code G2216). Additionally, we used our discretionary authority in section 1861(jjj)(1)(F) of the Act (which generally authorizes us to include as an OTP treatment service other items and services we determine are appropriate) to extend the definition of OUD treatment services to include short-acting opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, such as naloxone, and overdose education furnished in conjunction with opioid antagonist medication. We also established an adjustment at § 410.67(d)(4)(i)(E) to the weekly bundled payments when the OTP furnishes take-home supplies of these medications. This adjustment includes both a drug component and a non-drug component for overdose education. The payment methodology for the drug component of the adjustment was finalized at § 410.67(d)(2)(i) and is updated annually using the most recent data available at the time of ratesetting. The amount of the non-drug component of the adjustment, which includes overdose education, is based on the CY 2020 Medicare payment rate for CPT code 96161 (*Administration of caregiver focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*). We also finalized that any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and that we would recoup any duplicative payment made to an OTP for naloxone.

Furthermore, in the CY 2022 PFS final rule (86 FR 65340 and 65341), we established a new add-on code and payment for a higher dose of nasal naloxone (G0128). We also finalized that the adjustment includes take-home supplies of opioid antagonist medications in the list of items for which the non-drug component will be geographically adjusted using the Geographic Adjustment Factor (GAF) and the payment amount will be updated annually by the growth in the Medicare Economic Index (MEI). Lastly, we revised our regulations at § 410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. We clarified that this revision would apply not only to duplicative payments for take-home supplies of naloxone, but also to duplicative payments for additional take-home supplies of other medications that are made under § 410.67(d)(4)(i)(D).

In light of a novel nalmefene product, Opvee®, receiving FDA approval as an opioid antagonist medication for the emergency treatment of known or suspected opioid overdose, we proposed to make payment for this new drug under the Medicare OTP benefit in the CY 2025 PFS proposed rule. Expanding access to overdose reversal medications, such as nalmefene, is a critical component to confronting the opioid crisis. The number of drug overdose deaths involving prescription opioids was nearly 330 percent higher in 2022 than in 1999; however, deaths involving prescription opioids has decreased in recent years. From May 2023 through April 2024, there were approximately 75,000 predicted opioid overdose deaths in the US, and nearly 92 percent of opioid-involved deaths involved synthetic opioids other than methadone (mainly illegally-made fentanyl and fentanyl analogs such as acetylfentanyl, furanylfentanyl, and carfentanil).[473]

These increasing rates of drug overdose deaths over the past few decades have also been seen among the Medicare-eligible population with adults aged 65 and over experiencing the largest percentage increase (28 percent) in drug overdose deaths rates between 2020 and 2021,[474] and the rate of drug overdose deaths involving synthetic opioids among this age group increased by over 53 percent in only one year (between 2019 and 2020).[475] Over 50,000 Medicare Part D beneficiaries were estimated to have experienced an opioid overdose in 2021, and the number of these beneficiaries receiving

[470] *https://www.fda.gov/news-events/press-announcements/fda-approves-prescription-nasal-spray-reverse-opioid-overdose.*

[471] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217470Orig1s000.pdf.*

[472] Harris, E. (2023). ''FDA approves nalmefene, a longer-lasting opioid reversal nasal spray.'' JAMA, 329(23), 2012. *https://doi.org/10.1001/jama.2023.9608.*

[473] *Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2024.*

[474] *https://www.cdc.gov/nchs/products/databriefs/db457.htm.*

[475] *https://blogs.cdc.gov/nchs/2023/06/30/7408/.*

naloxone has grown.[476] Not only has the opioid crisis impacted the Medicare-eligible population, but health disparities in drug overdose deaths have persisted. Non-Hispanic Black men aged 65 and over have experienced drug overdose death rates that are more than four times higher than Hispanics and non-Hispanic whites.[477] In addition, death rates from drug overdoses among people aged 65 and over have increased at faster rates for men than women.[478] Expanding access to overdose reversal medications is important, including for populations at a greater risk for drug overdose, as overdose reversal medications have been regarded as an evidence-based strategy to help individuals quickly respond to an overdose to reduce drug overdose deaths, and increase survival rates.[479] Lastly, we believe this proposal to pay for nalmefene nasal spray under the OTP benefit would further the objectives of the HHS Overdose Prevention Strategy and the National Drug Control Strategy, which both aim to widen availability and access to opioid overdose reversal treatments.[480]

Section 1861(jjj)(1)(A) of the Act recognizes opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the FDA under section 505 of the FFDCA for the use in treatment of OUD, but nalmefene is not on the list of drugs for the treatment of OUD.[481] When CMS first finalized payment for nasal and injectable naloxone under the OTP benefit in the CY 2021 PFS final rule (85 FR 84682 through 84689 and 85026 through 85027), we used our discretionary authority under section 1861(jjj)(1)(F) of the Act to finalize and extend the definition of OUD treatment services to include short acting opioid antagonist medications (for example, naloxone) that are approved by the FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose. Since nalmefene nasal spray was approved by the FDA under section 505(b)(1) authority,[482] and is an opioid antagonist and on the list of overdose reversal drugs approved by the FDA,[483] we believe nalmefene is consistent with our definition of OUD treatment service at § 410.67(d), which describes opioid antagonist medications that are approved by the FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose at paragraph (viii). Therefore, we believe it was appropriate to propose new payment for nalmefene as it would align with existing authority under § 410.67(b) that recognizes opioid antagonist medications which treat known or suspected opioid overdose as an OUD treatment service.

We proposed to create a new adjustment to the bundled payment for nalmefene hydrochloride nasal spray described by GOTP1 *[Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)].* We proposed to price this new add-on code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). This adjustment would include both a drug component and a non-drug component. The amount of the drug component would be determined using the methodology for pricing the drug component of an episode of care at § 410.67(d)(2)(i), which tends to use average sales price (ASP) data when available (with certain exceptions). Accordingly, consistent with the approach used to price the drug component for nasal naloxone (HCPCS code G2215 & G1028), we proposed to apply the ASP payment methodology set forth in section 1847A of the Act to determine the payment for the new naloxone hydrochloride nasal spray product, except that payment amounts would not include any add-on percentages if either ASP or wholesale acquisition cost (WAC) is used. As stated in the CY 2021 PFS final rule (85 FR 84685), we continue to believe that using ASP provides a transparent and public benchmark for manufacturers' actual pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices, including for the new nalmefene nasal spray. As we stated in the CY 2020 PFS final rule, we also continue to believe that limiting the payment amount to 100-percent of the volume-weighted ASP for a HCPCS code will incentivize the use of the most clinically appropriate drug for a given patient (84 FR 62651 through 62656). We understand that many OTPs purchase medications directly from manufacturers, thereby limiting the markup from distribution channels.

Furthermore, as stated in the CY 2020 PFS final rule (84 FR 62650), we usually use the typical maintenance dose to calculate the drug component for the OTP benefit. As part of determining a payment rate for the proposed bundles for OUD treatment services, a dosage of the applicable medication is often selected to calculate the costs of the drug component of the bundle. According to the prescribing information for Opvee®, each unit-dose nasal spray device delivers 2.7 mg of nalmefene in 0.1 mL.[484] Each unit-dose device contains a single dose of nalmefene and cannot be reused. Each carton contains two unit-dose nasal spray devices to allow for an additional repeat dose if needed. Thus, we proposed to price the drug component of the code for nalmefene nasal spray based on an assumption of a typical dosage for this new product to be a carton containing two 2.7-mg nasal sprays. We would, therefore, multiply the payment amount of 100-percent of the ASP for each unit-dose nasal spray containing 2.7 mg of nalmefene by two to reflect a carton of two nasal spray devices. We sought comment on whether this amount (a carton of two 2.7-mg nasal sprays) reflects the typical maintenance dosage for this drug when administered. The ASP+0 for Opvee® for sales in the fourth quarter of 2023 is $92.033, which reflects a carton of two 2.7-mg nasal sprays and would be used to price the drug component of GOTP1.

Additionally, consistent with the methodology established in § 410.67(d)(4)(i)(E), we proposed to include a non-drug component for GOTP1 that would include payment for overdose education. Overdose education is an important component of overdose prevention and includes educating patients and caregivers on how to recognize respiratory depression, the signs and symptoms of a possible opioid overdose, how to administer overdose reversal medications, and the importance of calling 911 or getting emergency medical help right away,

[476] *https://oig.hhs.gov/oei/reports/OEI-02-22-00390.pdf.*

[477] *https://www.cdc.gov/nchs/products/databriefs/db455.htm.*

[478] *https://blogs.cdc.gov/nchs/2022/11/30/7193/.*

[479] *https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf.*

[480] *https://www.hhs.gov/overdose-prevention/; https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf.*

[481] *https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.*

[482] *https://www.fda.gov/media/171605/download.*

[483] *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-naloxone-and-nalmefene.*

[484] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217470Orig1s000.pdf.*

even after the overdose reversal medication is administered.[485] Additionally, overdose education paired with distribution of overdose reversal medications has been found to be effective in improving knowledge about opioid overdose, improving attitudes toward using overdose reversal medications, training individuals to safely and effectively manage overdoses, and reducing opioid-related mortality.[486] For these reasons, we proposed to include a non-drug component to GOTP1 based on the CY 2020 Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument)* and updated to reflect the MEI updates that have been applied since that time. This is consistent with the payment methodology for naloxone and the language in § 410.67(d)(4)(i)(E). In addition, the language at § 410.67(d)(4)(ii) currently states that the non-drug component of the adjustments for take-home supplies of opioid antagonist medications will be geographically adjusted using the geographic adjustment factor described in § 414.26. Separately, § 410.67(d)(4)(iii) states that the non-drug component of the adjustments for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504. Since we proposed to establish payment for nasal nalmefene through an adjustment to the bundled payment, and since the drug is also considered an opioid antagonist medication, we also proposed to update the non-drug component for the adjustment of GOTP1 annually based on the GAF and MEI.

Furthermore, consistent with our established criteria for opioid antagonist medications at § 410.67(d)(4)(i)(E), we also proposed to limit payment for nasal nalmefene to one add-on code (GOTP1) every 30 days. However, we believe that access to the drug should not be limited when it is medically reasonable and necessary as part of the treatment for OUD and known or suspected opioid overdose. Therefore, similar to flexibilities established for frequency limits for naloxone, we proposed to allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of nalmefene dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional nalmefene. We noted that section 1862(a)(1)(A) of the Act requires that for payment to be made for most Part A and Part B services furnished to Medicare beneficiaries, those services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the malfunctioning of a malformed body member. If an additional supply of nasal nalmefene is needed within 30 days of the original supply being provided, we proposed that OTPs must document in the medical record the reason for the exception. Moreover, section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. Similar to naloxone, we recognized that nalmefene may also be appropriately available to beneficiaries through other Medicare benefits, including under Medicare Part D. At § 410.67(d)(5), we define duplicative payment to involve circumstances when medications are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medication (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Consistent with § 410.67(d)(5), we proposed that CMS recoup duplicative payments made to an OTP for nalmefene. We expect that if the OTP provides reasonable and necessary medications for an OUD as part of an episode of care, the OTP will take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payments. Thus, nalmefene billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Medicare Part D plan.

We solicited comments related to this proposal to establish an adjustment to the bundled payment for nasal nalmefene (Opvee®) *GOTP1* [*Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)*], as well as comments related to applicable requirements and criteria for billing this code. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to establish payment for nasal nalmefene. Commenters expressed that this policy would expand access to a new innovative treatment for reducing the risk of harm and death from opioid overdoses, and that the high potency of drugs in the nation's drug supply necessitates multiple doses of effective medications, like nalmefene, to treat patients. One commenter shared evidence from a computer-based simulated model study conducted by the drug manufacturer of Opvee®, where nalmefene nasal spray was found to predict a substantially greater reduction in the incidence of cardiac arrest compared to nasal naloxone following a synthetic opioid overdose.[487] A few commenters stated that they supported both the proposed coding and payment methodology for the add-on code of take-home supplies of nalmefene nasal spray, as it would be consistent with pricing provisions in section 1847A of the Act and CMS's method for pricing similar opioid antagonist medications under the Medicare OTP benefit.

Response: We thank commenters for their support of this proposal.

Comment: One commenter provided information on the typical dose of nalmefene hydrochloride: one spray by intranasal administration, and in the event a patient relapses into respiratory depression, an additional dose would be given of a new nasal spray.

Response: We thank the commenter for this information. In the proposed rule, we noted that each unit-dose nasal spray device contains a single dose of nalmefene, which is consistent with the information submitted by the commenter. Each carton contains two 2.7-mg unit-dose nasal spray devices of nalmefene, and we proposed to price the drug component of placeholder code GOTP1 based on a typical dosage, which we assumed is one carton containing two doses.

Comment: One commenter asked CMS to consider any interaction this proposal, to establish an add-on payment for take-home supplies of nalmefene, may have on treatments currently covered under Medicare Part D.

[485] *https://www.fda.gov/media/140360/download#.*

[486] Razaghizad, A., Windle, S.B., Filion, K.B., Gore, G., Kudrina, I., Paraskevopoulos, E., Kimmelman, J., Martel, M.O., & Eisenberg, M.J. (2021). ''The effect of overdose education and naloxone distribution: An umbrella review of systematic reviews.'' American Journal of Public Health, 111(8), e1–e12. *https://doi.org/10.2105/AJPH.2021.306306.*

[487] *https://www.frontiersin.org/journals/psychiatry/articles/10.3389/fpsyt.2024.1399803/full.*

Response: We appreciate the commenter raising this important question. We recognize that nalmefene nasal spray may be available by prescription through Medicare Part D. CMS does not seek to influence whether a Medicare beneficiary receives access to this emergency medication through either Medicare Part B or D. However, section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. Consistent with Medicare OTP regulations at § 410.67(d)(5), a medication (for example, nalmefene nasal spray) would be duplicative if separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. CMS expects that if the OTP provides reasonable and necessary medications for an OUD as part of an episode of care, the OTP will take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payments. Thus, GOTP1 billed by an OTP as an add-on to the bundled payment for take-home supplies of nalmefene nasal spray should not be reported to or paid under a Medicare Part D plan.

After consideration of public comments, we are finalizing our proposal to create a new adjustment to the bundled payment for nalmefene nasal spray described by HCPCS code G0532 (previously placeholder code GOTP1) [*Take-home supply of nasal nalmefene hydrochloride; one carton of two, 2.7 mg per 0.1 mL nasal sprays (provision of the services by a Medicare-enrolled Opioid Treatment Program); (List separately in addition to each primary code)*], based on the payment methodology for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). The amount of the drug component will be determined using the methodology for pricing the drug component of an episode of care at § 410.67(d)(2)(i), which uses ASP data when available (with certain exceptions). We are also including payment for overdose education within the non-drug component, consistent with the methodology established in § 410.67(d)(4)(i)(E). The non-drug component will be annually updated based on the GAF and MEI. Lastly, we are limiting billing G0532 to once every 30 days and finalizing that CMS will recoup duplicative payments made to an OTP for nalmefene, such as if the medication is billed for the same Medicare beneficiary through Part B or Part D on the same date of service.

b. Coding and Payment for New Injectable Buprenorphine Product

Another medication for the treatment of OUD for which the Secretary may establish payment is buprenorphine, which is a partial opioid agonist that is FDA approved to treat OUD. Buprenorphine is a schedule III substance, meaning it has low to moderate potential for physical dependence.[488] When taken as prescribed, it can diminish the effects of opioid withdrawal symptoms and cravings.[489] In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we established a weekly bundled payment under the Medicare OTP benefit for injectable buprenorphine (HCPCS G2069: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*). CMS also established payment for other formulations of buprenorphine, including weekly bundles for oral buprenorphine (G0268), buprenorphine implants (G2070 through G2072), and take-home supplies of oral buprenorphine (G2079), as well as other medications like methadone and naltrexone. At § 410.67(d)(2), we codified that the bundled payment for episodes of care in which a medication is provided will consist of a payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other OUD treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. In the CY 2020 PFS final rule, we finalized a payment methodology for the drug component related to implantable and injectable medications at § 410.67(d)(2)(i)(A), which applied to the bundled payment for injectable buprenorphine (G2069).

For implantable and injectable medications paid under the OTP benefit, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the WAC, if WAC is used. We also stated in the CY 2020 PFS final rule that the typical maintenance dose to calculate the drug component for payment under the OTP benefit, as dosing for some, but not all, of the drugs varies considerably (84 FR 62650). As part of determining a payment rate for the proposed bundles for OUD treatment services, a dosage of the applicable medication must be selected to calculate the costs of the drug component of the bundle. In the CY 2020 PFS final rule, we finalized using a 100 mg monthly dose for the extended-release buprenorphine injection to use as the typical or average maintenance dose to calculate the drug component of the bundle for injectable buprenorphine (G2069). At the time of ratesetting for the CY 2020 PFS rule, the only injectable extended-release buprenorphine drug available and approved by the FDA under section 505 of the FFDCA for the treatment of OUD was Sublocade®;[490] and, the drug component for the bundle was based on a crosswalk to its respective HCPCS codes Q9991 (Buprenorphine XR 100 mg or less) and Q9992 (Buprenorphine XR over 100 mg) using the methodology set forth in section 1874A of the Act, except that the payment amount was 100-percent of the ASP. In the CY 2020 PFS final rule, we noted that the HCPCS codes for extended-release buprenorphine injection had the same payment rate, thus we did not believe it was necessary to establish a second typical maintenance dose to calculate the payment rate for the drug. For the non-drug component of the weekly bundle for injectable buprenorphine (G2069), we finalized that in addition to services for substance use counseling, individual and group therapy, and toxicology testing, we would include the Medicare non-facility rate for administration of an injection in our determination of the payment rate based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*).

In May of 2023, the FDA approved a new drug application (NDA) under section 505(b)(2) of the FFDCA for

[488] *https://www.dea.gov/drug-information/drug-scheduling.*

[489] National Academies of Sciences, Engineering, and Medicine. (2019). ''The effectiveness of medication-based treatment for opioid use disorder.'' In M. Mancher & A.I. Leshner (Eds.), Medications for Opioid Use Disorder Save Lives. National Academies Press (U.S.). *https://www.ncbi.nlm.nih.gov/books/NBK541393/.*

[490] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

another extended-release buprenorphine injection (Brixadi®) for subcutaneous use to treat moderate to severe OUD.[491] Clinical data suggest that Brixadi® likely contributes to high rates of treatment retention, reductions in opioid withdrawal and cravings, and fewer levels of illicit opioid use.[492] Brixadi® is available as a weekly injection (containing 50 mg of buprenorphine per mL) that can be used in patients who have started treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine-containing products, and a monthly injection (containing 356 mg of buprenorphine per mL) for patients already being treated with buprenorphine. The weekly and monthly formulations of the drug are available at varying doses, including lower doses that may be appropriate for those who do not tolerate higher doses of extended-release buprenorphine that are currently available.[493] The weekly doses are 8 mg, 16 mg, 24 mg, and 32 mg, and should be administered in 7-day intervals; and the monthly doses are 64 mg, 96 mg, and 128 mg, and should be administered in 28-day intervals.[494]

Buprenorphine is associated with decreasing the risk for overdose, opioid-related mortality, and all-cause mortality.[495] Data also shows that buprenorphine helps retain individuals in treatment, lowers illicit opioid use, and reduces drug-related behaviors that increase the risk for HIV transmission.[496] In particular, long-acting (for example, extended-release) injectable forms of buprenorphine have been shown to promote adherence to treatment while reducing the need for daily dosing, and to enhance patient-reported outcomes through improvements in quality of life, accessibility, social relationships, participation in employment, more flexible personal and professional schedules, and other treatment satisfaction measures.[497] Finally, a large percentage of Medicare beneficiaries with an OUD continue to face challenges in accessing medication, especially enrollees who are older, female, and who identify as racial/ethnic minorities.[498] The most common reasons for not receiving SUD treatment include financial barriers in affordability and coverage.[499] Establishing coverage and payment for a new medication to treat OUD may provide more MOUD treatment options, reduce financial barriers to accessing medication, and aid health equity efforts among Medicare beneficiaries. Accordingly, for these reasons and because sections 1861(s)(2), 1861(jjj)(1)(A), and 1833(a)(1) of the Act provide that the Secretary is to provide coverage and payment for OUD treatment services including opioid agonist and antagonist medications that are FDA approved for use in the treatment of OUD, in the CY 2025 PFS proposed rule we proposed to establish payment for the weekly and monthly formulations for this new FDA-approved injectable buprenorphine product which we believe would further efforts to address the opioid crisis and expand access to evidence-based treatment for OUD.

We proposed to establish two different payments: one for weekly injectable buprenorphine weekly and one for monthly injectable buprenorphine. To establish payment for the weekly and monthly formulations, we proposed to use the existing payment methodology for implantable and injectable medications codified at § 410.67(d)(2)(i)(A). This regulation specifies that payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the WAC, if WAC is used.

Payment limits [500] for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are paid under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient. The ASP payment limit determined under section 1847A of the Act reflects a volume-weighted ASP for all national drug codes (NDCs) that are assigned to a HCPCS code. The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as for sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and

[491] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder.*

[492] Frost, M., Bailey, G.L., Lintzeris, N., Strang, J., Dunlop, A., Nunes, E.V., Jansen, J.B., Frey, L.C., Weber, B., Haber, P., Oosman, S., Kim, S., & Tiberg, F. (2019). ''Long-term safety of a weekly and monthly subcutaneous buprenorphine depot in the treatment of adult out-patients with opioid use disorder.'' Addiction, 114(8), 1416–1426. *https://doi.org/10.1111/add.14636.*

[493] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder.*

[494] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/210136Orig1s000lbl.pdf.*

[495] Larochelle, M.R., Bernson, D., Land, T., Stopka, T.J., Wang, N., Xuan, Z., Bagley, S.M., Liebschutz, J.M., & Walley, A.Y. (2018). ''Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study.'' Annals of Internal Medicine, 169(3), 137. *https://doi.org/10.7326/M17-3107;* Wakeman, S.E., Larochelle, M.R., Ameli, O., Chaisson, C.E., McPheeters, J.T., Crown, W.H., Azocar, F., & Sanghavi, D.M. (2020). ''Comparative effectiveness of different treatment pathways for opioid use disorder.'' JAMA Network Open, 3(2), e1920622. *https://doi.org/10.1001/jamanetworkopen.2019.20622.*

[496] Shulman, M., Wai, J.M., & Nunes, E.V. (2019). Buprenorphine treatment for opioid use disorder: An overview. CNS Drugs, 33(6), 567–580. *https://doi.org/10.1007/s40263-019-00637-z;* Thomas, C.P., Fullerton, C.A., Kim, M., Montejano, L., Lyman, D.R., Dougherty, R.H., Daniels, A.S., Ghose, S.S., & Delphin-Rittmon, M.E. (2014). Medication-assisted treatment with buprenorphine: Assessing the evidence. Psychiatric Services (Washington, DC), 65(2), 158–170. *https://doi.org/10.1176/appi.ps.201300256;* Gowing, L., Farrell, M.F., Bornemann, R., Sullivan, L.E., & Ali, R. (2011). Oral substitution treatment of injecting opioid users for prevention of HIV infection. The Cochrane Database of Systematic Reviews, 8, CD004145. *https://doi.org/10.1002/14651858.CD004145.pub4.*

[497] Maremmani, I., Dematteis, M., Gorzelanczyk, E.J., Mugelli, A., Walcher, S., & Torrens, M. (2023). Long-acting buprenorphine formulations as a new strategy for the treatment of opioid use disorder. Journal of Clinical Medicine, 12(17), 5575. *https://doi.org/10.3390/jcm12175575;* Farrell, M., Shahbazi, J., Byrne, M., Grebely, J., Lintzeris, N., Chambers, M., Larance, B., Ali, R., Nielsen, S., Dunlop, A., Dore, G.J., McDonough, M., Montebello, M., Nicholas, T., Weiss, R., Rodgers, C., Cook, J., & Degenhardt, L. (2022). Outcomes of a single-arm implementation trial of extended-release subcutaneous buprenorphine depot injections in people with opioid dependence. International Journal of Drug Policy, 100, 103492. *https://doi.org/10.1016/j.drugpo.2021.103492;* Lintzeris, N., Dunlop, A.J., Haber, P.S., Lubman, D.I., Graham, R., Hutchinson, S., Arunogiri, S., Hayes, V., Hjelmström, P., Svedberg, A., Peterson, S., & Tiberg, F. (2021). Patient-reported outcomes of treatment of opioid dependence with weekly and monthly subcutaneous depot vs daily sublingual buprenorphine: A randomized clinical trial. JAMA Network Open, 4(5), e219041.*https://doi.org/10.1001/jamanetworkopen.2021.9041;* Martin, E., Maher, H., McKeon, G., Patterson, S., Blake, J., & Chen, K.Y. (2022). Long-acting injectable buprenorphine for opioid use disorder: A systematic review of impact of use on social determinants of health. Journal of Substance Abuse Treatment, 139, 108776. T=*https://doi.org/10.1016/j.jsat.2022.108776.*

[498] *https://oig.hhs.gov/oei/reports/OEI-02-23-00250.pdf.*

[499] Parish, W.J., Mark, T.L., Weber, E.M., & Steinberg, D.G. (2022). Substance use disorders among Medicare beneficiaries: Prevalence, mental and physical comorbidities, and treatment barriers. American Journal of Preventive Medicine, 63(2), 225–232. *https://doi.org/10.1016/j.amepre.2022.01.021.*

[500] In general, CMS establishes a single, national payment limit to Medicare Administrative Contractors (MACs) for payment of some Part B-covered drugs and biologicals whose payment is determined based on the methodology described in section 1847A of the Act. CMS provides an ASP pricing file to MACs, which is updated quarterly. *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

price concessions reflected in the manufacturer's determination of ASP.

Paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment limit for a single-source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction,[501] as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are crosswalked to the same billing and payment code.

In the CY 2025 PFS proposed rule, we stated that we continue to believe that use of ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Additionally, since many other injectable drugs are paid for under Medicare part B through the ASP payment methodology in 1847A, we presume that this methodology is appropriate for pricing Brixadi®. We also proposed to limit the payment amount to 100-percent of ASP without a 6-percent add-on percentage since, as we have previously noted, it is our understanding that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels.

As we stated in our discussion above, we use the typical or average maintenance dose of a drug to determine the drug costs for each of the bundles. In the CY 2020 PFS final rule, we noted that there are often variations in the dosage and frequency of administration of medications, but that ''payment based on the typical dose means that, across the Medicare beneficiaries served by the OTP, the payment amount should be reasonable and represent the average costs incurred in furnishing the drug component of the OUD treatment services.'' (84 FR 62650). Therefore, in the CY 2020 PFS final rule, we finalized using the typical maintenance dose to establish the drug costs for each of the bundles as our approach to addressing variable dosing of medications. (84 FR 62650).

In the CY 2020 PFS final rule, we finalized a 100 mg monthly dose for the extended-release buprenorphine injection as the typical maintenance dose, which we used to calculate the drug component of the weekly bundle for injectable buprenorphine (G2069). At the time, we did not establish a second typical maintenance dose because both HCPCS codes for the extended release buprenorphine injection, that is, Sublocade® [Q9991 *(Buprenorphine XR 100 mg or less*) and Q9992 (*Buprenorphine XR over 100 mg*)] had the same payment limit because, as explained above in this section, all NDCs marketed under the same FDA approval number are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are crosswalked to the same billing and payment code. The weekly and monthly formulations of Brixadi® are described by HCPCS codes J0577 (*Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy*) and J0578 (*Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*). In the same manner as Sublocade®, and as explained in the coding announcement for HCPCS codes J0577 and J0578,[502] because all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number are considered the same drug or biological for purposes of payments made under section 1847A of the Act, the payment limits for both J0577 and J0578 are calculated using all the NDCs marketed under the applicable FDA approval. However, since the dose descriptions for these codes are based on days of therapy (and not a measurement of the amount of drug, like per 1 mg, as is the case with Sublocade®), the ASP+0 for the two codes are different; ASP+0 for J0577 is $381.213 and ASP+0 for J0578 is $1524.855, based on sales from the fourth calendar quarter of 2023. Therefore, we stated in the CY 2025 PFS proposed rule that we do not believe it is appropriate to bundle the weekly and monthly formulations into a single bundled payment since, unlike Sublocade®, Brixadi® formulations have different payment limits, and pricing them under the same bundle would not adequately represent the average costs incurred in furnishing these different formulations in an OTP setting. Additionally, creating a single bundled payment rate that does not reflect the type and cost of the drug used could result in access issues for beneficiaries, especially if the bundled payment amount for one drug significantly drops and unintentionally incentivizes treatment towards a drug with a higher bundled payment amount.

In establishing the two different payments for the weekly and monthly injectable buprenorphine formulations, first, we proposed to crosswalk the monthly formulation of Brixadi® (J0578: *Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) to the drug component of our existing bundled payment for injectable buprenorphine described by HCPCS code G2069 (*Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*). We proposed to average the ASP+0 of Sublocade® and ASP+0 of monthly Brixadi® by adding their two ASP+0 payment amounts together and dividing the sum by two, to update the payment for the drug component of HCPCS code G2069. We believe including the average of the ASP+0 of Sublocade® and Brixadi® in the drug component of G2069 rather than the sum of their respective individual ASPs is appropriate because we do not expect that a beneficiary would receive two different types of buprenorphine monthly medication injections simultaneously from an OTP (for example, both Sublocade® and Brixadi® during the same episode of care and date of service). We believe that averaging the price of the two types of buprenorphine monthly medication injections would be appropriate because the individual payment limits for each of the drug codes (Q9991, Q9992, and J0578) would both be informed by ASP data and comparable as they would be priced by the same ASP payment methodology (ASP+0). We also noted that bundling the monthly formulation of Brixadi® into the existing HCPCS code (G2069) for injectable

[501] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf.*

[502] *https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-updated-03/04/2024.pdf.*

buprenorphine will be appropriate and no more administratively complex for OTPs since G2069 is already billed on a monthly basis; Sublocade®, which is already reflected in the drug component of G2069 is administered on a monthly basis to beneficiaries as would be the monthly formulation of Brixadi®, so OTPs could continue to bill G2069 once each month when either monthly Brixadi® or Sublocade® is administered, as appropriate.[503]

Additionally, the average typical dose of G2069 is 100mg of buprenorphine administered monthly, as finalized in the CY 2020 PFS final rule (84 FR 62651). The monthly formulations of Brixadi® can range from 64 mg, to 96 mg, to 128 mg. The median of these different doses for the monthly formulation of Brixadi® (96 mg) would approximate the average typical dose of the current injectable buprenorphine bundle (100 mg). We note that the different monthly doses of Brixadi® are assigned to the same HCPCS code J0578 (*Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) and have the same payment limit regardless of the monthly dose (64 mg, 96 mg, or 128 mg), so selecting a typical dose of monthly Brixadi® to potentially adjust the drug component of G2069 would not meaningfully change the payment rate. Therefore, we did not propose to establish an average typical dose different than 100 mg for injectable buprenorphine administered on a monthly basis for purposes of calculating the drug component under the OTP benefit, though we solicited comment on whether this average typical dose (100 mg) is close to the dose for the monthly formulation of Brixadi® that patients receive on average.

In all, we believe that bundling the monthly formulation of Brixadi® into our current injectable buprenorphine coding under the OTP benefit will be appropriate for several reasons, including: the costs for furnishing these drugs, as shown by similar ASP+0 amounts for monthly Brixadi® (J0578) and the two HCPCS codes for Sublocade® (Q9991 and Q9992) ($1524.855 and $1768.775, respectively, are comparable based on sales from the fourth calendar quarter of 2023); the average maintenance dosage for Sublocade® (100 mg) is comparable to the median monthly dosage for Brixadi ® (96 mg) and; both drugs have similar frequencies and costs of administration (on a monthly basis) with a fee paid to the OTP for one administration of an injection once a month. We stated that we believe that our proposed payment methodology would be consistent with section 1834(w)(2) of the Act, which allows the Secretary to implement bundled payments for OUD treatment services with considerations to the type of medication provided and the frequency of the services, and thus permit multiple bundles that represent injectable buprenorphine (proposed GOTP2 and G2069) and the frequency with which injectable buprenorphine is administered (weekly versus monthly). We proposed to still calculate the non-drug component of HCPCS code G2069 consistent with the methodology we use to calculate the non-drug component, which is specified at § 410.67(d)(2)(ii). We proposed to change the code descriptor for HCPCS code G2069 to take out references to a ''weekly bundle'' to make it clear that the code is to be billed on a monthly basis. Specifically, we proposed to revise the code descriptor to state the following: HCPCS code G2069 (*Medication assisted treatment, buprenorphine (injectable) administered on a monthly basis; bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)*). Lastly, consistent with current guidance in Chapter 39 of the Medicare Claims Processing Manual, we will still expect that HCPCS code G2069 ''would be billed for the week during which the injection was administered and that HCPCS code G2074, which describes a bundle not including the drug, will billed during any subsequent weeks that at least one non-drug service is furnished until the injection is administered again, at which time HCPCS code G2069 would be billed again for that week.'' [504]

For the weekly injectable buprenorphine, we proposed to calculate a new bundled payment described by GOTP2 (*Medication assisted treatment, buprenorphine (injectable) administered on a weekly basis; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*). For the drug component of HCPCS code GOTP2, we proposed to base the payment on a crosswalk to the weekly formulation described by HCPCS code J0577 *(Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy),* which would also be based on the payment methodology specified at § 410.67(d)(2)(i)(A) for implantable and injectable medications, consistent with the existing monthly injectable buprenorphine bundle. We believe that establishing a separate weekly bundled payment reflecting the weekly formulation of Brixadi® would more appropriately pay for the subset of beneficiaries who receive less than a monthly dosage of injectable buprenorphine on average, or who choose to discontinue treatment for the drug before the end of the month. Additionally, establishing a separate weekly bundled payment would contribute to stabilizing the payment of the drug component for the monthly bundle of injectable buprenorphine (G2069) since the ASP+0 for weekly Brixadi® costs less than the payment for the drug component of G2069 ($381.213 April 2024 ASP+0, based on sales from the fourth calendar quarter of 2023 versus $1,780.167 for the CY 2024 payment rate of the drug component of G2069) and may decrease payment after the weekly Brixadi is averaged into the drug component of G2069®. Establishing a separate weekly bundled payment is also more appropriate because weekly injectable buprenorphine requires more frequent administration costs than monthly injectable buprenorphine (weekly Brixadi® must be injected at least once every 7 days compared to once a month for Sublocade® and monthly Brixadi®). Thus, a different bundle for weekly injectable burpeorphine may more closely reflect the costs incurred by OTPs. Furthermore, as noted above in this section, different weekly doses are assigned to the same HCPCS code J0577 *(Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy)* and have the same payment limit regardless of the weekly dose. Therefore, we did not believe it was appropriate to propose an average typical dose for the weekly formulation of Brixadi® for purposes of calculating the drug component of GOTP2 under the OTP benefit.

Second, we proposed to also establish payment for the non-drug component of GOTP2 consistent with the methodology utilized for the monthly bundle of injectable buprenorphine (G2069). Specifically, we stated we will continue to pay for substance use counseling, individual and group therapy, and toxicology testing that are included in the non-drug components for each of the

[503] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[504] *https://www.cms.gov/files/document/chapter-39-opioid-treatment-programs-otps.pdf.*

bundled payments reflecting an episode of care, but will include the Medicare non-facility rate for administration of an injection in our determination of the non-drug component payment rate based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Consistent with the payment amounts for the non-drug component of other bundled payments for an episode of care, we also proposed to continue to update the value of this non-drug component for GOTP2 by the GAF as described in § 410.67(d)(4)(ii), and by the MEI as described in § 410.67(d)(4)(iii).

We solicited comments on these proposals to establish payment for the weekly and monthly formulations of the new injectable buprenorphine drug. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported CMS' efforts to expand access to a new, innovative injectable buprenorphine product for MOUD treatment and stated it would bolster efforts to combat the opioid epidemic. Multiple commenters also expressed support for CMS' proposed payment approach to create a new weekly bundled payment code to reflect the weekly formulation of Brixadi®, and to update the existing bundled payment for monthly injectable buprenorphine to account for the monthly formulation of Brixadi®.

Response: We appreciate commenters' support of this proposal.

Comment: One commenter recommended that CMS develop an expedited pathway separate from the annual rulemaking cycle to allow for more timely payment decisions of new drugs as they become available.

Response: We appreciate this commenter's feedback. CMS supports efforts to provide Medicare beneficiaries with timely access to important medications, including for the treatment of an OUD. We note that in the CY 2020 PFS final rule (84 FR 62643), we finalized coding to provide payment for new FDA-approved opioid agonist and antagonist treatment medications to treat OUD. Specifically, we created a medication not otherwise specified (NOS) code (HCPCS code G2075) in the scenario where an OTP furnishes MOUD treatment using a new FDA-approved opioid agonist or antagonist that is not specified by one of our existing codes. In Chapter 39, section 30.4, of the Medicare Claims Processing Manual, we describe the payment methodology for how the drug component may be priced for medications that are not otherwise specified. OTPs should consider billing HCPCS code G2075 for new FDA-approved opioid agonist or antagonist medications that are not specified by one of our existing codes, as long as they are medically reasonable and necessary, and all applicable requirements are met. However, we note that HCPCS code G2075 may not always apply to medications that are adjustments to the OTP bundle payment, such as unspecified, take-home doses of opioid overdose reversal medications that are not typically furnished on a weekly basis during an episode of care. We may consider this topic for future rulemaking.

Comment: One commenter asked CMS to consider any interaction this proposal, to establish payment for the weekly and monthly formulations of Brixadi®, may have on treatments currently covered under Medicare Part D.

Response: We appreciate the commenter raising this important question. We note that injectable buprenorphine can only be given if administered by an authorized healthcare provider.[505] Therefore, it is not available for self-administration and prescription through the Medicare Part D benefit.

Comment: One commenter advised CMS not to identify specific pharmaceutical brands when discussing the payment methodology in the final rule.

Response: We thank the commenter for this feedback. We note that the brand names of nalmefene hydrochloride (Opvee®) and injectable buprenorphine (Brixadi®) were specified to adequately estimate pricing of the drug component for proposed new codes GOTP1, GOTP2, and updating the existing bundled payment for monthly injectable buprenorphine (HCPCS code G2069). Brixadi® was also utilized in the payment methodology in order to distinguish this drug from another type of injectable buprenorphine: Sublocade®. The code descriptors for these aforementioned codes include the generic name instead of the brand name for these medications, so that they may be inclusive of comparable drugs in the future. Moreover, payment for these codes is made directly to the OTP for furnishing MOUD treatment instead of the drug manufacturer.

Comment: One commenter did not support our proposed monthly payment methodology for Brixadi® of adding the payment limits of Brixadi® and Sublocade® together under the same drug component in the existing monthly bundled payment (HCPCS code G2069) for injectable buprenorphine and averaging their two ASP+0 values. The commenter reasoned that separate bundled payments for each product are needed under the Medicare OTP benefit because Sublocade® and Brixadi® are clinically different due to several factors, including that the medications are not interchangeable, they have pharmacokinetic differences (for example, 2.46 ng/mL trough concentration for Sublocade® 100mg versus 2.0 ng/mL for Brixadi® 96mg), differences in minimum time between monthly dosing (26 days for Sublocade® versus 28 days for monthly Brixadi®), and differences in buprenorphine half-lives (19–26 days for Sublocade® versus 43–60 days for Brixadi®). The commenter added that section 1834(w)(2) of the Act allows the Secretary to make one or more bundles based on a variety of criteria, including by ''other factors as the Secretary determine appropriate,'' which may allow CMS the flexibility to create multiple bundled payments for injectable buprenorphine. The commenter noted that if the payment rate of the existing bundled payment for monthly injectable buprenorphine were to decrease, then it may incentivize OTPs to prescribe one type of medication over the other based on the medication with the higher financial return. The commenter expressed concern that such incentive could inadvertently influence an OTPs' ability to prescribe the most suitable medication for a patient's needs.

Response: We appreciate the commenter's concerns regarding the payment methodology for monthly injectable buprenorphine. We agree with the commenter that there are certain clinical differences in the drugs and that section 1834(w)(2) of the Act supports the Secretary in making multiple bundled payments under the OTP benefit based on a variety of factors. However, we do not believe that monthly Brixadi® and Sublocade® are significantly clinically different from each other to support creating a separate bundled payment for monthly Brixadi®. For example, while there are slight differences in the minimum days between maintenance doses and the half-lives of the two drugs, the FDA-approved labeling of both Brixadi® and Sublocade® specifies the same monthly interval for maintenance doses, and both can convert patients who require a

[505] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/210136Orig1s000lbl.pdf.*

maximum transmucosal buprenorphine dose of 24mg.[506] Additionally, since both drugs at maintenance doses reach plasma concentrations within the 2–3 ng/mL range of buprenorphine—identified as effective for reducing illicit opioid use [507]—we disagree with the commenter's suggestion that a higher concentration closer to 3 ng/mL is required to achieve a positive clinical outcome, which is measured using tools such as the Clinical Opiate Withdrawal Scale and Visual Analog Scale for craving.[508] Furthermore, in the CY 2020 PFS final rule, we finalized five medication categories [methadone (oral), buprenorphine (oral), buprenorphine (injection), buprenorphine (implant), and naltrexone (injection)] ''to represent the distinct types of covered OTP medications currently on the market based on primary active ingredient, method of administration, and cost.'' (84 FR 62642) Accordingly, monthly Brixadi® and Sublocade® have the same primary active ingredients (buprenorphine), methods of administration (by monthly injection), and comparable costs (April 2024 ASP+0: $1524.855 and $1768.775, based on sales from the fourth calendar quarter of 2023, and payment for administration of one monthly injection that would be included in the non-drug component). In the CY 2020 PFS final rule, we also stated that we believe ''these categories of bundled payments strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services.'' (84 FR 62642) Therefore, we don't believe the variable payment amounts for these two drugs would necessitate creating separate bundled payments. Although we proposed to create a separate weekly bundled payment for weekly injectable buprenorphine, we believed this is necessary due to the differences in the frequency of administration (weekly injections), and costs due to a lower ASP+0 ($381.214 April 2024 ASP+0, based on sales from the fourth calendar quarter of 2023) that would impact the drug component of the bundle, and the need for additional administration costs for multiple weekly injections that would also impact the non-drug component of the bundle.

Nevertheless, CMS agrees with the commenter that it is essential to promote access to MOUDs, and we believe that a payment for monthly buprenorphine injections that better reflects market conditions for these products would more accurately represent costs incurred by OTPs in providing this service. Therefore, instead of averaging each product's ASP+0 to calculate the drug component as proposed, we will calculate it using a volume-weighted ASP of all NDCs for both products using the calculation described in section 1847A(b)(6) of the Act. This approach better reflects the utilization of drugs in clinical practice since it accounts for the sales volume of each NDC for both products.

Based on the data used for the October 2024 ASP pricing file (that is, sales from the second calendar quarter of 2024), the drug component of the bundle for monthly injectable buprenorphine using the proposed calculation would be approximately $1,726.26. However, volume-weighting the ASP for all the NDCs crosswalked to HCPCS codes for monthly Brixadi® and Sublocade® would increase the payment of the drug component to approximately $1,797.29. Since calculating the drug component using the volume-weighted ASP of all NDCs crosswalked to both HCPCS codes better reflects actual utilization of the products, we are instead using this approach to price the drug component of the existing bundled payment for monthly injectable buprenorphine (HCPCS code G2069). We believe this revised payment approach will address the commenter's concerns due to the increased payment amount, which more closely reflects the market variables, including the volume of sales in each calendar quarter. We will continue to monitor utilization of each of the bundled payments for weekly and monthly injectable buprenorphine to ensure Medicare beneficiaries continue to have access to these medications, and propose additional refinements as needed through future rulemaking.

After consideration of public comments, we are finalizing our proposal to establish coding and payment for the weekly and monthly injectable buprenorphine. We will continue to use the payment methodology for implantable and injectable medications at § 410.67(d)(2)(i)(A) for the monthly and weekly injectable buprenorphine. We also are not finalizing a typical maintenance dose to establish the drug costs for these bundles since the doses under each formulation of Brixadi (weekly 8 mg, 16 mg, 24 mg, and 32mg; monthly: 64 mg, 96 mg, and 128 mg) have the same payment limit regardless of the dose. We are crosswalking the NDCs crosswalked to J0578 (*Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*) to the drug component of our existing bundled payment for injectable buprenorphine described by HCPCS code G2069 and calculating the drug component using a volume-weighted ASP of all NDCs crosswalked to HCPCS codes J0578 and Q9991 (which are the same NDCs crosswalked to HCPCS code Q9992). OTPs could continue to bill HCPCS code G2069 (*Medication assisted treatment, buprenorphine (injectable) administered on a monthly basis; bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*) once each month when either monthly Brixadi® or Sublocade® is administered, as appropriate. We are also establishing a separate weekly bundled payment to reflect the cost of furnishing weekly injectable buprenorphine described by HCPCS code G0533 (previously placeholder code GOTP2) (G0533: *Medication assisted treatment, buprenorphine (injectable) administered on a weekly basis; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).* Lastly, we will apply the GAF as described in § 410.67(d)(4)(ii), and MEI as described in § 410.67(d)(4)(iii), to the non-drug component for this code.

5. Clarification to Require an Opioid Use Disorder Diagnosis on Claims for OUD Treatment Services

Section 1861(s)(2)(HH) of the Act, as amended by section 2005 of the SUPPORT Act, implemented Medicare coverage for ''opioid use disorder treatment services.'' Section 1861(jjj)(1) of the Act describes opioid use disorder treatment services as items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder. Section 1834 of the

[506] *https://www.sublocade.com/Content/pdf/prescribing-information.pdf; https://www.brixadi.com/pdfs/brixadi-prescribing-information.pdf.*

[507] Jones AK, Ngaimisi E, Gopalakrishnan M, Young MA, Laffont CM. Population Pharmacokinetics of a Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder: A Combined Analysis of Phase II and Phase III Trials. Clin Pharmacokinet. 2021 Apr;60(4):527–540.

[508] Wesson, D.R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs, 35(2), 253–9 *https://pubmed.ncbi.nlm.nih.gov/12924748/*; Hayes, M.H.S. and Patterson, D.G. (1921) Experimental development of the graphic rating method. Psychological Bulletin, 18, 98–99.

Act specifies payments to OTPs for providing opioid use disorder treatment services. We interpreted these statutory provisions to mean that services paid to OTPs under Medicare Part B must be for the treatment of opioid use disorder. Consequently, at § 410.67(a) we reflect that those statutory provisions provide for coverage and payment to OTPs for OUD treatment services, which we define at § 410.67(b).

In August of 2023, an Office of Inspector General (OIG) report (A–09–22–03005) found that Medicare made over $1.3 million in payments to 70 OTPs for OUD treatment services that were claimed without an OUD diagnosis.[509] Of the claims paid without an OUD diagnosis code, 39 percent were for alcohol dependence, uncomplicated (F1020), 7 percent were for cocaine dependence, uncomplicated (F1420), and 5 percent were for generalized anxiety disorder (F411). As a result of these findings, OIG recommended that CMS ''develop billing requirements for OTPs to include OUD diagnosis codes on claims for OUD treatment services to indicate that enrollees have OUD diagnoses and consider working with MACs to implement a system edit to ensure that OTP payments are made for enrollees only when OUD diagnosis codes are included on claims.'' OIG also stated that ''requiring OTPs to include OUD diagnosis codes on claims could be a way for CMS to monitor whether OTPs furnished OUD treatment services to enrollees who had an OUD.'' In our response to the OIG report, we raised that the lack of an OUD diagnosis code on a claim is not conclusive evidence of an improper claim because an OUD diagnosis code is not required for payment when an OTP submits a claim for OUD treatment services. However, we agreed to explore ways to educate providers about including an OUD diagnosis on claims.

We continue to monitor claims paid by Medicare to OTPs for furnishing OUD treatment services, including for potential fraud and abuse. In analyzing our claims data at the beginning of CY 2024, we found data indicating that the majority of claims paid to OTPs have an OUD diagnosis code appended, meaning that only a small number of OTPs do not append an OUD diagnosis code to claims. However, we do intend to ensure that payments made to OTPs are in alignment with statutory requirements, which is that payments made must be for services furnished for the treatment of an OUD.

Therefore, in the CY 2025 PFS proposed rule, we clarified that all claims submitted to Medicare, on Form CMS–1450 for institutional providers, and on Form CMS–1500 for professional providers, or the electronic equivalents, under the OTP benefit must include an OUD diagnosis. These diagnosis codes must apply to HCPCS G-codes representing both the bundled payments (G2067 through G2075) and add-on codes to the bundled payments (G2076–G2080, G2215–G2216, G1028, and G0137). Applicable diagnosis codes for an OUD that must be submitted on claims include ICD–10–CM codes in the F11 range for ''disorders related or resulting from abuse or misuse of opioids.'' [510] We plan to issue additional guidance on appending these diagnosis codes to claims. We believe clarifying these billing requirements is consistent with CMS's strategic pillars to be a responsible steward of public funds,[511] and that these requirements are consistent with statutory provisions under sections 1861(s)(2)(HH), 1861(jjj)(1), and 1834 of the Act.

We received a few public comments related to this OUD ICD–10–CM diagnosis code billing clarification. The following is a summary of the comments we received on this topic and our responses.

Comment: A few commenters were pleased that CMS clarified billing requirements for OTPs in accordance with statutory requirements. One commenter agreed with the clarification since OTP physicians must affirm an OUD diagnosis prior to initiating treatment or developing a care plan for the patient. Another commenter raised that permitting providers to deliver OUD treatment services without a sufficient OUD diagnosis could influence treatment and recovery outcomes.

Response: We appreciate commenters' support regarding this billing clarification on claims for OUD treatment services. CMS will continue to educate OTPs on appending an OUD diagnosis to claims and update sub-regulatory guidance accordingly to ensure proper submission of claims that are in alignment with statutory requirements.

Comment: One commenter requested that CMS consider the population of patients who may receive opioid antagonist and/or agonist medications for chronic pain management. The commenter explained that some patients may receive a high dose of opioids for chronic pain, and naloxone may be given to these individuals for safety reasons. Another commenter raised that some medications prescribed by OTPs are approved to treat other conditions, including an alcohol use disorder, and requested that CMS add an alcohol use disorder diagnosis code to the list of acceptable diagnosis codes for claims submitted under the OTP benefit.

Response: We appreciate the feedback from these commenters. We understand how OTPs may treat patients with multiple diagnoses and various treatment needs, and those diagnosis codes may also be reflected on claims as OTPs should be coding appropriately per ICD–10–CM diagnosis coding guidelines. However, as stated in the discussion above, services paid to OTPs under Medicare Part B must be for the treatment of OUD, consistent with statutory provisions under sections 1861(s)(2)(HH), 1861(jjj)(1), and 1834 of the Act.

Finally, we received comments on several topics that were outside the scope of the proposed rule, and we've included a summary of those comments.

Comment: Out-of-scope comments included the following: a request that CMS develop an add-on code for contingency management services in OTPs for individuals with a stimulant use disorder; expanding services under the OTP benefit to include pain management services treated by certified athletic trainers and MOUD treatment provided by pharmacists in various settings; revising the Medicare OTP bundled payment structure to allow for more flexibility as it relates to take-home doses and counseling services; establishing coding for remote therapeutic monitoring services, which may include remotely observed take-home methadone dosing, along with coding for FDA-approved medical devices that prevent overdoses and reduce opioid withdrawal symptoms; issuing a clarification so that OTPs can bill Medicare for primary care services; modifying the definition of toxicology testing in the non-drug component of the bundled payments under the OTP benefit to exclude definitive testing; revising the update factor for the non-drug component of the bundled payments under the OTP benefit to use the inpatient prospective payment system market basket rather than the MEI; instructing Medicare Advantage plans to cover OTP services without prior authorization, primary care referral requirements, or copayments/coinsurance; creating a rural add-on payment to be applied to the non-drug component of the bundled payments

[509] *https://oig.hhs.gov/oas/reports/region9/92203005.asp.*

[510] *https://www.icd10data.com/ICD10CM/Codes/F01-F99/F10-F19/F11-.*

[511] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

under the OTP benefit to attend to low-population density areas that face health professional shortages; and, promulgating regulations to create protections for patients with an OUD who are seeking admission to skilled nursing facilities.

Response: While some of these comments are either outside of our statutory authority and/or out of scope for this final rule because they do not relate to the specific proposals included in the proposed rule, we appreciate the feedback and may consider these recommendations for future rulemaking.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO) and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending.

As of January 1, 2024, the Shared Savings Program has 480 ACOs with over 634,000 health care providers and organizations providing care to over 10.8 million assigned beneficiaries, making it the largest value-based care program in the country.[512] [513] The policy changes to the Shared Savings Program finalized in the CY 2023 PFS final rule (87 FR 69777 through 69979) and CY 2024 PFS final rule (88 FR 79093 through 79232) are expected to grow participation in the program and increase the number of beneficiaries assigned to ACOs by up to four million in the next 10 years (that is, between 2024–2034).[514] These policies are expected to drive growth in participation, particularly in rural and underserved areas, promote equity, and advance alignment across accountable care initiatives, and are central to achieving CMS' goal of having 100 percent of people with Traditional Medicare in a care relationship with accountability for quality and total cost of care by 2030.[515] Of note, 19 newly formed ACOs in the Shared Savings Program are participating in a new, permanent payment option beginning in 2024 that is enabling these ACOs to receive more than $20 million in advance investment payments (AIPs) for caring for underserved communities.[516] ACOs are now delivering care to people with Traditional Medicare in 9,032 Federally Qualified Health Centers, Rural Health Clinics, and critical access hospitals, an increase of 27 percent from 2023.[517]

To further advance Medicare's value-based care strategy of growth, alignment, and equity, and to allow for timely improvements to program policies and operations, we proposed changes to the Shared Savings Program as described in section III.G. of the CY 2025 PFS proposed rule (89 FR 61837 through 61924). We sought public comments which we summarize and respond to in sections III.G.2. through III.G.8. of this final rule. We proposed changes to the quality performance standard, benchmarks and other quality reporting requirements that aim to align the quality measures that Shared Savings Program ACOs would be required to report as part of the proposed APM Performance Pathway (APP) Plus measure set with the quality measures under the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set beginning in performance years 2025, and to prioritize the eCQM collection type as the gold standard collection type that underlies CMS' Digital Quality Measurement Strategic Roadmap while using Medicare CQMs as the transition step on our building block approach for ACOs' progress to adopt digital quality measurement.

Further, we proposed to establish a new ''prepaid shared savings'' option for eligible ACOs with a history of earning shared savings, to assist these ACOs with cash flow and encourage investments that would aid beneficiaries, such as investments in direct beneficiary services, staffing, or healthcare infrastructure. We proposed refinements to advance investment payment policies to allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program, and to specify that if CMS terminates an ACO's participation agreement, the ACO must repay any outstanding advance investment payments it received.

We proposed modifications to the Shared Savings Program's financial methodology including to (1) ensure the benchmarking methodology includes sufficient incentive for ACOs serving underserved communities [518] to enter and remain in the program through the application of a proposed health equity benchmark adjustment, (2) specify a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a), (3) establish a methodology for excluding payment amounts for HCPCS and CPT codes exhibiting significant, anomalous, and highly suspect (SAHS) billing activity during CY 2024 or subsequent calendar years that warrant adjustment, and (4) make technical changes to provide clarity on the methodology for capping the ACO's risk score growth and

[512] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2024, available at *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf*.

[513] See CMS Press Release, ''Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024'', January 29, 2024, available at *https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024*.

[514] Refer to 87 FR 69889. See also, CMS Press Release, ''CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship'', January 17, 2023, available at *https://www.cms.gov/newsroom/press-releases/cms-announces-increase-2023-organizations-and-beneficiaries-benefiting-coordinated-care-accountable*.

[515] For a description of CMS' strategic vision and objectives, see Seshamani M, Fowler E, Brooks-LaSure C. ''Building On The CMS Strategic Vision: Working Together For A Stronger Medicare''. Health Affairs. January 11, 2022. Available at*https://www.healthaffairs.org/content/forefront/building-cms-strategic-vision-working-together-stronger-medicare*. See also, CMS, Innovation Center Strategy Refresh, available at *https://innovation.cms.gov/strategic-direction-whitepaper* (Innovation Center Strategic Objective 1: Drive Accountable Care, pages 13–17).

[516] Refer to CMS Press Release, ''Participation Continues to Grow in CMS' Accountable Care Organization Initiatives in 2024'', January 29, 2024, available at *https://www.cms.gov/newsroom/press-releases/participation-continues-grow-cms-accountable-care-organization-initiatives-2024*.

[517] Ibid.

[518] As described in the *CMS Framework for Health Equity* and consistent with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009), the term ''underserved communities'' refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified in the definition of ''equity.'' See for example CMS Framework for Health Equity 2022–2032, available at *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf*.

regional risk score growth. Additionally, we solicited comments on financial arrangements that could allow for higher risk and potential reward under a revised ENHANCED track within the Shared Savings Program, including the designs of and trade-offs between financial model features.

We proposed changes to other program areas. We proposed changes in connection with Shared Savings Program eligibility requirements and application procedures, to permit continued participation by ACOs whose number of assigned beneficiaries falls below 5,000 during their agreement period, and to update provisions of the Shared Savings Program regulations on application procedures to reflect the latest approach Antitrust Agencies (the Department of Justice and the Federal Trade Commission [519]) use to evaluate ACOs and enforce the antitrust laws. We proposed changes to the Shared Savings Program beneficiary assignment methodology, to revise the definition of primary care services to align with payment policy proposals described elsewhere in the CY 2025 PFS proposed rule, and to broaden the existing exception to the program's voluntary alignment policy to allow for beneficiaries to be claims-based assigned to entities participating in certain disease- or condition-specific CMS Innovation Center ACO models notwithstanding their voluntary alignment to a Shared Savings Program ACO. We also proposed modifications to the beneficiary information notification requirements.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act,'' appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and

[519] Refer to Withdrawn Final Policy Statement, ''Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,'' available at *https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf*. See also, FTC Press Release, ''Federal Trade Commission Withdraws Health Care Enforcement Policy Statements'', July 14, 2023, available at *https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements*.

revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230), we removed the restriction that prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) allow ACOs whose agreement periods expired on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2020 PFS proposed rule (84 FR 40705), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780), and the CY 2024 PFS final rule (88 FR 79094 and 79095). In the CY 2024 PFS final rule (88 FR 79093 through 79232), we finalized changes to Shared Savings Program policies, including to: continue to move ACOs toward digital measurement of quality by revising the quality performance standard and reporting requirements under the APP within the Quality Payment Program (QPP); add a third step to the step-wise beneficiary assignment methodology under which we use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as related changes to how we identify assignable beneficiaries used in certain Shared Savings Program calculations; update the definition of primary care services used for purposes of beneficiary assignment to remain consistent with billing and coding guidelines; refine the financial benchmarking methodology for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years to (1) cap the risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth, (2) apply the same CMS–HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating risk scores for Medicare FFS beneficiaries for each benchmark year, (3) further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries, and (4) specify the circumstances in which CMS would recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations; refine our policies for the newly established advance investment payments (AIP); make updates to other programmatic areas including the program's eligibility requirements; and make timely technical changes to the regulations for clarity and consistency. Further, we also summarized comments received in response to a comment solicitation on potential future developments to Shared Savings Program policies, including incorporating a track with higher risk and potential reward than the ENHANCED track.

In a proposed rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023,'' which appeared in the July 3, 2024 **Federal Register** (89 FR 55168) (hereinafter referred to as the ''SAHS billing activity proposed rule''), we proposed an approach to address the SAHS billing activity CMS identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations. We finalized our proposals in a final rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023,'' which was effective on October 15, 2024, and appeared in the September 27, 2024 **Federal Register** (89 FR 79152) (hereinafter referred to as the ''SAHS billing activity final rule'').

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in the statute. For instance, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Provisions

In sections III.G.2. through III.G.8. of this final rule, we summarize and respond to public comments received on the proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2025 PFS proposed rule (89 FR 61837 through 61924). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the proposals discussed in section III.G. of the CY 2025 PFS proposed rule and will not be addressed in this section of this final rule. As a general summary, we are finalizing the

following changes to Shared Savings Program policies to:

• Update Shared Savings Program eligibility requirements and application procedures, including the following (section III.G.2 of this final rule):

++ Update compliance obligations for the requirement that ACOs maintain at least 5,000 assigned beneficiaries by the end of the performance year specified by CMS in its request for a CAP (section III.G.2.b of this final rule).

++ Revise the requirement that newly formed ACOs must agree to allow CMS to share a copy of their application with the Antitrust Agencies (section III.G.2.c of this final rule).

• Revise the policies for determining beneficiary assignment, including the following (section III.G.3 of this final rule):

++ Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.a of this final rule).

++ Revise the Shared Savings Program regulations to broaden a limited exception to the program's voluntary alignment policy and allow a voluntarily aligned Shared Savings Program beneficiary to be claims-based assigned to an entity participating in a disease- or condition-specific CMS Innovation Center model when that model uses claims-based assignment that is based on primary care and/or other services and the Secretary has determined that a waiver is necessary solely for purposes of testing the model, in order for beneficiaries with certain diseases or conditions to benefit from the focused attention and care coordination related to the disease or condition that an entity participating in such a model can offer (section III.G.3.b of this final rule).

• Revise the quality reporting and the quality performance standard requirements, including the following (section III.G.4. of this final rule):

++ Require Shared Savings Program ACOs to report the APP Plus quality measure set (section III.G.4.b.(2)(a) of this final rule).

++ Focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs by performance year 2027 (section III.G.4.b.(2)(b) of this final rule). Specifically, we are finalizing that:

—For performance years 2025 and 2026, ACOs will be required to report the APP Plus quality measure set using the eCQM/MIPS CQM/Medicare CQM collection type or a combination of these collection types.

—For performance year 2027 and any subsequent performance years, ACOs will be required to report the APP Plus quality measure set using the eCQM/Medicare CQM collection type or a combination of these collection types.

++ Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all required measures in the APP Plus quality measure set, as applicable (section III.G.4.c.(2)(a) of this final rule).

++ Establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs (section III.G.4.c.(2)(b) of this final rule).

++ Score Medicare CQMs using flat benchmarks in their first two performance periods in MIPS (section III.G.4.c.(2)(c) of this final rule).

++ Extend the eCQM/MIPS CQM reporting incentive for meeting the Shared Savings Program quality performance standard to performance years 2025 and 2026 and extend the eCQM reporting incentive for performance year 2027 and subsequent performance years (section III.G.4.d of this final rule).

• Allow eligible ACOs to receive prepaid shared savings (section III.G.5 of this final rule).

• Refine AIP policies, including the following (section III.G.6 of this final rule):

++ Allow ACOs receiving advance investment payments to voluntarily terminate from the payment option while remaining in the Shared Savings Program (section III.G.6.a of this final rule).

++ Codify a policy for recouping advance investment payments from ACOs whose participation agreements are terminated by CMS (section III.G.6.b of this final rule).

• Revise the policies on the Shared Savings Program's financial methodology, including the following (section III.G.7 of this final rule):

++ Apply a health equity benchmark adjustment (HEBA) which would adjust upward an ACO's historical benchmark, based on the number of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D and receive the Low-Income Subsidy (LIS).[520] This will encourage and sustain participation by ACOs serving underserved populations that do not benefit from existing benchmark adjustments for regional efficiency or from generating prior savings (section III.G.7.b of this final rule).

++ Establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination pursuant to § 425.315(a) (section III.G.7.c of this final rule).

++ Establish an approach to identify SAHS billing activity occurring in CY 2024 or subsequent calendar years, and specify approaches to mitigating the impact of the SAHS billing activity on Shared Savings Program financial calculations in CY 2024 or subsequent calendar years. Under this approach we will exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified, as well as from historical benchmarks used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity is identified (section III.G.7.d of this final rule).

++ Make technical changes in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth, respectively. The weight for a given enrollment type will be equal to the product of the ACO's historical benchmark expenditures after the application of any adjustment applied under § 425.652(a)(8) of the regulations (that is, the regional adjustment, prior savings adjustment or HEBA, or no adjustment) for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type (section III.G.7.f of this final rule).

• Modify beneficiary notification requirements, including the following (section III.G.8 of this final rule):

++ ACOs must provide the follow-up beneficiary communication no later than 180 days after the date that the ACO provided the standardized written notice to the beneficiary (section III.G.8.a of this final rule).

++ For ACOs that select preliminary prospective assignment with

[520] The low-income subsidy helps people with Medicare pay for prescription drugs and lowers the costs of Medicare prescription drug coverage. For more information about the LIS, refer to *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/LimitedIncomeandResources.* We note that we work with our partners to find and enroll people who may qualify for the LIS. For brevity, in section III.G. of this final rule, we sometimes refer to beneficiaries enrolled in the Medicare Part D LIS.

retrospective reconciliation, limit the distribution of the standardized written beneficiary information notification to beneficiaries who are more likely to be assigned to the ACO, when compared to the beneficiaries who must receive the written notification under current regulations (section III.G.8.b of this final rule).

In addition, in the CY 2025 PFS proposed rule, we solicited comments on establishing a higher risk and reward participation option than the current ENHANCED track, as discussed in section III.G.7.e of this final rule.

Taken together, the policies we are adopting for the Shared Savings Program in this final rule are anticipated to improve ACOs' incentives to join the program and continue participating in future years and earn shared savings. The provisions are projected to reduce program spending by $200 million in total over the 10-year period 2025 through 2034. These changes will support the goals outlined in the CY 2023 PFS final rule (87 FR 69777 through 69978) and CY 2024 PFS final rule (88 FR 79093 through 79232) for growing the program, with a particular focus on including underserved communities.

Certain policies, including both existing policies and new policies adopted in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: allowing eligible ACOs to receive prepaid shared savings, as described in section III.G.5 of this final rule; using a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts for certain Shared Savings Program financial calculations, upon reopening an ACO's payment determination and issuing a revised initial determination pursuant to § 425.315(a), as described in section III.G.7.c of this final rule; using a methodology for certain Shared Savings Program financial calculations to mitigate the impact of SAHS billing activity occurring in CY 2024 or subsequent calendar years, as described in section III.G.7.d of this final rule; and making technical changes to the provision describing how we calculate the weights applied when capping growth in regional risk scores as part of the regional component of the three-way blended benchmark update factor, as described in section III.G.7.f of this final rule. As described in the Regulatory Impact Analysis in section VI. and elsewhere in this final rule, these changes to our payment methodology are expected to improve the quality and efficiency of care and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

2. Eligibility Requirements and Application Procedures

a. Overview

In the CY 2025 PFS proposed rule (89 FR 61842 through 61843), we proposed two modifications to the Shared Savings Program eligibility and application procedures that will be implemented for performance years beginning on or after January 1, 2025. Specifically, we proposed the following, which are discussed in more detail in sections (b) and (c) below:

- Sunset the requirement after January 1, 2025, at § 425.110(b)(2) that CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a Corrective Action Plan (CAP); and
- Revise the antitrust language in the application procedures at §§ 425.202(a)(3) and 425.224(a)(3) for the Shared Savings Program.

b. Monitoring Compliance With the Requirement That ACOs Maintain at Least 5,000 Assigned Beneficiaries

Section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and that at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it. In the November 2011 final rule (76 FR 67808), in alignment with the statutory requirement at section 1899(b)(2)(D) of the Act, CMS established that, at a minimum, an ACO shall have at least 5,000 such beneficiaries assigned to it to be eligible to participate in the Shared Savings Program under § 425.110. We described the importance of maintaining at least 5,000 assigned beneficiaries with respect to both eligibility of the ACO to participate in the program and the statistical stability for purposes of calculating per capita expenditures and assessing financial and quality performance. We noted, however, that we understood circumstances may change during the agreement period, and that an ACO's assigned population may vary accordingly.

To enforce program requirements under § 425.110, while still recognizing that variations may occur for an ACO's assigned population, CMS generally issues a warning notice and requests the ACO submit a CAP should the ACO's assigned population fall below 5,000 beneficiaries. Few ACOs have had a beneficiary population that fell below 5,000. Between calendar year 2020 and 2023, based on the program's compliance monitoring review, 24 ACOs have been below this assignment threshold at the start of one or more performance years within an agreement period, which led CMS to issue compliance actions. Approximately 55 percent of these ACOs opted to voluntarily terminate ahead of the CAP deadline imposed by CMS, while approximately 40 percent were able to increase their beneficiary assignment over the threshold and remain in the program. Given additional time, more ACOs likely would be able to increase their beneficiary assignment, keeping more beneficiaries in accountable care relationships, and maintain their participation in the Shared Savings Program.

Separately, we had established a policy in the December 2018 final rule (83 FR 67925) providing for an ACO to select the Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) that CMS would use when performing shared savings and shared losses calculations for the ACO. As we have previously discussed, the MSR/MLR protects against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation

rather than an actual change in performance (see, for example, 83 FR 67923 through 67926).

In the December 2018 final rule (83 FR 67925 through 67929), we revised § 425.110(b) to provide for the use of a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population fell below 5,000 for the performance year regardless of whether the ACO had previously selected a fixed or variable MSR/MLR. This policy protects the statistical stability of the program's expenditure calculations. As an ACO's assigned beneficiary population decreases, variability in the population's expenditures increases. We thus expressed concern that the reduction in the size of the ACO's assigned beneficiary population would cause shared savings payments made to the ACO to not reflect true cost savings, but normal expenditure fluctuations (83 FR 67926). The use of a variable MSR/MLR thus made it more difficult for an ACO under performance-based risk that falls below the 5,000-beneficiary threshold to earn shared savings or be responsible for shared losses to ensure that the savings or losses reflected the ACO's actual performance and not merely statistical noise. This policy provided additional protection to the Medicare Trust Funds and greater protection for ACOs against owing shared losses.

As described above, an ACO's failure to maintain at least 5,000 assigned beneficiaries may result in compliance actions, up to and including termination of the ACO from the Shared Savings Program. When originally developed, this program policy was intended in part to protect both CMS and the ACO from variability in the expenditure calculations caused by a small assigned beneficiary population. With the MSR and MLR adjustments finalized in the December 2018 final rule, we developed protections against issues with the benchmark calculation for ACOs with fewer assigned beneficiaries, which provide adequate protection against variability in the short term. The MSR and MLR sliding scale varies based on the number of beneficiaries assigned to the ACO from 1 up to 60,000. Currently, this adjustment to the MSR/MLR protects both CMS and the ACO from inappropriate over or underpayments, reducing the financial risk of allowing ACOs to continue to participate in the Shared Savings Program if they experience a reduction in assigned beneficiaries.

In light of the effectiveness of the variable MSR/MLR policy described above, we proposed to sunset the requirement at § 425.110(b)(2) that CMS will terminate an ACO's participation agreement and determine that an ACO is not eligible to share in savings for that performance year if an ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP. Specifically, we proposed to revise § 425.110(b)(2) to limit its application to performance years starting before January 1, 2025. Thus, for performance years beginning on or after January 1, 2025, if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS will not be required to terminate the participation agreement. (Refer to 89 FR 61842.)

This proposal will not modify the requirement at § 425.110(a), which implements the statutory requirement at section 1899(b)(2)(D) of the Act that ACOs have 5,000 beneficiaries at critical points in CMS's determination of the ACO's eligibility to participate in the Shared Savings Program, including: at the time of application in order to be eligible for the Shared Savings Program, and at any point when an ACO elects to renew its participation in the program. As discussed in the November 2011 final rule (76 RF 67808), CMS has found ''[a] minimum threshold is important with respect to both the eligibility of the ACO to participate in the program and to the statistical stability for purposes of calculating per capita expenditures and assessing quality performance.'' A 5,000 beneficiary minimum, paired with a variable MSR/MLR, enables ACOs to have their work of improving beneficiary care best reflected in their financial performance and shared savings results. Additionally, we will retain § 425.110(b), which states that an ACO may be subject to actions under §§ 425.216 and 425.218 if its assigned population falls below 5,000 at any time during the performance year. This proposed approach provides CMS with additional flexibility in the compliance actions that we take in working with ACOs to help them return to the 5,000 beneficiary threshold.

The proposed modification aligns with CMS's broader goals to expand the number of beneficiaries in accountable care relationships. We anticipated this flexibility would provide ACOs with additional time and opportunities to recruit additional providers and suppliers to increase their assigned beneficiary population rather than being required to exit the Shared Savings Program due to their beneficiary attribution. We solicited comment on this proposal. This proposed change would be effective beginning on January 1, 2025.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support in response to this proposal. These commenters appreciated the additional flexibility this change allows ACOs and agree that it will increase ACO, provider, and supplier retention in the program.

Response: We agree with commenters that this will provide additional flexibility for ACO participants.

Comment: Several commenters provided additional suggestions for CMS's consideration. These included a recommendation that CMS consider factors outside of an ACO's control when determining compliance actions, such as geographic location or serving an underserved population, which commenters suggested can lead to fluctuations in their assigned beneficiary population. Additional commenters suggested that CMS consider offering additional levels of flexibility beyond this modification, including grace periods, additional resources for ACOs with ''significant challenges,'' or gradual enforcement of this threshold requirement for new or small ACOs. One commenter suggests that low-revenue ACOs receive a 1-year extension on their agreement renewals to meet the 5,000 beneficiary threshold.

Response: We agree that it is appropriate to consider ACOs' individual circumstances when determining compliance actions. This proposed policy gives CMS more flexibility in determining appropriate compliance actions for individual ACOs and providing additional resources or flexibilities to ACOs in this area is not appropriate at this time. CMS is required to ensure that ACOs have at least 5,000 assigned beneficiaries to be eligible to participate in the Shared Savings Program by section 1899(b)(2)(D) of the Act, and therefore is unable to offer extensions to ACOs who are unable to meet that requirement at the start of any agreement period. Our policy provides ACOs and CMS with an appropriate amount of flexibility while complying with our statutory requirements. After consideration of public comments, we are finalizing our proposal, without modification, to amend § 425.110(b)(2) to sunset the requirement after January 1, 2025, that CMS must terminate the participation agreement and the ACO is not eligible to share in savings for that performance year if the ACO's assigned population is not at least 5,000 by the end of the

performance year specified by CMS in its request for a CAP. ACOs will still be required to meet the requirement of 5,000 assigned beneficiaries when they renew for a new agreement period.

c. Update Antitrust Language

Section 425.202(a)(3) requires that ACOs that are newly formed after March 23, 2010, agree to allow CMS to share a copy of their application with the Antitrust Agencies (the Federal Trade Commission (FTC) and the Department of Justice (DOJ), as defined in the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program). This policy has been in effect since the enactment of the November 2011 final rule (76 FR 67822). We stated at the time that this policy was in the public interest to harmonize the eligibility criteria for ACOs that wished to participate in the Shared Savings Program with similar antitrust criteria on clinical integration, because competition among ACOs was expected to have significant benefits for Medicare beneficiaries.

In 2023, both the DOJ and the FTC withdrew the outdated Antitrust Enforcement Policy Statement because the policy no longer served its intended purpose of providing useful guidance to market participants.[521] Instead, both Antitrust Agencies have stated that they will continue to vigorously enforce the antitrust laws in the health care markets by evaluating mergers and conduct that harm competition on a case-by-case basis.

As a result, in the CY 2025 PFS proposed rule (89 FR 61843) we proposed to modify the Shared Savings Program eligibility requirements that will be implemented on January 1, 2025, by removing the reference to the Antitrust Enforcement Policy Statement in § 425.202(a)(3), and also in § 425.224(a)(3). This proposal aligns the Shared Savings Program with the Antitrust Agencies' decisions to withdraw the Antitrust Enforcement Policy Statement. We proposed to edit § 425.202(a)(3) to state, ''An ACO that seeks to participate in the Shared Savings Program must agree that CMS can share a copy of their application with the Antitrust Agencies.'' Similarly, we proposed to edit § 425.224(a)(3) to state, ''An ACO that seeks to enter a new participation agreement under the Shared Savings Program must agree that CMS can share a copy of its application with the Antitrust Agencies.'' We also plan to remove guidance from the Shared Savings Program website detailing how an ACO could calculate their share of services in each applicable Primary Service Area (PSA), as described in the Antitrust Policy Statement, as this is no longer useful to ACOs.

In the CY 2025 PFS proposed rule (89 FR 61843) we explained that, as we stated in earlier rulemaking (76 FR 67842), we intend to coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program to ensure there are no detrimental impacts to competition. We will share application and participation information including aggregate claims data regarding allowed charges and fee-for-service payments for all ACOs accepted in the Shared Savings Program, with the Antitrust Agencies needed to further any investigations or support their enforcement of the antitrust laws.

We solicited comment on this proposal. This proposed change would be effective beginning on January 1, 2025.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters agreed with this proposal and noted it improved clarity following the withdrawal of the Antitrust Policy Statement.

Response: We agree with commenters. After consideration of public comments, we are finalizing without modification the proposed changes to § 425.202(a)(3) and § 425.224(a)(3), to remove the reference to the Antitrust Policy Statement from provisions on application procedures.

3. Beneficiary Assignment Methodology

a. Revisions to the Definition of Primary Care Services

(1) Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the performance year beginning on January 1, 2024, and subsequent performance years, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 in § 425.400(c)(1)(viii).

(2) Revisions

As described in the CY 2025 PFS proposed rule (89 FR 61844 through 61851), based on feedback from ACOs and our further review of the HCPCS and CPT codes that are currently recognized for payment under the PFS or that we proposed to recognize for payment starting in CY 2025, we stated that we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the performance year starting on January 1, 2025, and subsequent performance years, in order to remain consistent with billing and coding under the PFS.

We proposed to specify a revised definition of primary care services used for assignment in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(ix) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(viii), as well as the

[521] U.S. Department of Justice, Press Release, *Justice Department Withdraws Outdated Enforcement Policy Statements* (Feb. 3, 2023), available at *https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements;* Federal Trade Commission, Press Release, *Federal Trade Commission Withdraws Health Care Enforcement Policy Statements* (July 14, 2023), available at *https://www.ftc.gov/news-events/news/press-releases/2023/07/federal-trade-commission-withdraws-health-care-enforcement-policy-statements.*

following additions: (1) Safety Planning Interventions (HCPCS code GSPI1) when the base code is also a primary care service code, if finalized under Medicare FFS payment policy; (2) Post-Discharge Telephonic Follow-up Contacts Intervention (HCPCS code GFCI1), if finalized under Medicare FFS payment policy; (3) Virtual Check-in Service (CPT code 9X091), if finalized under Medicare FFS payment policy; (4) Advanced Primary Care Management Services (HCPCS GPCM1, GPCM2, and GPCM3), if finalized under Medicare FFS payment policy; (5) Cardiovascular Risk Assessment and Risk Management Services (HCPCS codes GCDRA and GCDRM), if finalized under Medicare FFS payment policy; (6) Interprofessional Consultation Services (CPT codes 99446, 99447, 99448, 99449, 99451, 99452); (7) Direct Care Caregiver Training Services (HCPCS codes GCTD1, GCTD2 and GCTD3), if finalized under Medicare FFS payment policy; and (8) Individual Behavior Management/Modification Caregiver Training Services (HCPCS codes GCTB1 and GCTB2), if finalized under Medicare FFS payment policy.

We proposed that the new provision at § 425.400(c)(1)(ix) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2025, and subsequent performance years.

The following provides additional information about the CPT and HCPCS codes that we proposed to add to the definition of primary care services used for purposes of beneficiary assignment:

• *Safety Planning Interventions (SPI) (HCPCS code GSPI1 (Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy)):* In the CY 2025 PFS proposed rule (89 FR 61741), we proposed under the PFS to create an add-on G-code that would be billed along with an E/M visit or psychotherapy visit when safety planning interventions are personally performed by the billing practitioner in a variety of settings. Safety planning interventions involve a person working with a clinician to develop a personalized list of coping strategies and sources of support that the person could use in the event of experiencing thoughts of harm to themselves or others. This is not a suicide risk assessment, but rather, an intervention provided to people determined to have elevated risk. Safety planning interventions have also been used to reduce the risk of suicide. The basic components of a safety plan include the following: (1) recognizing warning signs of an impending suicidal crisis or actions that increase the risk of overdose; (2) employing internal coping strategies; (3) utilizing social contacts and social settings as a means of distraction from suicidal thoughts and/or taking steps to reduce the risk of suicide; (4) utilizing family members or friends to help resolve the crisis; (5) contacting mental health professionals, crisis services, or agencies; and (6) making the environment safe, including restricting access to lethal means, if applicable.

Refer to section II.I of this final rule for detailed, technical discussion regarding the finalized description, payment, and utilization of this HCPCS code.

In the CY 2019 PFS final rule (83 FR 59965 through 59966), we finalized the addition of prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355) to the definition of primary care services used for purposes of assignment because these two codes are ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. For the same reason, in the proposed rule we stated that we believe it would be appropriate to also include HCPCS code GSPI1, if finalized under Medicare FFS policy since GSPI1 is being proposed as an add-on service to an E/M or psychotherapy visit. Evaluation and management visits are included in the definition of primary care services used for purposes of assignment and so we stated that we believe it would be appropriate to also include GSPI1, when billed with an E/M visit, in the definition of primary care services used for purposes of assignment to assign beneficiaries more accurately to ACOs participating in the Shared Savings Program. We further believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve continuity of care. Including Safety Planning Intervention services in the definition of primary care services used for purposes of assignment would also align with the CMS Behavioral Health Strategy (*https://www.cms.gov/cms-behavioral-health-strategy*), the mission of which is to ensure that high-quality behavioral health services and supports are accessible to Medicare beneficiaries.

We note that, as proposed, HCPCS code GSPI1 could also be billed with psychotherapy services, which are not considered for purposes of beneficiary assignment under § 425.400(c). Therefore, we proposed to include the allowed charges for HCPCS code GSPI1, for purposes of assigning beneficiaries to ACOs, only when billed with a service which is also included in the definition of primary care services.

• *Post-Discharge Telephonic Follow-up Contacts Intervention (FCI) (HCPCS code GFCI1: Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month).* In the CY 2025 PFS proposed rule (89 FR 61741 through 61742), we described FCI as a specific protocol of services for individuals with suicide risk involving a series of telephone contacts between a provider and person in the weeks and sometimes months following discharge from the emergency department and other relevant care settings, that occurs when the person is in the community and is designed to reduce the risk of subsequent adverse outcomes. FCI calls are typically 10–20 minutes in duration and aim to encourage use of the Safety Plan (as needed in a crisis) and updating it to optimize effectiveness, expressing psychosocial support, and helping to facilitate engagement in any indicated follow-up care and services. We proposed to create a monthly billing code to describe the specific protocols involved in furnishing post-discharge telephonic follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month, each lasting between 10–20 minutes. We proposed to price this service based on a direct crosswalk to CPT code 99426 (*Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional*) because we stated that we believe the work would be similar in nature and intensity.

Refer to section II.I. of this final rule for detailed, technical discussion regarding the finalized description,

payment, and utilization of this HCPCS code.

These services are similar to TCM services (CPT codes 99495 and 99496), which are included in the definition of primary care services used for purposes of assignment under § 425.400(c), in that these services help eligible people transition back to a community setting after a stay at certain facility types like TCM. Similar to the rationale described December 2014 proposed rule (79 FR 72792) and later finalized in the June 2015 final rule (80 FR 32746 through 32748) where we finalized the inclusion of TCM services in the definition of primary care services used for purposes of assignment, providing separate payment for the work of community physicians and practitioners in treating a patient following discharge from a hospital or nursing facility would ensure better continuity of care for these patients and help reduce avoidable readmissions. Therefore, in the CY 2025 PFS proposed rule (89 FR 61845), we stated that FCI services should also be included in the definition of primary care services used for beneficiary assignment since FCI services are designed to assist in the transition from the emergency department into the community. We stated that we believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. Thus, we stated that we believe that FCI services should also be included.

Further, in determining the recommended pricing for HCPCS code GFCI1, we recommended pricing this service based on a direct crosswalk to Principal Care Management (PCM) service (CPT code 99426) because we stated that we believe the work would be similar in nature, as well as time and intensity. In the CY 2021 PFS final rule (85 FR 84749), we finalized the inclusion of HCPCS codes G2064 and G2065 in the definition of primary care services used for purposes of assignment since we expect that most services billed under these codes will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. These HCPCS codes were replaced by CPT codes 99424, 99425, 99426, and 99427 in the CY 2022 PFS final rule (86 FR 65275). PCM services (CPT codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065) are included in the definition of primary care services used for purposes of assignment and since FCI services are similar in nature, time, and intensity to PCM services, we stated that we believe it would be appropriate to include these services in the definition of primary care services used for purposes of assignment. Including FCI services in the definition of primary care services used for purposes of assignment would also align with the CMS Behavioral Health Strategy as the FCI services are designed to support beneficiaries with follow-up care related to suicide risk.

- *Virtual Check-in Service (CPT code 9X091):*

++ CPT code 9X091 (*Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related evaluation and management service provided within the previous 7 days nor leading to an evaluation and management service or procedure within the next 24 hours or soonest available appointment, 5–10 minutes of medical discussion*).

The CPT Editorial Panel established a new CPT code 9X091 describing a brief virtual check-in encounter that is intended to evaluate the need for a more extensive visit. The code descriptor for CPT code 9X091 mirrors that of existing HCPCS code G2012 (*Brief communication technology-based service, for example, virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*) and, per the CPT Editorial Panel materials, is intended to replace that code. HCPCS code G2012 is included in the Shared Savings Program definition of primary care services used for purposes of assignment.

In the CY 2025 PFS proposed rule (89 FR 61651 through 61654), we proposed separate payment for CPT code 9X091. Because the code description for CPT code 9X091 mirrors HCPCS code G2012 and because, per CPT Editorial Panel materials, CPT code 9X091 is intended to replace HCPCS code G2012, we proposed to make CPT code 9X091 separately payable under Medicare. We note we proposed to delete HCPCS code G2012 for purposes of Medicare PFS payment policy, however, HCPCS code G2012 will continue to be included in the definition of primary care services used for purposes of assignment, consistent with how deleted CPT and HCPCS codes have been handled historically and to allow for consistency with calculating historical benchmarks.

We proposed that we would include CPT code 9X091 in the definition of primary care services used for purposes of assignment as the code description of brief communication technology-based service mirrors the description of HCPCS code G2012, which is included in the definition of primary care services used for purposes of assignment since these services are furnished to established patients by physicians or qualified health care professionals that can report E/M services in lieu of an in person primary care visit (85 FR 84753). Since CPT code 9X091 is a direct replacement of HCPCS code G2012, 9X091 would be included in the definition of primary care services used for purposes of assignment, under proposed § 425.400(c)(1)(ix)(C). In the CY 2022 PFS final rule (86 FR 65277 through 65279), we finalized a policy wherein we will incorporate into the definition of primary care services a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, a G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program. Additionally, CPT code 9X091, per the CPT Editorial Panel materials, is intended to be reported instead of HCPCS code G2012, which is already included in the definition of primary care services used for purposes of assignment. We further believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

We explained that this approach would help to ensure the appropriate identification of primary care services used in the Shared Savings Program's assignment methodology by allowing for the immediate inclusion of replacement CPT codes in the determination of beneficiary assignment and lead to continuity in the assignment of beneficiaries receiving those services based on current coding (89 FR 61845). This continuity would improve predictability for ACOs, while also increasing the consistency of care coordination for their assigned beneficiaries. We further finalized that such replacement codes would be incorporated into the definition of the primary care services for purposes of determining beneficiary assignment for the performance year, when the assignment window for a benchmark or performance year (as defined in

§ 425.20) includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare. CPT code 9X091 has an effective date of January 1, 2025. Refer to section II.E of this final rule for detailed, technical discussion regarding the finalized description, payment, and utilization of this CPT code.

• *Advanced Primary Care Management (HCPCS codes GPCM1, GPCM2, and GPCM3);*

(1) HCPCS code GPCM1: (*Advanced primary care management services provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the following elements, as appropriate:*

• *Consent;*

++ *Inform the patient regarding availability of the service; that only one practitioner can furnish and be paid for the service during a calendar month; of the right to stop the services at any time (effective at the end of the calendar month); and that cost sharing may apply.*

++ *Document in patient's medical record that consent was obtained.*

• *Initiation during a qualifying visit for new patients or patients not seen within 3 years;*

• *Provide 24/7 access for urgent needs to care team/practitioners, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent needs regardless of the time of day or day of week;*

• *Continuity of care with a designated member of the care team with whom the patient is able to schedule successive routine appointments;*

• *Deliver care in alternative ways to traditional office visits to best meet the patient's needs, such as home visits, and/or expanded hours;*

• *Overall comprehensive care management;*

++ *Systematic needs assessment (medical and psychosocial).*

++ *System-based approaches to ensure receipt of preventive services.*

++ *Medication reconciliation, management and oversight of self-management.*

• *Development, implementation, revision, and maintenance of an electronic patient-centered comprehensive care plan;*

++ *Care plan is available timely within and outside the billing practice as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and copy of care plan to patient/caregiver.*

• *Coordination of care transitions between and among health care providers and settings, including referrals to other clinicians and follow-up after an emergency department visit and discharges from hospitals, skilled nursing facilities or other health care facilities as applicable;*

++ *Ensure timely exchange of electronic health information with other practitioners and providers to support continuity of care.*

++ *Ensure timely follow-up communication (direct contact, telephone, electronic) with the patient and/or caregiver after an emergency department visit and discharges from hospitals, skilled nursing facilities, or other health care facilities, within 7 calendar days of discharge, as clinically indicated.*

• *Ongoing communication and coordinating receipt of needed services from practitioners, home- and community-based service providers, community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), and document communication regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors, in the patient's medical record;*

• *Enhanced opportunities for the beneficiary and any caregiver to communicate with the care team/practitioner regarding the beneficiary's care through the use of asynchronous non-face-to-face consultation methods other than telephone, such as secure messaging, email, internet, or patient portal, and other communication-technology based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate;*

++ *Ensure access to patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits).*

• *Analyze patient population data to identify gaps in care and offer additional interventions, as appropriate;*

• *Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients*;

• *Be assessed through performance measurement of primary care quality, total cost of care, and meaningful use of Certified EHR Technology.*

(2) HCPCS code GPCM2 (*Advanced primary care management services for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*), and

(3) HCPCS code GPCM3 (*Advanced primary care management services for a patient who is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by clinical staff and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate*).

In the CY 2025 PFS proposed rule (89 FR 61698 through 61725), we proposed to establish coding and make payment under the PFS for a newly defined set of APCM services as described and defined by three HCPCS codes (GPCM1, GPCM2, and GPCM3) to recognize the resource costs associated with furnishing services using an ''advanced primary care approach'' supported by a team-based care structure under the PFS. Delivery of care using an advanced primary care model involves restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices. This restructuring creates several advantages for patients, and provides more broad accessibility and alternative methods for patients to communicate with their care team/practitioner about their care outside of in-person visits (for example, virtual, asynchronous interactions, such as online chat), which can lead to more timely and efficient identification of, and responses to, health care needs (for example, practitioners can route patients to the optimal clinician and setting—to a synchronous visit, an asynchronous chat, or a direct referral to the optimal site of care). Practitioners using an advanced primary care delivery model can more easily collaborate across

clinical disciplines through remote interprofessional consultations with specialists, as well as standardize condition management into evidence-based clinical workflows, which allow for closed-loop follow-up and more real-time management for patients with acute or evolving complex issues, partner on complex decisions, and personalize their patients' care plans.

Specifically, we proposed (89 FR 62011) to adopt specific coding and payment policies for APCM services for use by practitioners who are providing services under this specific model of advanced primary care, when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services.

Providing care using an advanced primary care delivery model involves resource costs associated with maintaining certain practice capabilities and continuous readiness and monitoring activities to support a team-based approach to care, where significant resources are used on virtual, asynchronous patient interactions, collaboration across clinical disciplines, and real-time management of patients with acute and complex concerns that are not fully recognized or paid for by the existing care management codes. As the delivery of primary care has evolved to embrace advanced primary care more fully, in the proposed rule we stated that we believe that it is prudent to now adopt specific coding and payment policies to better recognize the resources involved in care management under an advanced primary care delivery model.

We seek to ensure that the APCM codes would fully and appropriately capture the care management and CTBS services that are characteristic of the changes in medical practice toward advanced primary care, as demonstrated in select CMS Innovation Center models. As we do for CCM and PCM services, we proposed to require for APCM services that the practitioner provide an initiating visit and obtain beneficiary consent (see section II.G.2.c.(1) and II.G.2.c.(2) of the proposed rule). We proposed to incorporate as elements of APCM services ''Management of Care Transitions'' and ''Enhanced Communications Opportunities.'' For the ''Management of Care Transitions'' APCM service element, we proposed to specify timely follow-up during care transitions (see section II.G.2.c.(6) of the proposed rule). For the ''Enhanced Communications Opportunities'' APCM service element, we proposed to incorporate digital access through CTBS services, such as virtual check-ins and remote evaluation of images, to maintain ongoing communication with the patient (see section II.G.2.c.(8) of the proposed rule). We also proposed to specify for APCM services the practice-level characteristics and capabilities that we stated that we believe to be inherent to, and necessarily present when a practitioner is providing covered services using, the ''advanced primary care'' model. Included in the service descriptors for GPCM1, GPCM2, and GPCM3 are proposed practice-level capabilities that reflect care delivery using an advanced primary care model that focused around 24/7 access and continuity of care (see section II.G.2.c.(3) of the proposed rule), patient population-level management (see section II.G.2.c.(9) of the final rule), and performance measurement (see section II.G.2.c.(10) of the final rule). We stated that we believe these practice capabilities are indicative of, and necessary to, care delivery using the advanced primary care model.

Refer to section II.G. of this final for detailed, technical discussion regarding the proposed description, payment and utilization of these HCPCS codes as well as information about requirements for billing providers participating in ACOs.

As described in section II.G. of this final rule, HCPCS codes GPCM1 through GPCM3 would describe APCM services furnished per calendar month, following the initial qualifying visit (see section II.G.2.c.(1) of this final rule for more on the initiating visit). Physicians and NPPs, including nurse practitioners (NPs), physician assistants (PAs), certified nurse midwives (CNMs) and clinical nurse specialists (CNSs), could bill for APCM services. As we described in more detail in section II.G.2.c. of this final rule, within the code descriptors for GPCM1, GPCM2, and GPCM3, we included the elements of the scope of service for APCM as well as the capabilities and requirements that we stated that we believed to be inherent to care delivery by the practitioner using an advanced primary care model, and necessary to fully furnish and, therefore, bill for APCM services.

We proposed that the practitioner who bills for APCM services must intend to be responsible for the patient's primary care and serve as the continuing focal point for all needed health care services. We anticipated that most practitioners furnishing APCM services would be managing all the patient's health care services over the month and have either already been providing ongoing care for the patient or have the intention of being responsible for the patient's primary care and serving as the continuing focal point for all of the patient's health care services. As detailed in sections II.G.2.b. through II.G.2.d. of this final rule, this proposed coding and payment would incorporate elements of several specific, existing care management and communication technology-based services (CTBS) into a bundle of services that reflects the essential elements of the delivery of advanced primary care, for payment under the PFS starting in 2025.

These new codes are designed to bundle the individual utilization of codes that are already included in the definition of primary care services used for purposes of assignment, specifically CCM (CPT codes 99437, 99487, 99489, 99490, 99491, and 99439 and HCPCS codes G0506 and G2058), PCM (CPT codes 99424, 99425, 99426, and 99427 and HCPCS codes G2064 and G2065), TCM (CPT codes 99495 and 99496), remote evaluation of patient videos/images (HCPCS code G2010), and virtual check-in and e-visits (HCPCS codes G2012 and G2252). These new codes also bundle IPC (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452), which we proposed to include in the definition of primary care services used for purposes of assignment. Further, as proposed, this new APCM bundle represents a broader application of advanced primary care and incorporates elements included in care management and CTBS services. We stated that we believe the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management and so it would be appropriate to include HCPCS codes GPCM1, GPCM2, and GPCM3 in the definition of primary care services used for purposes of assignment since these HCPCS codes bundle services furnished under CPT and HCPCS codes already included in the definition of primary care services used for purposes of assignment.

As we explained in the proposed rule (89 FR 61703), we anticipated that these codes would mostly be used by primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics, or in some instances, certain specialists functioning as primary care practitioners—for example, an OB/GYN or a cardiologist. Since primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics are primary care physicians (as defined in § 425.20) and OB/GYN or a cardiologist are two of the specialty designations (as described in § 425.402(c)) used for purposes of assignment we stated that we believe it would be appropriate to include HCPCS codes GPCM1, GPCM2,

and GPCM3 in the definition of primary care services used for purposes of assignment. Inclusion of these APCM services in the definition of primary care services used for purposes of assignment would also strengthen and invest in primary care in alignment with the goals of the U.S. Department of Health and Human Services (HHS) Initiative to Strengthen Primary Care.[522] We also believe that updating the definition of primary care services used for purposes of assignment to include the APCM bundle would increase the accuracy of assignment based on the provision of primary care.

• *Cardiovascular Risk Assessment and Risk Management—*

++ *Cardiovascular Disease Risk Assessment HCPCS code GCDRA (Administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment for patients with ASCVD risk factors on the same date as an E/M visit, 5–15 minutes, not more often than every 12 months):* As described in the CY 2025 PFS proposed rule (89 FR 61727 through 61731), we proposed a new stand-alone HCPCS code, GCDRA, to identify and value the work involved in administering an *ASCVD risk* assessment when medically reasonable and necessary in relation to *an E/M visit.* Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment refers to a review of the individual's demographic factors, modifiable risk factors for CVD, and risk enhancers for CVD.

We proposed that the ASCVD risk assessment must be furnished by the practitioner on the same date they furnish an E/M visit, as the ASCVD risk assessment would be reasonable and necessary when used to inform the patient's diagnosis, and treatment plan established during the visit. ASCVD risk assessment is reasonable and necessary for a patient who has at least one predisposing condition to cardiovascular disease that may put them at increased risk for future ASCVD diagnosis.

++ *Atherosclerotic Cardiovascular Disease Prevention Risk Management Services HCPCS code GCDRM (Atherosclerotic Cardiovascular Disease (ASCVD) risk management services with the following required elements: patient is without a current diagnosis of ASCVD, but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment; ASCVD-Specific care plan established, implemented, revised, or monitored that addresses risk factors and risk enhancers and must incorporate shared decision-making between the practitioner and the patient; clinical staff time directed by physician or other qualified health care professional; per calendar month).* As described in section II.G of this final rule, over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other healthcare professionals, especially in the context of evolving changes in medical practice using evidence-based models of care, such as the Million Hearts® model. We proposed to establish a G-code, GCDRM, for ASCVD risk management services which refers to the development, implementation, and monitoring of individualized care plans for reducing cardiovascular risk, including shared decision-making and the use of the ''ABCS'' of cardiovascular risk reduction, as well as counseling and monitoring to improve diet and exercise.

We stated that we believe that ASCVD risk management services include continuous care and coordination to reduce or eliminate further elevation of ASCVD risk over time, and potentially prevent the development of future cardiovascular disease diagnoses or first-time heart attacks or strokes. Physicians and Non-Physician Practitioners (NPPs) who can furnish E/M services could bill for ASCVD risk management services. In the proposed rule, we explained that we anticipated that ASCVD risk management services would ordinarily be provided by clinical staff incident to the professional services of the billing practitioner in accordance with § 410.26. We proposed that ASCVD risk management services would be considered a ''designated care management service'' under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner.

Refer to section II.G of this final rule for detailed, technical discussion regarding the proposed description, payment and utilization of HCPCS codes GCDRA and GCDRM.

Because HCPCS codes GCDRA and GCDRM are proposed to be care management services similar to CCM (CPT codes 99437, 99439, 99487, 99489, 99490, and 99491) which are included in the Shared Savings Program definition of primary care services used for purposes of assignment, we explained in the proposed rule that we believed it would be consistent and appropriate to include GCDRA and GCDRM in the definition of primary care services used for purposes of assignment. In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, 99490, and 99491 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), CY 2018 PFS final rule (82 FR 53212 through 53213), and CY 2021 PFS final rule (85 FR 84749 through 84750 and 84754). ''Complex'' CCM services (CPT codes 99487 and 99489) and ''non-complex'' CCM services (CPT codes 99490 and 99491) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions.

Elements of care management services include: (1) an initial visit, which can be an E/M service, Annual Wellness Visit (AWV) or initial preventive physical exam (IPPE or ''Welcome to Medicare''); (2) continuity of care with a designated practitioner; (3) comprehensive care management; (4) comprehensive care plan; (5) management of care transitions; and (6) care coordination. In the November 2011 final rule (76 FR 67852 through 67853), we finalized the inclusion of E/M services, the AWV, and the IPPE since those services align the definition of primary care services used in the Shared Savings Program with the definition of primary care services included in section 5501 of the Affordable Care Act. Because care management, E/M services, the AWV, and the IPPE are all included in the definition of primary care services used for purposes of assignment, in the proposed rule (89 FR 61848), we stated that we believe GCDRA and GCDRM reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. Additionally, GCDRA and GCDRM are care and risk management services that include

[522] Refer to U.S. Department of Health and Human Services, Issue Brief: HHS is Taking Action to Strengthen Primary Care (November 7, 2023), available at *https://www.hhs.gov/sites/default/files/primary-care-issue-brief.pdf.*

elements of continuous and coordinated care, which the Shared Savings Program is intended to promote.

• *Interprofessional Consultation (IPC) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452):* In the CY 2019 PFS final rule (83 FR 59489), CMS finalized six codes:

++ 99446 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5–10 minutes of medical consultative discussion and review*);

++ 99447 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11–20 minutes of medical consultative discussion and review*);

++ 99448 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21–30 minutes of medical consultative discussion and review*);

++ 99449 (*Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review*);

++ 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time*); and

++ 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*).

These CPT codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face, in-person contact with the consulting physician or qualified healthcare professional. In the CY 2025 PFS proposed rule (89 FR 61745), we stated that we believe that payment for these interprofessional consultations performed via communications technology such as telephone or internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS. Accordingly, because these CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 recognize and reflect medical practice trends in primary care and patient-centered care, we continue to believe they should be included in the definition of primary care services used for purposes of assignment.

Beginning in the CY 2012 PFS proposed rule (76 FR 42793), we recognized the changing focus in medical practice toward managing patients' chronic conditions, many of which particularly challenge the Medicare population, including heart disease, diabetes, respiratory disease, breast cancer, allergies, Alzheimer's disease, and factors associated with obesity. Current E/M coding does not adequately reflect the changes that have occurred in medical practice, and the activities and resource costs associated with the treatment of these complex patients in the primary care setting In the years since 2012, we have acknowledged the shift in medical practice away from an episodic treatment-based approach to one that involves comprehensive patient-centered care management, and have taken steps through rulemaking to better reflect that approach in payment under the PFS. In the CY 2013 PFS final rule (77 FR 68979), we established new codes to pay separately for TCM services. Next, in the CY 2015 PFS final rule (79 FR 67715), we finalized new coding and separate payment beginning in CY 2015 for CCM services provided by clinical staff. In the CY 2017 PFS final rule (81 FR 80225), we established separate payment for complex CCM services, an add-on code to the visit during which CCM is initiated to reflect the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan and established separate payment for Behavioral Health Integration (BHI) services (81 FR 80226 through 80227). As part of this shift in medical practice, and with the proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, we stated that we believe that making separate payment for interprofessional consultations undertaken for the benefit of treating a patient would contribute to payment accuracy for primary care and care management services. Refer to the CY 2019 PFS final rule (83 FR 59489) for detailed, technical discussion regarding the description, payment and utilization of these CPT codes.

Since the services associated with CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 include TCM, CCM, and BHI services, which are included in our definition of primary care services and are included in the proposed APCM bundle that we proposed to be included in the definition of primary care services used for purposes of assignment, we explained in the proposed rule that we believe that the services associated with CPT codes 99446, 99447, 99448, 99449, 99451, and 99452 should be included in the definition of primary care services for purposes of assignment. We additionally stated that we believe the services billed under this code reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management. These IPC services were also designed to reimburse for comprehensive patient-centered care management and primary care, which the Shared Savings Program is intended to promote.

• *Direct Care Caregiver Training Services (HCPCS codes GCTD1, GCTD2, and* GCTD3*):* GCTD1 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; initial 30 minutes)*), GCTD2 (*Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTD2 in conjunction with GCTD1)*), and GCTD3 (*Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce*

complications including, but not limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control) (without the patient present), face-to-face with multiple sets of caregivers). In the CY 2025 PFS proposed rule (89 FR 61666 through 61667) we proposed to establish new coding and payment for caregiver training services (CTS) for direct care services and supports. The topics of training could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, and infection control. Refer to section II.E. of this final rule for detailed, technical discussion regarding the proposed description, payment, and utilization of this HCPCS code.

Unlike other caregiver training codes that are currently paid under the PFS, the caregiver training codes for direct care services and support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications, and monitoring the patient. Like other codes describing caregiver training services, these proposed new codes would reflect the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. In the proposed rule (89 FR 61666), we explained that we believe that CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established. The CTS themselves need to be congruent with the treatment plan and designed to effectuate the desired patient outcomes. Direct care training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. We stated that we believe that since CTS may be integral to a patient's overall treatment and furnished after the treatment plan is established, these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to promote coordinated, high-quality care to an ACO's assigned beneficiaries. In the CY 2024 PFS final rule (88 FR 79168 through 79169), we finalized the inclusion of other caregiver training services (CPT codes 96202, 96203, 97550, 97551, and 97552) in the definition of primary care services used for purposes of assignment in the Shared Savings Program. These new caregiver training services codes (HCPCS GCTD1, GCTD2, and GCTD3) are similar to the caregiver training services currently included in the Shared Savings Program definition of primary care services in that these codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan. In the proposed rule, we stated that we also believed the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

- *Individual Behavior Management/Modification Caregiver Training Services (HCPCS codes GCTB1 and GCTB2):* GCTB1 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes*) and GCTB2 (*Caregiver training in behavior management/modification for caregiver(s) of a patient with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service) (Use GCTB2 in conjunction with GCTB1)*). In the CY 2025 PFS proposed rule (89 FR 61667 through 61668), we proposed to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver(s) of an individual patient. Behavior management/modification training for caregivers of Medicare beneficiaries should be directly relevant to the person-centered treatment plan for the patient in order for the services to be considered reasonable and necessary under the Medicare program. Each training activity should be clearly identified and documented in the treatment plan. All other policies and procedures surrounding CPT 96202 and 96203 would also apply to these services (88 FR 78914 through 78920). Refer to section II.E. of this final rule for detailed, technical discussion regarding the proposed description, payment and utilization of this HCPCS code.

We explained in the proposed rule that we believe that, since CTS may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan is established especially in the case of medical treatment scenarios where assistance by the caregiver receiving the CTS is necessary to ensure a successful treatment outcome for the patient (for example when the patient cannot follow through with the treatment plan for themselves), these services should be included in the definition of primary care services for purposes of beneficiary assignment in support of the Shared Savings Program's goal to promote coordinated, high quality care to an ACO's assigned beneficiaries. In the CY 2024 PFS final rule (88 FR 79168 through 79169), we finalized the inclusion of other caregiver training services (CPT codes 96202, 96203, 97550, 97551, and 97552) in the definition of primary care services used for purposes of assignment in the Shared Savings Program. These new caregiver training services codes (HCPCS codes GCTD1, GCTD2, GCTD3, GCTB1, and GCTB2) are similar to the caregiver training services currently included in the Shared Savings Program definition of primary care services in that these codes allow treating practitioners to report the training furnished to a caregiver, in tandem with the diagnostic and treatment services furnished directly to the patient, in strategies and specific activities to assist the patient to carry out the treatment plan, which is integral to care coordination. We also stated in the proposed rule that we believe the services billed under these codes reflect the types of services we expect primary care providers to provide in order to improve care coordination and care management.

As part of this revised definition of primary care services used for assigning beneficiaries under § 425.402, we proposed to incorporate a provision in § 425.400(c)(1)(ix)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified in § 425.400(c)(1)(ix)(A) or a HCPCS code specified in § 425.400(c)(1)(ix)(B), when the assignment window or expanded assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We solicited comments on these proposed changes to the definition of primary care services used for assigning beneficiaries under § 425.400(c)(1)(ix) to Shared Savings Program ACOs for the performance year starting on January 1, 2025, and subsequent performance

years. We solicited comments on any other existing HCPCS or CPT codes and new HCPCS or CPT codes proposed in the proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS's proposed revisions to the definition of primary care services, noting that they would capture more of the services rendered by primary care physicians to Medicare beneficiaries and increase participation in the Shared Savings Program. Commenters stated that the additional service codes proposed by CMS in the proposed rule support the delivery of comprehensive, coordinated, whole-person care and are reflective of other primary care services CMS has used to assign beneficiaries to ACOs. One commenter supported the proposed additions to the definition of primary care services that are provided in conjunction with office/outpatient E/M services, other preventive services, and care management services currently included in the definition of primary care services used for purposes of assignment under (§ 425.400(c)).

Response: We agree with commenters who stated that the proposed revisions to the definition of primary care services will capture more of the services rendered by primary care providers and increase participation in the Shared Savings Program. We also agree that use of these additional services for purposes of assignment would support the delivery of comprehensive, coordinated, whole-person care.

Comment: A couple of commenters urged CMS to continue to monitor the impact of expanding the definition of primary care services to include the additional PFS codes on beneficiary assignment. They suggested that as part of this monitoring, CMS should identify any patterns in population types and characteristics that may be captured by the additional codes and evaluate the effect that the additions to the definition may have on beneficiary assignment. One commenter recommended that CMS use claims data on current codes used for beneficiary assignment to confirm those claims are truly primary care service claims. The same commenter contended that codes that are infrequently billed by primary care providers associated with ACOs should be removed from the definition of primary care services used for purposes of assignment.

Response: As a ''pre-step'' in the claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations specified in § 425.402(c). *See* § 425.402(b)(1), (b)(2), and (b)(3). Under claims-based assignment, CMS assigns beneficiaries to ACOs through either one of two steps. Under Step 1, CMS assigns a beneficiary to a Shared Savings Program ACO when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CMS Certification Number (CCN), or non-ACO individual or group Taxpayer Identification Number (TIN). *See* § 425.402(b)(3). Step 2 only applies to assignable beneficiaries who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO, and were therefore not assigned as part of Step 1. *See* § 425.402(b)(4). CMS assigns a beneficiary to a Shared Savings Program ACO under step 2 when the beneficiary receives more primary care services (measured by Medicare-allowed charges) furnished by physicians who are ACO professionals with specialty designations as specified in § 425.402(c) in the participating ACO than from the same type of providers at any other Shared Savings Program ACO, non-ACO CCN, or non-ACO individual or group TIN. *See* § 425.402(b)(4).

Beginning with PY 2025, Step 3 will utilize the expanded window for assignment to identify additional beneficiaries for assignment among Medicare FFS beneficiaries who were not identified under the existing pre-step. (Refer to 88 FR 52444 through 52446.) Specifically, step 3 will identify all such beneficiaries not identified by the pre-step criterion specified in § 425.402(b)(1), who also meet the following criteria:

(1) Received at least one primary care service with a non-physician ACO professional (NP, PA, or CNS) in the ACO during the applicable 12-month assignment window.

(2) Received at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c) during the applicable 24-month expanded window for assignment. *See* § 425.402(b)(5).

As we have previously explained in rulemaking (see, for example, 76 FR 67853 through 67855; see also 80 FR 32748 and 32754), the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services, such as in areas with primary care physician shortages. Additionally, we noted in the June 2015 final rule (80 FR 32750), that we expect that specialist physicians often take the role of primary care physicians in the overall treatment of beneficiaries with certain chronic conditions, and such patterns are captured in step 2 in the current assignment methodology. Further, if services billed under these codes are provided by specialists not considered for purposes of beneficiary assignment, then the services will not be considered in beneficiary assignment.

We will monitor the billing and utilization of the current primary care service codes used for purposes of beneficiary assignment, and other codes, to ensure that the Shared Savings Program considers appropriate billing codes for purposes of beneficiary assignment. If monitoring shows that the inclusion of service codes in the definition of primary care services used for beneficiary assignment is not appropriate, we will address that issue in future notice and comment rulemaking.

Comment: One commenter expressed concern about using the direct caregiver training service code for purposes of assignment, because it can be used by a wide range of providers across various settings. Another commenter disagreed with adding the proposed GSPI1 (safety planning intervention services), the interprofessional consultation service codes (CPT codes 99446, 99447, 99448, 99449, 99451, 99452), and other codes that are not ''predominantly primary care services'' to the definition of primary care service codes used for purposes of assignment. This commenter stated that many of those service codes correspond almost exclusively to specialist, non-primary care services (''in some cases by design'') and thus does not believe the aforementioned codes reflect the provision of primary care. The commenter also stated that add-on codes should not be used for assignment

''because they are not distinct from the base code and would inappropriately weight the encounter.'' Another commenter stated that they did not support the inclusion of the interprofessional consultation codes, except for 99452, as they are usually performed by neurologists, cardiologists, internal medicine sub-specialties, and NPs/PAs (whose specialty affiliation is unknown).

Response: Regarding the inclusion of direct caregiver services, in section II.E of this final rule, we clarify for commenters that Caregiver Training Services (CTS) will be covered and paid under the physician fee schedule (PFS) when furnished personally by physicians and nonphysician practitioners who are authorized under an ''incident to'' provision under their statutory benefit category. Additionally, CTS are covered and paid to physicians and certain nonphysician practitioners under the PFS when provided by auxiliary personnel (as defined in program regulations at § 410.26(a)(1)) when all the ''incident to'' requirements are met. Since these services are covered and paid under the physician fee schedule (PFS) when furnished personally by physicians and nonphysician practitioners who are authorized under an ''incident to'' provision under their statutory benefit category, and since CTS may be integral to a patient's overall treatment and furnished after the treatment plan is established, we continue to believe it is appropriate to include them in the definition of primary care services used for purposes of assignment.

With regard to the comment opposed to the inclusion of these services in the definition of primary care services because they can be furnished in a variety of settings, although these services may be furnished in a variety of settings, we continue to believe it is appropriate to include them in the definition of primary care used for purposes of assignment when they are furnished by a physician or nonphysician practitioner who is an ACO professional given that both primary care providers and specialists provide care in a variety of settings. The safety planning intervention HCPCS code, GSPI1, is being finalized as HCPCS G0560 and as a standalone service in Section II.I of this final rule. Even though the payment policy for this HCPCS code is being finalized with modifications, we continue to believe the services billed under this code reflect the types of primary care services we expect primary care providers to provide related to continuity of care. This code reflects important enhancements to support improvement and integration of care provided for beneficiaries receiving behavioral health treatment from primary care providers. Including safety planning intervention services (HCPCS G0560) in the definition of primary care services used for purposes of assignment also aligns with the CMS Behavioral Health Strategy, the mission of which is to ensure that high-quality behavioral health services and supports are accessible to Medicare beneficiaries.

It is not clear which services the commenter referred to as ''other codes that are not predominantly primary care services'' and so we are not persuaded by this comment. Additionally, as part of the Shared Savings Program step-wise assignment methodology, according to § 425.400(a), CMS employs the step-wise assignment methodology described in § 425.402 and § 425.404 a Medicare FFS beneficiary is assigned to an ACO if the—(A) beneficiary meets the eligibility criteria under § 425.401(a); and (B) beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402 and § 425.404, which includes specialist physicians that take the role of primary care physicians in the overall treatment of beneficiaries with certain chronic conditions (see 80 FR 32750). Although these services may be furnished in a variety of settings, we continue to believe it is appropriate to include them in the definition of primary care used for purposes of assignment when they are furnished by physician or nonphysician practitioner who is an ACO professional. As a result, and as explained in prior rulemaking (88 FR 79170), we believe the assignment methodology minimizes the potential for a beneficiary to be assigned based on specialty care.

Regarding the comment that add-on codes are not distinct from the base code and would inappropriately weight the encounter, we believe that including add on services in determining where a beneficiary has received the plurality of primary care services in step 1 of the assignment methodology helps ensure that a beneficiary is assigned to the ACO whose ACO participants are actually providing the plurality of primary care for that beneficiary, and thus, should be responsible for managing the patient's overall care, or is not assigned to any ACO if the plurality of the beneficiary's primary care is furnished by practitioners in a non-ACO entity (see, for example, 80 FR 32748).

We are persuaded by comments that oppose the addition of interprofessional consultation services to the definition of primary care services used for purposes of assignment, except for CPT code 99452. As part of the CY 2019 PFS final rule (83 FR 59489 through 59491), we finalized interprofessional consultation services codes that differentiate between primary care and consultative practitioners, which support payment both to the treating, requesting (primary care) practitioner (CPT code 99452) and the receiving, consultative specialist (CPT codes 99446–99449 and 99451), who engage in electronic consults. As a result, some practitioners have already become accustomed to providing and billing for these services. We agree with the commenter that, of the set of CPT codes included in the interprofessional consultation services category, only 99452 should be included in the definition of primary care services for purposes of assignment because the other services in this category are furnished by consultative providers, not the beneficiaries' primary care provider. While some of specialties performing these consultative services may be included in the list of specialties used in steps 2 and 3 of our claims-based assignment methodology, when these specialties furnish the services described by CPT codes 99456, 99457, 99448, 99449, and 99451, they are furnishing these services in a consultative role at the request of the patient's treating/requesting physician or other qualified health care professional, not in a primary care role. If CPT codes 99456, 99457, 99448, 99449, and 99451 were included in the definition of primary care services used for purposes of assignment, it could lead to inappropriate assignment based on the furnishing of consultative visits, not primary care. In reviewing utilization of CPT code 99452, we found that 43.6.percent of the services were furnished by physicians included in the step 1 of assignment and almost 43.3 percent were furnished by non-physician practitioners or specialists included in step 2. In the final policies described in section II.G of this final rule, we are finalizing interprofessional consultation code 99452 as part of the APCM service.

Comment: We also received feedback on our solicitation for additional modifications to the primary care service codes used for purposes of beneficiary assignment. One commenter supports the policy proposed but not finalized in the CY 2024 PFS final rule (88 FR 79164) to revise the definition of primary care services to include RPM CPT codes 99457 and 99458, which builds on support provided for digital health in (for example, adding HCPCS

codes G2012 and G2252 codes for virtual check-ins). Another commenter recommended that CMS utilize the nursing facility as a key site of primary care and account for it in our beneficiary assignment methodology to ''facilitate greater partnership between ACOs and nursing facility staff and mitigate issues in misalignment which occurs when new institutionalized beneficiaries are misaligned to their historic community based primary care providers.'' Another commenter opposed the inclusion of caregiver training service codes (97550–97552), which were finalized in the CY 2024 PFS final rule (88 FR 79168), as 2024 is the first year they were in the CPT book and there are no claims data available on these codes.

Response: We appreciate this feedback and will consider it in future rulemaking. Regarding the comment suggesting that CMS use the nursing facility as a key site of primary care and account for it in our beneficiary assignment methodology, the Shared Savings Program has several participating ACOs that have large institutional populations or high-need, high-cost beneficiaries that receive home based primary care assigned beneficiary populations and we do consider primary care services provided in the nursing facility for purposes of assignment in the Shared Savings Program. With regard to the opposition to the inclusion of caregiver training service codes 97550–97552, we continue to believe that their inclusion is appropriate for the reasons explained in the CY 2024 PFS final rule (88 FR 79168 through 79169).

After consideration of public comments, we are finalizing our proposal with modifications.

We are finalizing a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(ix) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(viii) along with the following additions: CPT codes 99452 and 9X091 (which is being finalized as 98016); and HCPCS codes GFCI1 (which is being finalized as G0544), GSPI1 (which is being finalized as G0560), GPCM1, GPCM2, and GPCM3 (which are being finalized as G0556, G0557, and G0558, respectively), GCDRA and GCDRM (which are being finalized as G0537 and G0538, respectively), GCTD1, GCTD2 and GCTD3 (which are being finalized as G0541, G0542, and G0543, respectively), and GCTB1 and GCTB2 (which are being finalized as G0539 and G0540, respectively), as discussed in the preceding paragraphs.

We are not finalizing our proposal to include CPT codes 99446, 99447, 99448, 99449, and 99451. We are additionally not finalizing that GSPI1 will only be considered a primary care service when billed with a base code that is also a primary care service. This is because the payment policy finalized in section II.I of this final rule regards this HCPCS code as a standalone service. We are finalizing as proposed that the new provision at § 425.400(c)(1)(ix), which will be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2025, and subsequent performance years.

The code descriptions for HCPCS codes GPCM1, GPCM2, GPCM3 (G0556, G0557, and G0558, respectively), GCDRA, and GCDRM (G0537 and G0538, respectively) are being finalized with revisions in section II.G of this final rule.

Further, the text of the proposed regulations in the CY 2025 PFS proposed rule (89 FR 62221 through 62222) included a proposed technical modification (to the introductory text in § 425.400(c)(1)(viii), to limit the applicability of this provision to the performance year starting on January 1, 2024) that was not described in preamble. This change is necessary so that we can effectuate § 425.400(c)(1)(ix) as explained in the proposed rule and its regulatory text: to apply for the performance year starting on January 1, 2025, and subsequent performance years. We received no comments addressing the proposed technical modification to § 425.400(c)(1)(viii), and we are finalizing this change without modification.

b. Revisions to Criteria for ACO Models to Waive Shared Savings Program Statutory Requirements Giving Precedence for Assignment based on Beneficiary Voluntary Alignment

(1) Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment. In earlier rulemaking (81 FR 80501 through 80510 and 83 FR 59959 through 59964), CMS finalized modifications to the Shared Savings Program regulations at § 425.402(e) to implement the statutory requirements governing voluntary alignment.

In the November 2018 final rule (83 FR 59959 through 59964), we finalized changes to the beneficiary voluntary alignment policies (refer to § 425.402(e)) to revise the requirements previously established for the voluntary alignment process. We explained that it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific CMS Innovation Center models to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for Medicare beneficiaries while lowering costs to Medicare Parts A and B. Additionally, we explained that it could be difficult for the CMS Innovation Center to conduct a viable test of a specialty or disease-specific model, if we were to require that beneficiaries who previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. We applied this exception for the Comprehensive ESRD Care (CEC) model, which assigned beneficiaries to entities participating in the model through the beneficiaries' first treatment at a participating dialysis facility.

Currently, under § 425.402(e)(2)(ii)(D), we will not assign a beneficiary who has voluntarily identified a Shared Savings Program ACO professional to a Shared Savings Program ACO when the beneficiary is also eligible for claims-based assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

(2) Revisions

As discussed in the CY 2025 PFS proposed rule (89 FR 61851 through 61853), since finalization of this limited exception to the Shared Savings Program's voluntary alignment policy, disease-specific CMS Innovation Center models have been developed that use claims for both primary care services and services other than primary care in determining claims-based assignment to entities participating in these models. In the proposed rule, we explained that we believed it would be appropriate to propose to broaden this limited exception and allow a voluntarily

aligned Shared Savings Program beneficiary to be claims-based assigned to an entity participating in a disease- or condition-specific CMS Innovation Center model when that model uses claims-based assignment that is based on primary care and/or other services. Disease- or condition-specific CMS Innovation Center models are designed to support condition management, coordination, and services for patients that have a specific disease or condition that often requires coordination of care across specialties and settings. For example, the CMS Innovation Center has tested disease- and condition-based episode payment models, such as those focused on oncology and kidney disease.[523] Doing so would help beneficiaries with certain diseases or conditions benefit from the focused attention and care coordination related to the disease or condition that an entity participating in such a model could provide. In the proposed rule, we stated we would identify models for which the exception would apply in our Shared Savings and Losses and Assignment Methodology and Quality Performance Specifications document, which is located on the Shared Savings Program website, *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos*. We stated that this proposed expanded exception would be applicable to beneficiaries assigned to entities participating in CMS Innovation Center models under which assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, when the Secretary has determined that a waiver is necessary solely for purposes of testing the model.

An example of a CMS Innovation Center model whose assigned beneficiaries may be impacted by the proposed expanded exception is the Kidney Care Choices (KCC) model,[524] which is designed to help health care providers reduce the cost and improve the quality of care for patients with late-stage chronic kidney disease and ESRD. The KCC model builds on the previous CEC model [525] by adding strong financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stage 4 and ESRD, to delay the onset of dialysis and to incentivize kidney transplantation. Under the CEC model, the CMS Innovation Center worked with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals received. We determined that an ESRD beneficiary, who was otherwise eligible for assignment to an entity participating in the CEC model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC model. As described above, we created a narrow exception to the general policy that a beneficiary who had voluntarily aligned to a Shared Savings Program ACO professional would supersede their alignment to a CMS Innovation Center model. Specifically, we did not assign a beneficiary to the ACO when the beneficiary was also eligible for alignment to an entity participating in the CEC model.

KCC is more complex than CEC and is designed to capture multiple care relationships and uses a mix of E/M codes for alignment of beneficiaries with CKD and managing clinician Monthly Capitation Payments for aligning ESRD beneficiaries. The existing exception is not applicable to KCC in part because claims for primary care and other services related to the treatment of one or more specific diseases or conditions targeted by the model (chronic kidney disease (CKD) stage 4 and ESRD) are considered as part of the model's beneficiary alignment methodology, which takes into consideration where a beneficiary receives the majority of their kidney care as well as the beneficiary's diagnosis of CKD stages 4 or ESRD receiving maintenance dialysis. KCC's alignment methodology could align beneficiaries receiving primary care services that are also considered for Shared Savings Program assignment if furnished and billed under one of the HCPCS/CPT codes included in § 425.400(c) by ACO professionals who are primary care physicians, physicians with one of the primary specialty designations in § 425.402(c), NPs, PAs, and/or CNSs. In the proposed rule, we noted that outpatient/office E/M services are included in § 425.400(c) and that nephrology is one of the primary specialty designations under § 425.402(c) so we anticipated that, if this proposal is finalized, most, if not all, beneficiaries who voluntarily align to a physician that participates in a Shared Savings Program ACO and meet the KCC alignment criteria would be claims-based align to the KCC model, assuming there is a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

As discussed in the CY 2025 PFS proposed rule (89 FR 61851 through 61853), we proposed expanding upon current Shared Savings Program regulations to broaden the existing exception to the program's voluntary alignment policy, which would allow the exception to apply to beneficiaries assigned to entities in a CMS Innovation Center model under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model.

Under the proposed revisions, if a beneficiary voluntarily aligns to a Shared Savings Program ACO under § 425.402(e), we would not assign the beneficiary to that Shared Savings Program ACO when the beneficiary is also eligible for claims-based assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model or (2) claims for services other than primary care service, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model. We would not supersede voluntary alignment for CMS Innovation Center models that are not designed to target a specific disease or condition, such as ACO REACH. While ACO REACH contains design features for organizations serving high needs beneficiaries, it is designed more broadly, and not for beneficiaries with a specific disease or condition. Such models do not target a specific disease or condition. Therefore, a beneficiary's claims-based assignment to an entity participating in such a model would not supersede their voluntary alignment to

[523] Refer to Innovation Models website: *https://www.cms.gov/priorities/innovation/models#views=models&cat=disease-specific%20&%20episode-based%20models.*

[524] Refer to *https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model.*

[525] Refer to *https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-esrd-care.*

a Shared Savings Program ACO under our proposal.

For example, under the KCC model, alignment is based on where a beneficiary receives the majority of their nephrology services and/or dialysis management services. Claims for those kidney care services could include claims for services that, under the Shared Savings Program's claims-based assignment policies, would lead a beneficiary to be assigned to a Shared Savings Program ACO. Since under the KCC model, claims-based assignment is based solely on claims for primary care and/or other services (kidney care services) related to the treatment of one or more specific diseases or conditions targeted by the model (chronic kidney disease (CKD) stage 4 and ESRD), our proposed exception would apply and a beneficiary who voluntarily aligned to a Shared Savings Program ACO and who received kidney care services from an entity participating in the KCC model would nonetheless be claims-based assigned to the KCC model, if there is a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the KCC model. This proposed expansion of the voluntary alignment exception would support assignment of beneficiaries to entities participating in CMS Innovation Center models, which would reduce barriers for the CMS Innovation Center to conduct viable tests of disease-or condition-specific models and thereby improve access to high-quality, value-based specialty care, such as that provided by an entity participating in a model focused on diabetes care or care provided by specific specialists, such as cardiologists or gastroenterologists.

This proposal would also support CMS's goals of improving patient care, lowering costs, and better aligning payment systems to promote patient-centered practices through accountable and value-based care. We continue to believe that specific subpopulations of Medicare beneficiaries who are otherwise eligible for assignment to an entity participating in a disease or condition-specific CMS Innovation Center model, but who may not be captured by § 425.402(e)(2)(ii)(D) because their models consider primary care services for purposes of assignment, could benefit from the focused attention and increased care coordination offered by an entity participating in a disease or condition-specific model. Application of this exception would require a determination from the Secretary to waive the voluntary alignment provision.

Under this proposal, if a beneficiary designated an ACO professional participating in a Shared Savings Program ACO as the physician or practitioner they consider responsible for coordinating their overall care (that is, their primary clinician), but the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model, the CMS Innovation Center or its designee would notify the beneficiary of their assignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify an ACO professional participating in a Shared Savings Program ACO as their primary clinician and seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is an ACO professional in a Shared Savings Program ACO.

For PY 2024, there are approximately 152,000 beneficiaries with a primary clinician selection who is a Shared Savings Program ACO professional as defined at § 425.20, and approximately 83,000 are voluntarily aligned to a Shared Savings Program ACO after meeting all the assignment eligibility criteria as described at § 425.401(a). Overall, this represents an exceedingly small share of the overall Shared Savings Program assigned beneficiary population, currently 10.8 million [526] beneficiaries. Additionally, simulating our proposed § 425.402(e)(2)(ii)(D) using PY 2024 data, less than 1 percent (703) of beneficiaries who are voluntarily aligned to a Shared Savings Program ACO would instead be claims-based assigned to an entity participating in a CMS Innovation Center model.

The benefit of allowing beneficiaries who voluntarily align to a Shared Savings Program ACO to be claims-based assigned to an entity participating in a CMS Innovation Center tailored to the needs of their specific disease or condition far outweighs any cost to the Shared Savings Program. The impact of assigning these beneficiaries to an entity participating in a CMS Innovation Center model notwithstanding their voluntary designation would be minimal because so few beneficiaries would be impacted by this proposed expansion of the exception (for PY 2024, less than 1 percent of all beneficiaries who voluntarily align to a Shared Savings Program ACO). As explained in the proposed rule, this proposal would enable us to better test CMS Innovation Center models and ultimately improve health outcomes for Medicare beneficiaries with the specific diseases and conditions targeted by CMS Innovation Center models. We also recognize the importance of continuing to allow beneficiaries to voluntarily identify an ACO professional as their primary clinician for purposes of assignment to a Shared Savings Program ACO, and we reiterate that, based on PY 2024 data, this proposal would impact very few beneficiaries who voluntarily align to Shared Savings Program ACOs (less than 1 percent of all such beneficiaries). Beneficiaries who voluntarily align to a Shared Savings Program ACO but are, under our proposal, ultimately claims-based assigned to an entity participating in a CMS Innovation Center model would be notified of this in accordance with the CMS Innovation Center model's participation agreement. We proposed to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance year 2025, and subsequent performance years. We proposed to incorporate these new requirements into new regulations at § 425.402(e)(2)(iii). We solicited comments on this proposal.

Accordingly, since the new proposed provisions § 425.402(e)(2)(iii) would supersede the existing provisions at § 425.402(e)(2)(ii) for performance year 2025 and subsequent performance years, we proposed to revise the introductory text at § 425.402(e)(2)(ii) to designate that provision's applicability for performance years starting on January 1, 2019, through 2024.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commentors supported our proposal to expand the voluntary alignment waiver and indicated that the proposal would streamline model attribution and allow for those beneficiaries voluntarily aligned to a Shared Savings Program ACO to be more easily assigned to entities participating in other non-ACO value-based care models. Other commentors stated that if this proposal

[526] Refer to *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf.*

is finalized, CMS should provide additional clarification in this final rule around the limitations for when this proposal would be applied and propose any future expansions of the voluntary alignment waiver outside of the contexts of oncology and nephrology through rulemaking.

Response: CMS agrees that assigning beneficiaries to entities participating in disease- and condition-specific models, has great potential to improve outcomes for those beneficiaries, particularly for beneficiaries who may benefit from specialized ESRD and cancer care.

The use of this expanded voluntary alignment waiver will be limited: if a beneficiary designated an ACO professional participating in a Shared Savings Program ACO as the physician or practitioner they consider responsible for coordinating their overall care (that is, their primary clinician), but the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model, the CMS Innovation Center or its designee will notify the beneficiary of their assignment to an entity participating in the model. Application of this waiver will be announced by the Innovation Center. As we explained in the proposed rule, this proposed policy is designed to be responsive to innovations in disease- and condition-specific models, will be applied narrowly, and will have a limited impact on beneficiaries that are voluntarily aligned to a Shared Savings Program ACO. We refer commenters to discussion in the CY 2025 PFS proposed rule (89 FR 61851 through 61853) and earlier in this section of this final rule for additional details on how this policy will be applied and its anticipated limited impact. CMS plans to issue guidance and communicate with ACOs and interested parties about these topics, including when the waiver will be applicable to a disease- or condition-specific model.

In the future, if we determined that it would be appropriate to further modify our voluntary alignment waiver policy, we would do so through notice-and-comment rulemaking.

Comment: Most commentors expressed opposition to the proposed changes to expand the voluntary alignment waiver. Commenters stated that the Shared Savings Program, ''a proven model that benefits all parties, patients foremost, and exists 'perpetually,' is more consistent and has demonstrated efficacy,'' whereas Innovation Center Models are temporary and such programs terminate or ''may fall out of favor''. Several commenters explained that pulling beneficiaries out of the Shared Savings Program and putting them into a time-limited model goes against the principles of accountable care by ''carving up accountability'' and works against CMS's longstanding efforts to grow the Shared Savings Program. Several other commentors cited voluntary alignment as the ''gold standard'' for beneficiary assignment, noting that if a beneficiary voluntarily aligns themselves to their primary clinician, that should take precedence over claims-based assignment, even if that beneficiary could benefit from the specialized care that an entity participating in a disease- or condition-specific model can offer. Numerous commentors expressed opposition to the policy on the grounds that it ''weakens voluntary alignment.'' Another commentor noted that ''prioritizing assignment for administrative reasons'' might disproportionately (negatively) affect beneficiaries from marginalized or underserved populations, who may have fewer options in selecting healthcare providers or face ''additional barriers in accessing preferred care settings.''

Response: CMS seeks to continuously improve beneficiary care and outcomes. Beneficiaries from marginalized and underserved populations face obstacles to receiving quality and efficient care and several policies finalized in this rule, including the prepaid shared savings option and Health Equity Benchmark Adjustment, are designed to support ACO efforts to provide quality and efficient care to these populations.

The success of the Shared Savings Program notwithstanding, we explained in the CY 2025 PFS proposed rule (89 FR 61852) that targeting a subset of beneficiaries with specific diseases or conditions who received care from entities participating in certain disease- or condition-specific models and allowing them to more easily align to those entities will lead to better care and outcomes. We refer readers to our discussion on this subject in the proposed rule (89 FR 61852). In addition, as explained in greater detail in the proposed rule (89 FR 61851 through 61853) and based on our simulation of the impact of proposed § 425.402(e)(2)(ii)(D) using PY 2024 data, while Innovation Center Models are, by their nature, time-limited, but the models themselves have informed, and continue to inform, permanent Medicare policies, including Shared Savings Program policies (for example, the SNF 3-day Rule Waiver, AIP, and HEBA).

We also do not believe that the proposed expansion of the voluntary alignment waiver is an ''administrative'' change, as it will result in CMS assigning beneficiaries to entities participating in the models that can most appropriately care for their specific disease or condition (refer to 89 FR 61853). We are not clear why this commenter believes this proposal would be considered administrative as opposed to programmatic.

We additionally do not believe that this expansion will result in a negative impact on beneficiaries. To the contrary, for the reasons stated in the proposed rule (89 FR 61853), we continue to believe that the specific subpopulations of Medicare beneficiaries who are otherwise eligible for assignment to an entity participating in a disease- or condition-specific CMS Innovation Center model, but who may not be captured by § 425.402(e)(2)(ii)(D) because their models consider primary care services for purposes of assignment, could benefit from the focused attention and increased care coordination offered by an entity participating in a disease- or condition-specific model. We also recognize the importance of continuing to allow beneficiaries to voluntarily identify an ACO professional as their primary clinician for purposes of assignment to a Shared Savings Program ACO, and we reiterate that, based on PY 2024 data, this policy will impact very few beneficiaries who voluntarily align to Shared Savings Program ACOs (less than 1 percent of all such beneficiaries). We also note that this policy does not undermine beneficiary choice in any way because beneficiaries may continue to receive care at providers of their choosing.

We reiterate that application of this broadened voluntary alignment waiver policy will be limited to beneficiaries assigned to entities in a CMS Innovation Center model under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination

by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model. The application of this policy will not supersede voluntary alignment for CMS Innovation Center models that are not designed to target a specific disease or condition, such as the ACO REACH Model. While the ACO REACH Model contains design features for organizations serving high needs beneficiaries, it was designed more broadly, and not for beneficiaries with a specific disease or condition. It therefore does not target a specific disease or condition, and a beneficiary's claims-based assignment to an entity participating in such a model will not supersede their voluntary alignment to a Shared Savings Program ACO under this policy.

After consideration of public comments, we are finalizing our proposal to add new § 425.402(e)(2)(iii) as proposed, to allow the voluntary alignment exception to apply to beneficiaries assigned to entities in a CMS Innovation Center model under which claims-based assignment is based solely on (1) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (2) claims for services other than primary care services, and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary for purposes of testing the model. However, we are finalizing technical modifications to the phrasing and the proposed structure § 425.402(e)(2)(iii)(D) for clarity and consistency with our intended meaning. Specifically, we are finalizing modifications to clarify that a condition of the applicability of the exception is the determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model (as specified in § 425.402(e)(2)(iii)(D)(*2*)), in addition to claims-based assignment for the model being based on either (i) claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model, or (ii) claims for services other than primary care services (as specified in § 425.402(e)(2)(iii)(D)(*1*)). Absent these technical modifications, the provision on the waiver of the requirement in section 1899(c)(2)(B) of the Act could be read as applying only in the case of models with claim-based assignment based on claims for services other than primary care services. We are also finalizing our proposal to revise the introductory text at § 425.402(e)(2)(ii) to designate that provision's applicability for performance years starting on January 1, 2019, through 2024.

4. Quality Performance Standard & Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care and wherever practicable, caregiver experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, 2023, and 2024 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 87 FR 69860 through 69863, and 88 FR 79112 through 79114, respectively).

b. Requiring Shared Savings Program ACOs To Report the Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set

(1) Background

In the CY 2021 PFS final rule, we finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for performance year 2021 and subsequent performance years (85 FR 84720 through 84743). For performance year 2021 and subsequent years, ACOs are required to report quality data via the APP codified at § 414.1367. Pursuant to policies finalized under the CY 2022 and CY 2023 PFS (86 FR 65685; 87 FR 69858), to meet the quality performance standard under the Shared Savings Program through performance year 2024, ACOs must report the APP quality measure set, through which they: (1) must report either the ten CMS Web Interface measures or the three electronic clinical quality measures (eCQMs)/Merit-based Incentive Payment System (MIPS) clinical quality measures (CQMs); and (2) must administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. In the CY 2024 PFS final rule, we established the Medicare Clinical Quality Measures for Accountable Care Organizations participating in the Medicare Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs reporting the APP quality measure set for performance year 2024 and subsequent performance years (88 FR 79107). In performance year 2024, Shared Savings Program ACOs have the option to report on Medicare CQMs, which are reported on an ACO's eligible Medicare fee-for-service beneficiaries, instead of an ACO's all payer/all patient population. Medicare CQMs are aligned with MIPS standards for data completeness as described at 414.1340, measure benchmarking as described at 414.1380(b)(1)(ii) and scoring as described at 414.1367 (88 FR 79099 and 88 FR 79108). In the CY 2024 PFS final rule, we stated that Medicare CQMs would serve as a transition collection type to help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient eCQMs/MIPS CQMs and support ACOs in the transition to all payer/all patient quality measure reporting (88 FR 79097 through 79098). Since the CY 2021 PFS final rule was issued, ACOs and other interested parties have continued to express concerns about requiring ACOs to report all payer/all patient eCQMs/MIPS CQMs due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant taxpayer identification numbers (TINs) and varying electronic health record (EHR) systems (86 FR 65257). In the CY 2022 PFS final rule, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQMs/MIPS CQMs (86 FR 65259). In public comments on the CY 2023 PFS proposed rule, some commenters expressed multiple concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in performance year 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and

interoperability issues among different EHRs (87 FR 69837).

Some ACOs face continued difficulties in aggregating data on the three all payer/all patient eCQMs/MIPS CQMs that are part of the existing APP quality measure set. The Shared Savings Program continues to receive feedback from ACOs and other stakeholders about the difficulties with reporting on the three all payer/all patient eCQMs/MIPS CQMs and meeting data management requirements given their muti-practice/multi EHR structure. Additionally, we continue to receive feedback on the challenges of aggregating data due to the health information technology (IT) infrastructure in use by ACOs and the current state of interoperability. Building on our goal to provide technical support to ACOs and help ACOs build the skills necessary to aggregate and match patient data to report all payer/all patient eCQMs/MIPS CQMs, in December 2022, we hosted a webinar to support ACOs in the transition to reporting all payer/all patient eCQMs/MIPS CQMs and released a guidance document on the topic. Resources from the ''Reporting MIPS CQMs and eCQMs in the APM Performance Pathway'' webinar are available at *https://youtu.be/LDrpoGnnRQs*. The guidance document, entitled ''Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP)'' is available in the Quality Payment Program Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf*. Over the past two years, we have learned that there are complexities and hurdles concerning ACOs adopting the all payer/all patient collection types; as a result, the widespread adoption of the all payer/all patient collection types require further time and support. For example, our internal data indicate that in performance year 2021, 12 out of 475 ACOs reported eCQMs/MIPS CQMs under the APP, while 37 out of 482 ACOs reported eCQMs/MIPS CQMs in performance year 2022.[527] Submission data for performance year 2023 indicate that 72 out of 456 ACOs reported eCQMs/MIPS CQMs under the APP. Further, we have come to understand that additional maturation processes are needed to support large, complex organizations like ACOs that participate in the Shared Savings Program to fully and equitably participate in the all payer/all patient collection types.

CMS' goal, as stated in the CY 2024 PFS final rule, is to support ACOs in the adoption of all payer/all patient measures (88 FR 79098). In that rule, we described our intention to monitor the reporting of quality data utilizing the Medicare CQM collection type, which would include assessing if any Medicare CQMs qualify as topped out as described at § 414.1380(b)(1)(iv) (88 FR 79098). We also noted that, ''[s]eparately, we may specify higher standards, new measures, or both—up to and including proposing to sunset the Medicare CQM collection type in future rulemaking—to ensure that Medicare CQMs conform to the intent of section 1899(b)(3)(C) of the Act and the priorities established in the CMS National Quality Strategy'' (88 FR 79098).

Under the goals of the CMS National Quality Strategy to improve the quality and safety of healthcare for everyone, CMS is implementing a building-block approach and aligning the measures used to establish the Shared Savings Program quality performance standard with the Universal Foundation of quality measures and streamlining quality measures across CMS quality programs for measuring primary care clinician performance in the adult and pediatric populations.[528] In the CY 2024 PFS proposed rule, we stated that ''we intend to propose future policies aligning the APP [quality] measure set for Shared Savings Program ACOs with the quality measures under the 'Universal Foundation' beginning in performance year 2025'' (88 FR 52423). A few commenters were supportive of aligning the APP quality measure set with the Universal Foundation measures, while other commenters were opposed. Several commenters urged CMS to first test measures before making them required for the Shared Savings Program and scored for Shared Savings Program ACOs. Shared Savings Program ACOs were also concerned about balancing the alignment of the Universal Foundation measures with efforts to reduce administrative burden, potential growth in the number of measures Shared Savings Program ACOs would have to report, and implementing multiple substantive changes applicable to Shared Savings Program ACOs in performance year 2025. In the CY 2024 PFS final rule, we stated that we will take the comments under consideration in future rulemaking, as we evaluate the impact of aligning the APP quality measure set with the Universal Foundation measures (88 FR 79114).

(2) Revisions

(a) Requiring Shared Savings Program ACOs To Report the APP Plus Quality Measure Set

In section IV.A.4.c.(2) of the CY 2025 PFS proposed rule (89 FR 62023 through 62024), we proposed to create the APP Plus quality measure set to align with the Adult Universal Foundation measures. Out of the ten Adult Universal Foundation measures, five of the measures are already in the APP quality measure set for performance year 2025 under policies finalized in the CY 2024 PFS final rule (88 FR 79112 through 79113). There is one measure—Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Measure # 484)—in the APP quality measure set that is not an Adult Universal Foundation measure, resulting in a total of six measures that are in the APP quality measure set.

Under the approach we proposed in the CY 2025 PFS proposed rule, the APP Plus quality measure set would incrementally grow to comprise of eleven measures, consisting of the six measures in the existing APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. The proposed new measures and the timeline for incorporating the measures into the APP Plus quality measure set are described in section IV.A.4.c.(3) of the CY 2025 PFS proposed rule and below. In section IV.A.4.c.(2) of the CY 2025 PFS proposed rule, we discussed how the APP Plus quality measure set would be an optional measure set for APP reporters. For performance year 2025 and subsequent performance years, we proposed to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section III.G.4.b.(2)(a) of the CY 2025 PFS proposed rule (89 FR 61854 through 61855). Consequently, the APP quality measure set would no longer be available for reporting by Shared Savings Program ACOs beginning in performance year 2025. Our proposal would align the quality measures that Shared Savings Program ACOs would be required to report with the quality measures under the Adult Universal

[527] Counts based on internal analysis of ACOs' quality reporting in performance years 2021 and 2022.

[528] Centers for Medicare & Medicaid Services (2024). CMS National Quality Strategy. Accessed June 24, 2024. *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy*.

Foundation measure set incrementally beginning in performance year 2025.

Creating alignment with the Adult Universal Foundation measure set would better align the quality measures reported by Shared Savings Program ACOs with the Medicaid Core Sets and the Marketplace Quality Rating System, which have previously adopted the quality measures in the Universal Foundation.[529] As discussed in section IV.A.4.c.(2) of the CY 2025 PFS proposed rule, alignment of quality measures across CMS programs allows practitioners to better focus their quality efforts, reduce administrative burden, and drive digital transformation and stratification of a focused quality measure set to assess impact on disparities.[530] Our proposed alignment with the Adult Universal Foundation measure set would also better align the quality measures reported by Shared Savings Program ACOs with the Value in Primary Care MIPS Value Pathway (MVP), which contains the same Adult Universal Foundation measures. This may create a smoother transition for clinicians from MIPS to the Shared Savings Program. Alignment would allow clinicians moving into Shared Savings Program ACOs to leverage their familiarity and experience with the Adult Universal Foundation quality measures among primary care clinicians participating in this MVP as they transition to reporting the APP Plus quality measure set in the Shared Savings Program. Experience and familiarity with the same quality measures, redesigned care processes, and quality improvement activities that are commonplace in ACOs would streamline the pathway for clinicians to join ACOs in the future and is consistent with our goal to have all beneficiaries in an accountable care relationship by 2030.

Section 1899(b)(3)(C) of the Act requires CMS to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. In the November 2011 final rule, we finalized 33 quality measures for use in establishing the quality performance standard measure set for ACOs: including 22 measures that were actively reported by ACOs via the Group Practice Reporting Option (GPRO) Web Interface (76 FR 67889). As we stated in the November 2011 final rule establishing the Shared Savings Program, our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes (76 FR 67872). As we sought to improve the quality of care furnished by ACOs over time, we have subsequently updated this measure set through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, and 2023 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71268, 81 FR 80484 through 80489, 83 FR 59707 through 59715, 85 FR 84720 through 84734, and 87 FR 69860 through 69763, respectively). We have also sometimes increased the number of measures reported by ACOs through rulemaking. For example, in the CY 2016 PFS final rule, we increased the Shared Savings Program quality measure set from 33 total measures to 34 total measures (80 FR 71265). In the CY 2016 PFS final rule, we noted that since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and aligned with other CMS quality reporting programs (80 FR 71264). Also, through rulemaking, we sometimes reduced the number of measures reported by ACOs. For example, in the CY 2019 PFS final rule, we finalized policies which reduced the Shared Savings Program quality performance measure set to 23 measures in PY 2019 (83 FR 59715). In developing our proposals in the CY 2019 PFS final rule, we stated that we considered the agency's efforts to streamline quality measures, reduce regulatory burden, and promote innovation as part of broader CMS initiatives (83 FR 59711). In the CY 2021 PFS final rule, we again reduced the total number of measures that ACOs must report (85 FR 84733). Specifically, through the adoption of the APP quality measure set, we reduced the total number of measures from 23 to either 6 or 13 measures (depending on the ACO's chosen reporting option) for PY 2021 (85 FR 84723).

Our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set would increase the number of measures reported by ACOs that currently report the APP quality measure set using the eCQM/MIPS CQM collection types from three measures in performance year 2024 to five measures in performance year 2025. For Shared Savings Program ACOs that report quality through the CMS Web Interface collection type, our proposal to adopt the APP Plus quality measure set would decrease the number of measures reported from ten measures in performance year 2024 to eight measures in performance year 2025 after the CMS Web Interface sunsets. While we acknowledged in our proposal that the increased number of quality measures for ACOs that currently report the eCQM/MIPS CQM collection types may be an increased burden for those ACOs, we also stated that our proposal to phase-in the expansion of the APP Plus quality measure set between performance years 2025 and 2028 should help to minimize the impact of increased burden associated with reporting additional measures. The option for ACOs to report Medicare CQMs, which are MIPS CQMs that are reported on an ACO's fee-for-service population, may also alleviate the reporting burden for ACOs that report Medicare CQMs by focusing an ACO's patient matching and data aggregation efforts only on an ACO's eligible Medicare fee-for-service population. Additionally, we stated that we believe that the benefits of scoring an increased number of measures may offset the increased burden that some ACOs may face in adopting the additional measures. For example, as the number of measures in the measure set increases, the individual weight of each measure on the ACO's quality performance score decreases. Each measure in a six-measure set would account for roughly 16.67 percent of an ACO's MIPS Quality performance category score while each measure in an eight-measure set would account for 12.5 percent of an ACO's MIPS Quality performance category score. The scoring of more measures, in concert with the scoring policies proposed in sections IV.A.4.f.(1)(b)(iii) and IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule (89 FR 62080 through 62083), may result in improved quality performance scores for the ACOs as each individual measure carries less weight.

The proposed APP Plus quality measure sets for Shared Savings Program ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years are displayed in Tables 34, 35, and 36, respectively, of the CY 2025 PFS proposed rule (89 FR 61866 through 61868). Under our proposal, there would be eight quality measures (five

[529] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, February 1, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

[530] Jacobs D, et al., Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity. Health Affairs Forefront (March 14, 2024), available at *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in the APP Plus quality measure set for Shared Savings Program ACOs in performance year 2025 (Table 34), nine quality measures (six eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2026 and 2027 (Table 35), and 11 quality measures (eight eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance year 2028 and subsequent performance years (Table 36). In our proposal, we noted our intent to update the APP Plus quality measure set as new measures are added to or removed from the Adult Universal Foundation measure set in the future.

We solicited comments on our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set for performance year 2025 and subsequent performance years to meet the Shared Savings Program's quality performance standard. The following is a summary of comments received in response to our proposal and our responses. For comments and our responses related to the proposal to establish the APP Plus quality measure set and the timeline for incorporating quality measures into it, please see section IV.A.4.c.(2) of this final rule. As described in section IV.A.4.c.(2), we are finalizing with modification the phase-in schedule for incorporating measures into the APP Plus quality measure set, which affects when Shared Savings Program ACOs will first be required to report certain measures.

Comment: Several commenters supported our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set beginning in performance year 2025. These commenters applauded CMS' efforts to align a standardized set of quality measures across APMs and other Medicare programs, promoting greater efficiency in quality measure reporting by reducing burden associated with monitoring, collecting, and reporting quality measure data for multiple quality programs and enabling more meaningful longitudinal and comparative analysis of measures. One commenter stated that the proposal supports the strategic missions of interoperability, population health promotion, and health equity. Another commenter stated that the proposal will help increase participation in ACOs and enable ACOs to focus more on underserved populations.

Other commenters, while opposing the required reporting by Shared Savings Program ACOs of the proposed APP Plus quality measure set, for reasons summarized elsewhere in this section of this final rule, nevertheless stated their support for the broader goal of optimizing quality reporting and moving in the direction of ''low-burden, high-value measurement'', or the idea of aligning measures across quality programs with the Universal Foundation.

Response: We thank commenters for their support. We agree with commenters about the importance of streamlining quality reporting across CMS programs through alignment with the Universal Foundation measure set, which identifies a set of key quality measures for use where relevant throughout CMS programs. We further agree with commenters that aligning a standardized set of quality measures across Medicare programs will advance population health promotion, health equity, and interoperability, yield more meaningful analysis of quality measures, and reduce burden to increase time spent on patient care and improvement activities.

We are finalizing our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set for performance year 2025 and subsequent performance years to meet the Shared Savings Program's quality performance standard. For a discussion of proposals and finalized policies, including any modifications, related to the establishment of the APP Plus quality measure set and the phase-in schedule for incorporating measures into the APP Plus quality measure set, see section IV.A.4.c.(2) of this final rule.

Comment: Many commenters expressed reservations about the requirement that Shared Savings Program ACOs report the APP Plus quality measure set to meet the Shared Savings Program's quality performance standard. Multiple commenters stated that reporting the APP Plus quality measure set would increase reporting burden for ACOs and could discourage providers from adopting accountable care models. One commenter noted that an important benefit to participating in the Shared Savings Program has been reporting the APP quality measure set, which is a more concise, prioritized set of quality measures as compared to the quality measures available in traditional MIPS. Several commenters suggested that the APP Plus quality measure set's expanded size as compared to the existing APP quality measure set would be ''untenable'' for ACOs to report, at this time. Some of the commenters expressing these reservations urged CMS not to finalize the proposal.

Response: We acknowledge the commenters' concerns about our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set. We recognize that ACOs may perceive this larger quality measure set as an increased burden, even with the phase-in schedule we proposed for incorporating measures into the APP Plus quality measure set. As discussed in section IV.A.4.c.(2) of this final rule, when fully expanded, the APP Plus quality measure set will comprise of 11 measures, ten of which are also Adult Universal Foundation quality measures, as compared to the existing APP quality measure set's six measures. However, when we proposed to establish the APP Plus quality measure set, we did so with the goal of leveraging the Adult Universal Foundation of quality measures to align quality measures used across CMS programs and initiatives. By requiring Shared Savings Program ACOs to report the APP Plus quality measure set, there will be greater alignment of quality measures reported by Shared Savings Program ACOs with the Medicaid Core Sets and the Marketplace Quality Rating System, which have previously adopted the quality measures in the Universal Foundation, and also better alignment between the quality measures reported by Shared Savings Program ACOs with the Value in Primary Care MIPS Value Pathway (MVP), which contains the same Universal Foundation measures (89 FR 61854 through 61855). Additionally, there will be greater alignment of quality measures reported by Shared Savings Program ACOs with the Medicare Advantage and Part D Star Ratings, which is moving towards the Universal Foundation. Because it remains our goal to align quality measures across CMS program and initiatives, we are finalizing our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set for performance year 2025 and subsequent performance years.

In this final rule, we are finalizing several policies that aim to address commenters' concerns about increased burden and that incentivize and support ACOs reporting the APP Plus quality measure set. Specifically, as discussed in section IV.A.4.c.(2) of this final rule, we are finalizing with modification the phase-in schedule for incorporating measures into the APP Plus quality measure set. We are also finalizing with modification our proposal to extend the eCQM reporting incentive to support ACOs in meeting the Shared Savings

Program quality performance standard as described in section III.G.4.d of this final rule. We are also finalizing to extend this reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026. We are finalizing as proposed the Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs as described in section IV.A.4.f.(1)(b)(iii) of this final rule in recognition of commenters' concerns regarding increased burden and to incentivize ACOs to report eCQMs and support their transition to digital quality measurement. Furthermore, as described in section IV.A.4.f.(1)(c)(i) of this final rule, we are finalizing our policy to score measures in the Medicare CQM collection type using flat benchmarks for their first two performance periods in MIPS beginning in the CY 2025 performance period/ 2027 MIPS payment year. The use of flat benchmarks may allow ACOs with high scores to earn maximum or near maximum measure achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that ACOs with high quality performance on a measure are not penalized as low performers.

Comment: Some commenters stated that small independent practices and specialty practices are often unable to participate or continue to participate in the Shared Savings Program due to the technical and financial burden associated with the adoption of new technologies required to meet reporting requirements. Several commenters requested that CMS consider adding exceptions or exclusions for small practices and certain specialties and/or altering data completeness requirements to address ongoing challenges and allow for ACOs to be successful in reporting eCQMs, MIPS CQMs, and Medicare CQMs. These commenters noted that exceptions and exclusions already apply in MIPS for other performance categories and could easily be applied to ACOs reporting eCQMs, MIPS CQMs, and Medicare CQMs, and that making these changes in the Shared Savings Program could allow ACOs to maintain participation among small and specialty practices that cannot comply with these changes without undue costs and burdens.

Response: We recognize that reporting eCQMs can be particularly challenging for ACOs with small practice participants, particularly those who need to obtain data from multiple practices with different EHR systems. We are committed to supporting Shared Savings Program ACOs with small practice participants in their transition to digital quality measure reporting, and in the CY 2024 PFS final rule, we finalized for performance year 2024 and subsequent performance years the Medicare CQM collection type as a transitional reporting option for Shared Savings Program ACOs (88 FR 79107) that we believe may provide a more supportive option with more flexibility in reporting given the data completeness. In the CY 2024 PFS proposed rule (88 FR 52420), we stated that we recognized that Medicare CQMs might not be the most suitable collection type for some ACOs, particularly ACOs with a single-EHR platform, a high proportion of primary care practices, and/or ACOs composed of participants with experience reporting all payer/all patient measures in traditional MIPS (88 FR 79098). To that end, we have also provided technical guidance (updated for each performance year), entitled Medicare Shared Savings Program: Reporting MIPS CQMs and eCQMs in the Alternative Payment Model Performance Pathway (APP) which is posted in the QPP Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2179/APP%20Guidance%20Document%20for%20ACOs.pdf*, that recognizes the unique challenges facing ACOs and provides guidance on how to address patient matching across multiple EHR systems as a way to transition ACOs to all payer/patient quality measure reporting. We will continue to monitor challenges facing ACOs including those with small practices along with the ability of their electronic health record systems to collect and generate data necessary to successfully transition and report eCQMs and may make additional adjustments to address these challenges in future rulemaking.

Comment: A few commenters noted challenges with reporting that may cause some ACOs to narrow their Participant Lists, including removing specialists, which will result in fewer Medicare patients in an accountable care relationship, counter to CMS' goal to have 100 percent of Original Medicare beneficiaries in an accountable care relationship by 2030.

Response: We recognize the challenges associated with reporting the measures. We have provided support and incentives where appropriate that we believe address many of the challenges for broad inclusion of specialists. We believe that the broader quality strategy and expansion of Centers for Medicare and Medicaid Innovation models will continue to allow CMS to achieve our stated goals and that ACOs following the CMS dQM Strategic Roadmap will be able to expand and grow their capabilities over time.

Comment: Some commenters suggested that CMS introduce the new measures into the APP Plus quality measure set in a pay-for-reporting format for at least one year.

Response: The Shared Savings Program sunset its pay-for-reporting policy in performance year 2020 (85 FR 84724). As such, we will not apply pay for reporting to new measures in the APP Plus quality measure set. In addition, neither MIPS nor the APP provides for pay-for-reporting. Separately, we did not propose a pay-for-reporting policy when we proposed to require Shared Savings Program ACOs to report the APP Plus quality measure set and therefore consider these comments to be out of scope.

After consideration of public comments received, we are finalizing our proposal that, for performance year 2025 and subsequent performance years, Shared Savings Program ACOs will be required to report the APP Plus quality measure set, as specified in amendments to §§ 425.508 and 425.510 (as described in section III.G.4.b.(2)(a) of this final rule). Shared Savings Program ACOs will be required to report on and will be scored on all applicable quality measures in the APP Plus quality measure set according to modified phase-in schedule for incorporating measures into the APP Plus quality measure set as discussed in section IV.A.4.c.(2) of this final rule. The final APP Plus quality measure set for Shared Savings Program ACOs, for performance year 2025 and subsequent performance years, is specified in Tables 39 through Table 42 of this final rule. The existing APP quality measure set will no longer be available for reporting by Shared Savings Program ACOs beginning in performance year 2025.

(b) Collection Types Available for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set

Along with our proposal to require Shared Savings Program ACOs to report the APP Plus quality measure set, in the CY 2025 PFS proposed rule, we proposed to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and

Medicare CQM collection types for performance year 2025 and subsequent performance years (89 FR 61856 through 61857). We also stated that our proposal to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should aim to prioritize the eCQM collection type—the gold standard collection type that underlies the Digital Quality Measurement (dQM) Strategic Roadmap (available at *https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*)—and use Medicare CQMs as the transition step on our building-block approach for ACOs' progress to adopt digital quality measurement (89 FR 61838). We sought to reduce burden on ACOs as they adopt eCQMs for quality measure reporting by using a phased-in approach to expand the APP Plus quality measure set between performance years 2025 and 2028 (89 FR 61856). We noted that we would continue to provide the Medicare CQM reporting option as ACOs increase their experience and overcome their challenges with reporting all payer/all patient measures. As discussed more fully below, we proposed not including the MIPS CQM collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set to focus ACOs' efforts on the implementation of the APP Plus quality measure set, while continuing to encourage the adoption of eCQMs. We stated that our proposed approach would recognize the investments ACOs have made to report eCQMs and their benefits (that is, more efficient data collection, real time provider feedback, and less burden through the use of digital data) and allow ACOs that have invested in eCQMs to continue on that track and align with long term goals of digital quality measurement.[531]

Since Medicare CQMs are MIPS CQMs that are reported on an ACO's eligible Medicare fee-for-service population, ACOs that have invested in the infrastructure to report MIPS CQMs would be able to report Medicare CQMs on a subset of their all payer/all patient population. Furthermore, as noted in the CY 2024 PFS final rule, Medicare CQMs address ACO concerns regarding the difficulty of matching and aggregating patient data across multiple EHR systems (88 FR 79106). Medicare CQMs also provide a transition path and alternative for ACOs that have difficulty reporting patient data by limiting the beneficiaries for which an ACO must match and aggregate data to only the ACO's eligible Medicare fee-for-service beneficiaries, instead of their all payer/all patient population (88 FR 79106). As a logical next step in the reporting of digital quality measures, this population is larger than the sample currently used in the CMS Web Interface, but not as large as the all payer/all patient population that must be reported for an eCQM or MIPS CQM (88 FR 79106).

As we stated in the CY 2025 PFS proposed rule, we aim to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs, and we are working to convert current eCQMs to the Fast Healthcare Interoperability Resources (FHIR) standard (86 FR 65379). Including eCQMs as a collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set aligns with our goal to transition to digital quality measurement including the alignment and development of FHIR standards and tools for eCQM reporting in the CMS dQM Strategic Roadmap. We noted numerous benefits to using eCQMs, including their use of electronic standards that reduce the burden of manual extraction and reporting for measured entities, their use of clinical data to assess the outcomes of treatment by measured entities, and their fostering of access to real-time data for point of care quality improvement and decision support.[532] Furthermore, eCQMs align with the Meaningful Measures Framework 2.0 goal of improving quality reporting efficiency by transitioning to digital quality measures.[533] In addition, a recent study highlighted the resource intensity of quality reporting, underscoring the high cost of claims-based measures relative to others and recommended that policy makers shift to electronic metrics to ''optimize resources spent in the overall pursuit of higher quality.'' [534] For these reasons, and to continue encouraging ACOs on their progress to adopt digital quality measurement, we are not modifying the availability of eCQMs as a collection type for ACOs that reported the APP quality measure set by including eCQMs as a collection type in the APP Plus quality measure set in performance year 2025 and subsequent performance years. In section III.G.7.e. of the CY 2025 PFS proposed rule, we solicited comment on a higher risk, higher reward track for Shared Savings Program ACOs participating in the ENHANCED track. In this request for information, we solicited comment on questions relevant to our long-term goals of supporting ACOs in their transition to reporting all payer/all patient quality measures: How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?

In the CY 2024 PFS final rule, we stated that ''Medicare CQMs are intended to serve as a transition to all payer/all patient reporting and not as a permanent collection type. We acknowledge that ACOs are at different stages of readiness to adopt all payer/all patient measures, and we intend for Medicare CQMs to be available to ACOs during their transition to all payer/all patient reporting'' (88 FR 79106). We also stated that ''[w]e expect that the sunsetting of the Medicare CQM collection type may be paced with the uptake of FHIR Application Programming Interface (API) technology, but this will be assessed on industry readiness and CMS requirements'' (88 FR 79106). Specifically, we anticipated that the increased use of FHIR API technology for quality data exchange and aggregation would facilitate ACOs' reporting of eCQMs and thus increase their uptake of them. Future advancements in the use of FHIR API technology to share quality data and its uptake among Shared Savings Program ACOs may accelerate our future plans to sunset Medicare CQMs. As discussed earlier in this section of the final rule, we proposed to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types for performance year 2025 and subsequent performance years and use Medicare CQMs as the transition step on our building-block approach for ACOs' progress to adopt digital quality measurement (89 FR 61856 through 61857). As we continue to support ACOs in fully and equitably participating in all payer/all patient collection types with our proposed creation of the APP Plus quality measure set, our commitment to monitor ACOs' reporting of quality data using Medicare CQMs and to assess

[531] Centers for Medicare & Medicaid Services (2023). Electronic Clinical Quality Measure Basics (eCQM 101). Accessed June 24, 2024. *https://ecqi.healthit.gov/sites/default/files/eCQM-Basics-508.pdf*.

[532] eCQI Resource Center (2024). Get Started with eCQMs. *https://ecqi.healthit.gov/ecqms*.

[533] Centers for Medicare & Medicaid Services (2024). Meaningful Measures 2.0: Moving to Measure Prioritization and Modernization. *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20*.

[534] Saraswathula, A., et al., The Volume and Cost of Quality Metric Reporting. *JAMA* (June 6, 2023), available at *https://jamanetwork.com/journals/jama/fullarticle/2805705*.

their appropriateness as a collection type remains the same.

As we stated in the CY 2024 PFS final rule, ACOs that include or are composed solely of FQHCs or RHCs must report quality data on behalf of the FQHCs or RHCs that participate in the ACO. To clarify, while FQHCs and RHCs that provide services that are billed exclusively under FQHC or RHC payment methodologies are exempt from reporting traditional MIPS, FQHCs and RHCs that participate in APMs, such as the Shared Savings Program, are considered APM Entity groups as described at § 414.1370 (88 FR 79099). If our proposal is finalized, FQHCs and RHCs that participate in Shared Savings Program ACOs would have to report the APP Plus quality measure set through their ACO for performance year 2025 and subsequent performance years.

We solicited comments on our proposal to streamline collection types for Shared Savings Program ACOs to report the APP Plus quality measures through Medicare CQMs and/or eCQMs. The following is a summary of the public comments we received and our responses.

Comment: Many commenters expressed concern with the proposal to eliminate the MIPS CQM collection type for Shared Savings Program ACOs beginning in performance year 2025. These commenters stated that eliminating the MIPS CQM collection type would cause administrative burden, disparate electronic health records, and reporting challenges with the submission of the all payer/all patient eCQM collection type. Several commenters noted that their efforts and resources would need to focus on determining the best reporting approaches at the expense of innovations that support patients. Many commenters encouraged CMS to consider extending the availability of the MIPS CQM collection type for Shared Savings Program ACOs and requested that the collection type remain available for an additional one to three years. Some commenters stressed the challenges related to loss of prior investments made in preparing to report or actively reporting MIPS CQMs. Several of these commenters stated that having limited notice from CMS that the MIPS CQM collection type would not be available to Shared Savings Program ACOs reporting the APP Plus quality measure set provides ACOs with only a few months to pivot to another option if the proposal not to include MIPS CQMs in the APP Plus quality measure set is finalized.

A few commenters requested that the CMS Web Interface reporting option remain available until the Medicare CQM specification and patient reporting requirements are made clear, including benchmarks. Several commenters suggested making all reporting options available until CMS tests eCQM, MIPS CQM, Medicare CQM, and digital quality measure (dQM) reporting. One commenter objected to the exclusion of the MIPS CQM collection type from the APP Plus quality measure set and stated MIPS CQMs allow ACOs to leverage multiple data sources beyond just EMR data, including claims data, as an important component to ensuring the accuracy and completeness of data reported.

Response: We acknowledge commenters' feedback regarding the challenges associated with not having MIPS CQM available to ACOs as a collection type for reporting the APP Plus quality measure set. We agree with commenters that additional time is needed for ACOs who have invested in MIPS CQMs to transition to eCQMs. Having MIPS CQMs as a reporting option will allow ACOs to gain experience with all payer quality measure data collection and reporting before MIPS CQMs are phased out as a collection type for Shared Savings Program ACOs. We are aware that some Shared Savings ACOs have already contracted with vendors for the MIPS CQM collection type at their own expense and that for these ACOs additional time to transition to the eCQM collection type is desirable. We also understand that the MIPS CQM collection type allows ACOs to leverage multiple data sources beyond just EMR data, thereby allowing for improved accuracy and completeness of data submitted with this collection type.

For these reasons, we will provide Shared Savings Program ACOs with the option to use the MIPS CQM collection type for two additional performance years (*i.e.,* performance years 2025 and 2026) when reporting the APP Plus quality measure set, as finalized at IV.A.4.c.(2) of this final rule. We believe that making the MIPS CQM collection type available for ACOs for two additional performance years would fairly balance investments ACOs have already made with and CMS' long-term goals of digital quality measurement.

In response to suggestions that all collection types, including the CMS Web Interface, remain available to Shared Savings Program ACOs in the APP until CMS tests eCQM, MIPS CQM, and Medicare CQM reporting, we note that all these collection types are available in performance year 2024. The collection types available to ACOs reporting the APP Plus quality measure set for performance year 2025 and subsequent years that we are finalizing in this final rule recognize the need for some ACOs to build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures while incentivizing ACOs to transition to eCQMs. However, we will continue to monitor the uptake of collection types by ACOs in the coming years. We note that we finalized the sunsetting of the CMS Web Interface in the CY 2021 PFS final rule (85 FR 84722), giving ACOs and other interested parties multiple performance years to prepare for the sunsetting of the CMS Web Interface.

Comment: Several commenters expressed concern that the Medicare CQM collection type is technologically and methodologically complex and distinct from the MIPS CQM collection type in several ways that pose additional challenges and burdens for Shared Savings Program ACOs.

Response: As stated in the CY 2024 PFS final rule, a Medicare CQM is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare FFS beneficiaries, instead of its all payer/all patient population (88 FR 79098). ACOs with the infrastructure to report MIPS CQMs can readily transition to report Medicare CQMs. While we continue to believe that Medicare CQMs are a valuable transition step on our building-block approach for Shared Savings Program ACOs' progress to adopt digital quality measurement, under the policies we are finalizing in this section of this final rule, Shared Savings Program ACOs would continue to have the option to report the APP Plus quality measures using the MIPS CQM collection type for performance years 2025 and 2026. We believe this additional time will further allow ACOs to address challenges and burdens they may face when reporting Medicare CQMs. Therefore, for performance years 2025 and 2026, Shared Savings Program ACOs that report the APP Plus quality measure set will have the option to use any of the following collection types or a combination thereof, as applicable: Medicare CQM, MIPS CQM and eCQM.

Comment: We received numerous comments from interested parties expressing concern about the length of time the Medicare CQM collection type will remain available to Shared Savings Program ACOs reporting the APP Plus quality measure set. Some of those commenters recommended that CMS make the Medicare CQM reporting option permanent for the foreseeable future. Several of these commenters noted that, because of the uncertainty

surrounding the timeline for sunsetting the Medicare CQM collection type, Shared Savings Program ACOs and EHR vendors are reluctant to invest time and resources in an option that may be eliminated with little to no warning.

Response: In response to comments that ACOs and EHR vendors are reluctant to invest time and resources in a new reporting option, we want to reiterate our commitment to the CMS National Quality Strategy and the adoption of digital quality measurement. We anticipate that ACOs and their vendors will adopt Medicare CQMs to the extent that it is helpful within the timelines provided in this section of this final rule.

Regarding commenters who requested that we make Medicare CQMs a permanent collection type, we note that from the inception of the Medicare CQM collection type beginning in performance year 2024, we intend for the Medicare CQM collection type to serve as a transition collection type to help ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures (88 FR 79097 through 79098). In addition, as we stated in the CY 2025 PFS proposed rule, we believe that our policy to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should also aim to prioritize the eCQM collection type and the use of the Medicare CQM collection type is a transition step on our building-block approach for ACOs' progress to adopt digital quality measurement (89 FR 61838). We note in this final rule that the sunsetting of Medicare CQMs would take place no sooner than five years from now, when we anticipate there is widespread uptake of FHIR API technology. While FHIR technology is employed in other components of digital health information, we note that we would assess the uptake of FHIR API technology for quality reporting in alignment with the CMS Digital Quality Measurement Strategic Roadmap, specifically, Domain 3: Optimize Data Aggregation. In particular, CMS would assess whether ACOs broadly have developed capabilities to efficiently leverage FHIR API technology to aggregate quality reporting data and patient-centered measurement and are reporting eCQMs.[535]

Comment: Many commenters expressed concern with CMS' goal to require all Shared Savings Program ACOs to use the all payer/all patient eCQM collection type to report quality measures. For example, several commenters cited time and resource concerns, including cost, challenges specific to small and specialty practices, data and vendor-related challenges such as data aggregation and de-duplication, and a lack of standardization across electronic health record (EHR) vendor systems for the capture of and reporting on eCQM data elements. Commenters also stated that adoption of the eCQM collection type and reporting on all payer/all patient data requires ACOs to tailor data extracts and uploads across systems, which places considerable financial and administrative burden on ACOs and could require them to contract with additional vendors to be able to report eCQMs. For example, one commenter indicated their current vendor cannot support the de-duplication of data for all payers and stated they were concerned that resources and finances would go toward building and implementing eCQMs in the present while CMS may require reporting on other measures and artificial intelligence-enabled technology in the future. Few commenters noted further challenges with EHR certifications and vendors adopting new collection types and measures.

Response: In response to comments that were concerned with the transition to eCQMs, citing cost, time and resource concerns, challenges specific to small and specialty practices and similar comments related to the financial and administrative burden with adopting eCQMs, we note that we are finalizing a number of policies in this final rule to support ACOs in their transition to digital quality measurement. Specifically, we are finalizing the eCQM reporting incentive to performance year 2025 and subsequent performance years, and we are also extending the reporting incentive to MIPS CQMs for performance years 2025 and 2026, to support ACOs in meeting the Shared Savings Program quality performance standard as described in section III.G.4.d of this final rule. We are also finalizing the Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs as described in section IV.A.4.f.(1)(b)(iii) of this final rule. In addition to policies finalized in this final rule, we also refer readers to our discussion in section III.G.4.b(2)(a) of this final rule of previously finalized policies that support ACOs during the transition to digital quality measurement.

In response to concerns about data and vendor-related challenges such as data aggregation and de-duplication, and a lack of standardization across EHR vendor systems for the capture of and reporting on eCQM data elements, we direct readers to our guidance on reporting eCQMs/MIPS CQMs discussed earlier in this section of this final rule that recognizes challenges with patient matching and data aggregation. Specifically, for concerns related to de-duplication, we encourage ACOs and their vendors to consider using our DedupliFHIR open-source data deduplication and record matching tool. The project includes a backend library and a front-end desktop application that can be downloaded from the DedupliFHIR GitHub repository at *https://github.com/DSACMS/dedupliFHIR.* We also encourage ACOs and their vendors to participate in our regular QCDR and Qualified Registry support calls and Learning System Webinars and to submit questions to the Quality Payment Program help desk, as needed. Additionally, for ACOs with significant EHR vendor concerns, when issues of potential noncompliance with certification requirements are unresolvable, we note that ONC has provided a complaint process for certified products available to the public at *https://www.healthit.gov/topic/certified-health-it-complaint-process.*

In response to the recommendation that CMS revisit EHR vendor certification requirements to establish technology support for APP Plus quality measures that allow for data aggregation across systems, we note that most clinical information is digitized, accessible, and shareable due to several technology and policy advances making interoperable, electronic health record systems widely available. The CURES Act applied the law to healthcare providers, health IT developers of certified health IT, and health information exchanges (HIEs)/health information networks (HINs).[536] We encourage ACOs to work with their vendors, as appropriate, to report the APP Plus quality measure set and invest in the technology and services necessary to prepare and successfully report. CMS also understands that despite the resources made available to ACOs, there continue to be challenges in reporting eCQMs, and CMS is committed to working with ACOs to address barriers over time. We also note that we anticipate that the transition to all-payer eCQMs would take place no sooner than 5 years from now, giving CMS and

[536] Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (2024). *Information Blocking. https://www.healthit.gov/topic/information-blocking.*

ACOs additional time to work through these challenges.

Comment: One commenter stated that there are gaps in digital literacy within medical offices and, as a result, the extraction of meaningful data is a challenge. Commenters were also concerned that small practices and low-revenue ACOs, whose participants are drawn more heavily from small ambulatory, primary care practices and specialty practices will be the least likely to successfully adopt the eCQM collection type, and that adoption of the eCQM collection type contradicts the exception CMS granted to small practices and others with automatic reweighting of the Promoting Interoperability and CEHRT-use requirements in ACOs.

Another commenter explained that reporting MIPS CQMs serves as a ''temporary accommodation'' to mitigate concerns about reporting all patient data among community-based specialty practices participating in ACOs. The commenter explained that specialty practices that are participating in an ACO with a hospital system may experience competitive concerns when they are expected to share patient details with the ACO for purposes of quality reporting, such as the case where a community-based oncology clinic is in direct competition with hospital-based infusions.

Response: As detailed at § 425.116(a)(5), each ACO's Participant Agreement describes how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO. Moreover, as detailed at § 425.308(b)(4)(ii), ACOs are required to publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants. As such, it is appropriate for ACOs to reinvest shared savings as a means to comply with Shared Savings Program requirements and required processes, including to support their ACO participants with tasks such as digital literacy within medical offices, the utilization of structured data fields, and the extraction of meaningful data.

We disagree with comments that small practices and low-revenue ACOs are the least likely to successfully adopt the eCQM collection type. To the contrary, we note that an internal analysis of the performance year 2023 quality data submissions indicates similar patterns of eCQM/MIPS CQM adoption across practices of varying sizes and ACOs with varying revenue types. Of the ACOs reporting eCQMs in performance year 2023, 54 percent were low-revenue.

In response to the comment that adoption of eCQMs contradicts the exception CMS granted to small practices and others with automatic reweighting of the Promoting Interoperability and CEHRT requirements in ACOs, we note that MIPS makes a distinction between performance categories, that is quality, Promoting Interoperability, improvement activities, and cost. Some exclusions are specific to the performance category and codified by statute. While there is an automatic reweighting of the MIPS Promoting Interoperability performance category for those with Special Status as defined at 42 CFR 414.1305, including for the small practice designation, there is no automatic reweighting of the MIPS Quality performance category or exception for small practices. It is also important to note that MIPS eligible clinicians are required to report MIPS unless otherwise excluded or exempt using eCQMs or MIPS CQMs. The Shared Savings Program is a voluntary program and providers, including small practices, are not required to participate in a Shared Savings Program ACO. A Shared Savings Program ACO must report quality data on behalf of the eligible clinicians who bill under the TIN of the ACO participant for purposes of the MIPS quality performance category. As described at 42 CFR 414.1390(b) MIPS eligible clinicians and groups must submit data that are true, accurate, and complete. 42 CFR 425.510(c) applies these requirements to the Shared Savings Program ACOs. As such, they are not permitted to omit or exclude ACO participants, ACO providers/suppliers, or ACO professionals from the ACO's quality data submissions.

In response to the comment about situations where sharing patient details through quality reporting may impact specialty clinics in terms of competition with a hospital, when both entities are participating together in an ACO, we note that while entities may be using the MIPS CQM collection type to limit disclosure of patient data that would otherwise be needed for eCQM reporting, we are not persuaded, based on the circumstances described, that this would be a reason to further extend use of the MIPS CQM collection type beyond the extension being finalized. We further note that ACOs are groups of doctors, hospitals, and other health care providers, that come together voluntarily to give coordinated high-quality care to the Medicare patients they serve. We reiterate the importance of ACO providers/suppliers and ACO participants working together, within an ACO, to meet the goals of the Shared Savings Program and comply with program requirements, including quality reporting requirements. However, we recognize that under certain circumstances, ACOs may raise competitive concerns. HHS and CMS will coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program ACOs to ensure there are no detrimental impacts to competition. Further, in the CY 2022 PFS final rule, we stated our belief that the disclosure of all-payer data to CMS as required by § 414.1340(a) would be permitted by the HIPAA Privacy Rule under the provision that permits disclosures of PHI as ''required by law'' (86 FR 65258). We refer readers to our discussion of the disclosure of all-payer data to CMS at 86 FR 65258.

Comment: A few commenters stated that the transition to eCQMs, which requires reporting on an ACO's entire payer mix, will put ACOs with higher proportions of underserved non-Medicare patients at a disadvantage. One of these commenters speculated that ACOs with higher underserved populations who report eCQMs will see lower performance on certain metrics for reasons beyond the control of the ACO and urged CMS to consider the financial and administrative burdens that these ACOs face to sustain Shared Savings Program participation.

Response: All payer/all patient measures are valuable measures because they reflect the quality of care provided across all of a provider's patients and are consistent with CMS' health equity goals. All payer measures are broadly used across Medicare quality payment and quality reporting programs, including in MIPS (§ 414.1305 (defining ''collection type'' to include eCQMs)). Nonetheless, we acknowledge that there may be instances when ACOs have lower performance reporting all payer/all patient eCQMs. In IV.A.4.f.(1)(b)(iii) of this final rule, we are finalizing the Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs. Specifically, a Virtual Group

and an APM Entity will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340 as described in section IV.A.4.f.(1)(b)(iii) of this final rule. Adding one point for each reported eCQM would provide ACOs that serve higher proportions of underserved populations and report eCQMs with an upward adjustment of the MIPS Quality performance category score.

Further, in the CY 2023 PFS final rule, we discussed concerns that the quality performance standard and the quality performance measures did not adequately assess the quality of care provided by ACOs with clinicians who serve a high proportion of underserved individuals (87 FR 69839). As a result, we finalized the health equity adjustment beginning in performance year 2023 and subsequent performance years to upwardly adjust the MIPS Quality performance category score for ACOs that report quality measures using the eCQM/MIPS CQM collection types, are high performing on quality, and serve a higher proportion of underserved beneficiaries (87 FR 69838). In performance year 2023, out of all the ACOs that reported eCQMs/MIPS CQMs and met data completeness requirements, approximately 39 percent of ACOs earned health equity adjustment bonus points, and an average of 3.54 bonus points (out of 10) were added to eligible ACOs' quality scores. We will continue to evaluate whether ACOs serving higher underserved populations are being disproportionately disadvantaged through all-payer collection, which may inform future rulemaking.

Comment: Several commenters remarked on technical aspects of reporting Medicare CQMs as a collection type including patient identification and vendor support.

Response: While these comments are out of scope for this final rule, we acknowledge commenters' concerns identifying patients and operationalizing Medicare CQMs. We note that ACOs have the option to report the APP quality measure set using the Medicare CQM collection type in 2024, and as finalized in this section of the final rule, they will also have the option to report the APP Plus quality measure set using the Medicare CQM collection type in performance years 2025 and 2026. We will continue to support and provide guidance to ACOs reporting Medicare CQMs consistent with measure specifications.

We further direct readers to our guidance on the submission of Medicare CQMs. Specifically, the 2024 Medicare CQM Checklist for Shared Savings Program Accountable Care Organizations which is posted in the QPP Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2679/2024SSPACOMedicareCQMChecklist.pdf* for resources and support in reporting eCQMs, MIPS CQMs, and Medicare CQMs. We also encourage ACOs and their vendors to participate in our monthly QCDR and Qualified Registry support calls, Learning System Webinars and to submit questions to the Shared Savings Program helpdesk via ACO–MS, as needed.

Comment: A few commenters shared feedback on technical aspects of QRDA files that are beyond the scope of this rule. Specifically, a commenter stated that CMS should allow for the use of mature QRDA–III files rather than requiring the use of less mature, resource intensive QRDA–I files. Another commenter noted that EHR system they work with has struggled to produce a QRDA–I file which makes eCQM and Medicare CQM reporting an enormous challenge and causes their organizations to divert already limited resources to constantly evolving digital quality reporting requirements.

Response: While these comments are out of scope for this rule, we acknowledge the commenters' feedback regarding the complexity of ACOs using QRDA files. We will continue to monitor ACO quality reporting and support ACOs through guidance as well as working to understand concerns and challenges by working with the CMS QRDA Work Group to reduce burden, better inform interested parties, and reduce complexity where possible. Technical comments and responses around QRDAs are also accessible to the public via the ONC Jira website at *https://oncprojectracking.healthit.gov/support/projects/QRDA/summary*.

Comment: Some commenters expressed concerns about issues that were not related to our proposals in the proposed rule. We received several comments related to the previously finalized requirement that Shared Savings Program ACOs report the MIPS Promoting Interoperability performance category in performance 2025 and subsequent performance years as described at § 425.507. One commenter agreed that digital quality measurement is the goal and that ACOs are uniquely qualified to assist practices with needed upgrades in technology, but added their perspective that these policies are too aggressive and ignore the upcoming changes on the horizon that will require additional investment. Another commenter expressed that the policies result in substantial burden for physician practices with no clear positive impact on information exchange. Commenters expressed the concern that the policies will force ACOs and other APM Entities to omit practices that they are not convinced can meet both requirements, which will hinder, not help, CEHRT adoption and APM participation.

Response: We did not propose any changes to these previously finalized policies in the CY 2025 PFS proposed rule, and therefore, these comments are considered to be out of scope. However, we recently released additional guidance for ACOs to address questions on Promoting Interoperability reporting requirements at *https://www.cms.gov/files/document/frequently-asked-questions-shared-savings-program-requirement-report-objectives-and-measures-mips.pdf*; we are continuing to monitor the impact of these policies, and we are exploring how to address concerns raised by ACOs and other interested parties. We may revisit the Shared Savings Program MIPS Promoting Interoperability reporting requirement in future rulemaking to provide a less burdensome pathway for Shared Savings Program ACOs to meet the APM certified electronic health record technology (CEHRT) requirements that is consistent with our goal to gain additional insight and transparency into CEHRT use by APMs and level the playing field between Advanced APMs and APMs.

For reasons we discussed above in this section, we agree more time is needed before sunsetting MIPS CQMs as a collection type for Shared Savings Program ACOs given ACOs may have already contracted with vendors for this collection type. Including MIPS CQMs as a collection type for an additional two years would allow ACOs time to build the necessary infrastructure to transition to eCQM and Medicare CQM reporting in performance year 2027. Therefore, we are finalizing that MIPS CQM will be an available collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set in performance years 2025 and 2026. We also stated that Medicare CQMs are a valuable transition step on our building block approach, and the sunsetting of Medicare CQMs would take place no sooner than five years from now, when we anticipate there is widespread uptake of FHIR API technology. While FHIR technology is employed in other components of digital health information, we note that

we would assess the uptake of FHIR API technology for quality reporting in alignment with the CMS Digital Quality Measurement Strategic Roadmap, specifically, Domain 3: Optimize Data Aggregation. In particular, CMS would assess whether ACOs broadly have developed capabilities to efficiently leverage FHIR API technology to aggregate quality reporting data and successfully report eCQMs.

Because we are finalizing inclusion of MIPS CQM as a collection type available to Shared Savings Program ACOs reporting the APP Plus quality measure set in performance years 2025 and 2026, in section III.G.4.d of this final rule, we are also extending the reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026 to support ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track.

(3) Changes to Regulation Text

As discussed in section III.G.4.b.(2)(a) of the CY 2025 PFS proposed rule, for performance year 2025 and subsequent performance years, we proposed to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section IV.A.4.c.(3) of the CY 2025 PFS proposed rule. The APP Plus quality measure set would comprise of 11 measures, consisting of six measures from the existing APP quality measure set and five additional measures from the Adult Universal Foundation measure set not already included in the existing APP quality measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We also proposed to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to eCQMs and Medicare CQMs (89 FR 61856 through 61857). We refer readers to sections IV.A.4.c, IV.A.4.e.(1)(b)(i), IV.A.4.f.(1)(b)(iii), and IV.A.4.f.(1)(c)(i). of the CY 2025 PFS proposed rule for changes to 42 CFR part 414. We proposed conforming changes to 42 CFR part 425 as described below (see also 89 FR 61857 through 618578):

- We proposed to sunset the requirement that ACOs must submit quality data via the APP to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program, and to revise § 425.508(b) to indicate that the requirement will be applicable for performance years beginning in 2021—2024. We also proposed to replace the phrase ''Alternative Payment Model Performance Pathway (APP)'' with the phrase ''APM Performance Pathway (APP)'' to conform with the phrase used at § 414.1367.
- We proposed to add a new paragraph (c) at § 425.508 to establish that, for performance years beginning on or after January 1, 2025, ACOs must submit quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.
- We proposed to revise the section heading at § 425.510 to ''Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.''
- We proposed to sunset the requirement that ACOs must report quality data on the APP quality measure set according to the method of submission established by CMS and to revise § 425.510(b). We proposed to add a new paragraph (b)(1) at § 425.510 to indicate that the requirement will be applicable for performance years beginning in 2021 through 2024.
- We proposed to add a new paragraph (b)(2) at § 425.510 to establish that, for performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367, according to the submission method established by CMS.
- We proposed to revise § 425.512(a)(2)(iii) to establish that, for performance year 2025 and subsequent performance years, an ACO in the first performance year of the ACO's first agreement period under the Shared Savings Program will meet the quality performance standard if the ACO reports the APP Plus quality measure set and meets the data completeness requirement on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), and receives a MIPS Quality performance category score for the applicable performance year.
- We proposed to revise the introductory paragraph (a)(5)(i) to § 425.512 to read as follows: ''Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:''.
- We proposed to revise the introductory paragraph (a)(5)(i)(A) to read as follows: ''For performance year 2024, the ACO reporting quality data on the APP quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—''.
- We proposed to revise the introductory paragraph (a)(5)(i)(B) to read as follows: ''For performance year 2025 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—''.
- We proposed to add a new paragraph (a)(5)(ii)(A) to § 425.512 to indicate that an ACO will meet the alternative quality performance standard for performance year 2024 if the ACO reports quality data on the APP quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.
- We proposed to add a new paragraph (a)(5)(ii)(B) to § 425.512 to establish that an ACO will meet the alternative quality performance standard for performance year 2025 and subsequent years if the ACO reports the quality data on the APP Plus quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set.
- We proposed to revise § 425.512(a)(5)(iii)(B) to indicate that for performance year 2025 and subsequent performance years, an ACO will not meet the quality performance standard or the alternative quality performance standard if the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).
- We proposed to revise § 425.512(a)(7) introductory text and (a)(7)(i) and proposed to add new paragraphs (a)(7)(i)(A) and (B) to indicate for performance year 2024, we will use the higher of the ACO's health equity adjusted Quality performance

category score or the equivalent of the 40th percentile MIPS Quality performance category score when an ACO reports all of the required measures, meeting the data completeness requirement for each measure in the APP quality measure set and receiving a MIPS Quality performance category score and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We proposed to revise § 425.512(a)(7)(ii) and proposed to add new paragraphs (a)(7)(ii)(A) and (B) to indicate for performance year 2025 and subsequent performance years, an ACO will receive the higher of the ACO's health equity adjusted quality performance category score or the equivalent of the 40th percentile MIPS Quality performance category score when an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score, and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the eCQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We proposed to revise § 425.512(b)(1) and (2) and (b)(4)(i) by removing the phrase ''APP measure set'' and replacing with the phrase ''APP quality measure set'' to align naming conventions for the two quality measure sets within the APP: the APP quality measure set and the APP Plus quality measure set.

• We proposed to revise § 425.512(b)(1) to update a renumbered cross reference.

• We proposed to revise the heading for § 425.512(b)(2) by removing the phrase ''and subsequent performance years.''

• We proposed to renumber the current paragraph (b)(3) of § 425.512 to paragraph (b)(4) and revise the cross references therein to reflect this renumbering.

• We proposed to add a new paragraph (b)(3) to § 425.512 to establish for performance year 2025 and subsequent performance years that for an ACO that reports all of the eCQMs/Medicare CQMs in the APP Plus quality measure set, meeting the data completeness requirement for all of the eCQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points. The sum of these values may not exceed 100 percent.

• We proposed to renumber the current paragraph (b)(4) of § 425.512 to paragraph (b)(5) and revise the cross references therein to reflect this renumbering.

• We proposed to revise renumbered § 415.512(b)(5)(iv) to add reference to new paragraph (c)(3)(iv).

• We proposed to revise § 425.512(c)(3) introductory text by removing the phrase ''via the APP'' and adding in its place the phrase ''on the APP quality measure set or APP Plus quality measure set (as applicable)''.

• We proposed to revise § 425.512(c)(3)(iii) by removing the phrase ''and subsequent performance years'' after ''For performance year 2024''.

• We proposed to add new paragraph (c)(3)(iv) to § 425.512 to establish for performance year 2025 and subsequent performance years, if CMS determines the ACO meets the requirements of the Extreme and Uncontrollable Circumstances policy and the ACO reports the APP Plus quality measure set, meets the data completeness requirement, and receives a MIPS Quality performance category score, CMS will calculate the ACO's quality score as the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

After consideration of public comments received and for reasons discussed elsewhere in this final rule, we are finalizing our proposed regulation text changes as follows:

• We are finalizing as proposed to sunset the requirement that ACOs must submit quality data via the APP to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program, and to revise § 425.508(b) to indicate that the requirement will be applicable for performance years beginning in 2021–2024. We are also finalizing to replace the phrase ''Alternative Payment Model Performance Pathway (APP)'' with the phrase ''APM Performance Pathway (APP)'' to conform with the phrase used at § 414.1367.

• We are finalizing as proposed to add a new paragraph (c) at § 425.508 to establish that, for performance years beginning on or after January 1, 2025, ACOs must submit quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

• We are finalizing as proposed to revise the section heading at § 425.510 to ''Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.''

• We are finalizing as proposed to sunset the requirement that ACOs must report quality data on the APP quality measure set according to the method of submission established by CMS and to revise § 425.510(b). We added a new paragraph (b)(1) at § 425.510 to indicate that the requirement will be applicable for performance years beginning in 2021 through 2024.

• We are finalizing as proposed to add a new paragraph (b)(2) at § 425.510 to establish that, for performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367, according to the submission method established by CMS.

• We are finalizing with modifications revisions to § 425.512(a)(2)(iii) to establish that, for performance years 2025 and 2026, an ACO in the first performance year of the ACO's first agreement period under the Shared Savings Program will meet the quality performance standard if the ACO reports the APP Plus quality measure set and meets the data completeness requirement on all eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)),

and receives a MIPS Quality performance category score for the applicable performance year.

• Due to the modifications to § 425.512(a)(2)(iii) above, we are also finalizing to add a new paragraph (iv) at § 425.512(a)(2) to establish that, for performance years 2027 and subsequent performance years, an ACO in the first performance year of the ACO's first agreement period under the Shared Savings Program will meet the quality performance standard if the ACO reports the APP Plus quality measure set and meets the data completeness requirement on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), and receives a MIPS Quality performance category score for the applicable performance year.

• We are finalizing as proposed to revise the introductory paragraph (a)(5)(i) to § 425.512 to read as follows: ''Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:''.

• We finalizing as proposed to revise the introductory paragraph (a)(5)(i)(A) to read as follows: ''For performance year 2024, the ACO reporting quality data on the APP quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—''.

• We are finalizing with modifications revisions to the introductory paragraph (a)(5)(i)(B) to read as follows: ''For performance years 2025 and 2026, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—''.

• Due to the modifications to § 425.512(a)(5)(i)(B) above, we are adding new paragraph (a)(5)(i)(C) to § 425.512 to read as follows: ''For performance year 2027 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—''.

• We are also finalizing to add new paragraphs (a)(5)(i)(C)(*1*) and (a)(5)(i)(C)(*2*) to indicate that an ACO will meet quality performance standard for performance year 2027 and subsequent years if it (1) achieves a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring or (2) reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 of this subchapter for all eCQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

• We are finalizing as proposed to add a new paragraph (a)(5)(ii)(A) to § 425.512 to indicate that an ACO will meet the alternative quality performance standard for performance year 2024 if the ACO reports quality data on the APP quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.

• We are finalizing as proposed to add a new paragraph (a)(5)(ii)(B) to § 425.512 to establish that an ACO will meet the alternative quality performance standard for performance year 2025 and subsequent years if the ACO reports the quality data on the APP Plus quality measure set established under § 414.1367 according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set.

• We are finalizing with modification revisions to § 425.512(a)(5)(iii)(B) to indicate that for performance years 2025 and 2026, an ACO will not meet the quality performance standard or the alternative quality performance standard if the ACO does not report any of the eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)).

• Due to the modifications to § 425.512(a)(5)(iii)(B) above, we are also finalizing to add a new paragraph (a)(5)(iii)(C) to § 425.512 to indicate that for performance year 2027 and subsequent performance years, an ACO will not meet the quality performance standard or the alternative quality performance standard if the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

• We are finalizing to add a descriptive heading (''Facility-based scoring'') to § 425.512(a)(7) to more accurately describe the policy at paragraph (a)(7). This change was proposed in the revised and republished regulation text (see 89 FR 62223) but not noted in the preamble of the CY 2025 PFS proposed rule. We are finalizing the heading to read as follows: ''*Shared Savings Program Scoring Policy for Excluded APP Measures and APP Measures That Lack a Benchmark*.''

• We are finalizing with minor wording modifications revisions to § 425.512(a)(7) introductory text. We are also finalizing as proposed to revise (a)(7)(i) and to add new paragraphs (a)(7)(i)(A) and (B) to indicate for performance year 2024, we will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score when an ACO reports all of the required measures, meeting the data completeness requirement for each measure in the APP quality measure set and receiving a MIPS Quality performance category score and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score is reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We are finalizing with minor wording modifications to revise § 425.512(a)(7)(ii) and add new paragraphs (a)(7)(ii)(A) and (B) to indicate for performance year 2025 and subsequent performance years, an ACO will receive the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score when an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score, and the ACO meets either of the following:

++ The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score is reduced under § 414.1380(b)(1)(vii)(A).

++ At least one of the required measures in the APP Plus quality measure set does not have a benchmark as described at § 414.1380(b)(1)(i)(A).

• We are finalizing as proposed to revise § 425.512(b)(1) and (2) and (b)(4)(i) by removing the phrase ''APP measure set'' and replacing with the phrase ''APP quality measure set'' to align naming conventions for the two quality measure sets within the APP: the APP quality measure set and the APP Plus quality measure set.

• We are finalizing as proposed revisions to § 425.512(b)(1) to update a renumbered cross reference.

• We are finalizing as proposed to revise the heading for § 425.512(b)(2) by removing the phrase ''and subsequent performance years.''

• We are finalizing as proposed to renumber the current paragraph (b)(3) of § 425.512 to paragraph (b)(4) and to revise the cross references therein to reflect this renumbering.

• In the CY 2025 PFS proposed rule, we inadvertently omitted to propose a technical revision to § 425.512(b)(4)(i), which currently states, ''For each measure *in the APP quality measure set,* CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism'' (emphasis added). The revision would align the text of this section with our adoption of the APP Plus quality measure set for performance year 2025 and subsequent performance years. We are finalizing a revision to paragraph (b)(4)(i) to indicate that for each measure that an ACO is required to report for the applicable performance year, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

• We are finalizing with modifications to add a new paragraph (b)(3) to § 425.512 to establish for performance year 2025 and subsequent performance years that for an ACO that reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement for all of the required measures in the APP Plus quality measure set, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B)), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points. The sum of these values may not exceed 100 percent.

• We are finalizing as proposed to renumber the current paragraph (b)(4) of § 425.512 to paragraph (b)(5) and to revise the cross references therein to reflect this renumbering.

• We are finalizing as proposed to revise the renumbered § 415.512(b)(5)(iv) to add reference to new paragraph (c)(3)(iv).

• We are finalizing to add descriptive headings to redesignated paragraphs § 425.512(b)(4) and (b)(5). These changes were proposed in the revised and republished regulation text (see 89 FR 62222 through 62224) but not noted in the preamble of the CY 2025 PFS proposed rule.

• We are finalizing as proposed to revise § 425.512(c)(3) introductory text by removing the phrase ''via the APP'' and adding in its place the phrase ''on the APP quality measure set or APP Plus quality measure set (as applicable)''.

• We are finalizing as proposed to revise § 425.512(c)(3)(iii) by removing the phrase ''and subsequent performance years'' after ''For performance year 2024''.

• We are finalizing as proposed to add new paragraph (c)(3)(iv) to § 425.512 to establish for performance year 2025 and subsequent performance years, if CMS determines the ACO meets the requirements of the Extreme and Uncontrollable Circumstances policy and the ACO reports the APP Plus quality measure set, meets the data completeness requirement, and receives a MIPS Quality performance category score, we will calculate the ACO's quality score as the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

c. Changes to the Methodology for Calculating the MIPS Quality Performance Category Score for Shared Savings Program ACOs Reporting the APP Plus Quality Measure Set

(1) Background

Consistent with the authority to establish the quality reporting and other reporting requirements for the Medicare Shared Savings Program set forth in section 1899(b)(3) of the Act and the statutory requirements for the Quality Payment Program set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs, since the Shared Savings Program's alignment with the APP in performance year 2021, MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM—including ACOs that participate in the Medicare Shared Savings Program—that report data via the APP have been scored according to the APP scoring methodology described at § 414.1367. The MIPS Quality performance category score is calculated according to the APP scoring methodology at § 414.1367(c)(1) (85 FR 84864). Under the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs and at section 1899(f) of the Act for the Medicare Shared Savings Program, the Cost performance category weight is zero percent as described at § 414.1367(c)(2) (85 FR 84864) for MIPS eligible clinicians that report via the APP. As noted in section 1848(q)(5)(C)(ii) of the Act, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of one half of the highest potential score for the MIPS Improvement activities category for their participation in an APM for the performance period. These baseline scores are automatically applied to the MIPS Improvement activities performance category score for MIPS eligible clinician in an APM—including ACOs that participate in the Medicare Shared Savings Program—that report via the APP as described at § 414.1367(c)(3) (85 FR 84865). The Promoting Interoperability performance category under the APP is reported and calculated in the same manner described at § 414.1375 (85 FR 84865).

As described in the CY 2021 PFS final rule, we waived the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act using the waiver authority in section 1899(f) of the Act for Medicare Shared Savings Program for MIPS eligible clinicians that report via the APP—including ACOs that participate in the Medicare Shared Savings Program (85 FR 84865). The performance category weights used to calculate the final score for a MIPS eligible clinician who is scored through the APP at § 414.1367(d)(1) are:

- *Quality:* 50 percent.
- *Cost:* 0 percent.
- *Improvement Activities:* 20 percent.
- *Promoting Interoperability:* 30 percent.

Additionally, in the CY 2021 PFS final rule, we also stated that under the authority provided in section 1848(q)(5)(F) of the Act, it may become necessary to reweight one or more performance categories (85 FR 84866). As described at § 414.1367(d)(2), if CMS determines, in accordance with

§ 414.1380(c)(2), that a different scoring weight should be assigned to the Quality or Promoting Interoperability performance category, CMS will redistribute the performance category weights as follows:

- *If CMS reweights the Quality performance category to 0 percent:* Promoting Interoperability performance category is reweighted to 75 percent, and Improvement activities performance category is reweighted to 25 percent.
- *If CMS reweights the Promoting Interoperability performance category to 0 percent:* Quality performance category is reweighted to 75 percent, and Improvement activities performance category is reweighted to 25 percent.

Lastly, as codified at § 414.1367(e), final scoring for APM participants reporting to MIPS through the APP—including ACOs that participate in the Medicare Shared Savings Program—would follow the same methodology as established for MIPS generally at § 414.1380 (85 FR 84866).

In performance year 2024, ACOs are scored on either the three eCQMs/MIPS CQMs/Medicare CQMs or the ten CMS Web Interface measures, the CAHPS for MIPS survey, and two administrative claims-based measures. Under this methodology, an ACO's MIPS Quality performance category score is calculated according to MIPS scoring rules for the Quality performance category established at § 414.1380(b)(1) with exceptions for (1) measures that do not have a benchmark or do not meet the case minimum requirement and (2) measures that are identified as topped out. Specifically, each submitted measure that does not have a benchmark or does not meet the case minimum requirement is excluded from an ACO's total measure achievement points (numerator) and total available measure achievement points (denominator). Additionally, any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv). Under current APP scoring rules, each required measure of the APP quality measure set that is not submitted by an ACO via the APP receives zero measure achievement points.

(2) Revisions

(a) Establishing the Data Submission Criteria for the APP Plus Quality Measure Set

As discussed in section IV.A.4.e.(1)(b)(i) of the CY 2025 PFS proposed rule, for the APP Plus quality measure set, we proposed that Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all measures in the APP Plus quality measure set, as applicable (89 FR 61859). Specifically, in § 414.1335(b), we proposed to establish the data submission criteria for the APP Plus quality measure set, which would require the reporting of all measures within the APP Plus quality measure set, except for administrative claims-based quality measures.[537]

The MIPS Quality performance category score is calculated according to the APP scoring methodology at § 414.1367(c)(1) (85 FR 84864 through 85 FR 84865). As such, an ACO's MIPS Quality performance category score is calculated according to MIPS scoring rules for the Quality performance category established at § 414.1380(b)(1) with exceptions for (1) measures that do not have a benchmark or do not meet the case minimum requirement and (2) measures that are identified as topped out. Consistent with our proposal described above, under § 414.1380(b)(1), for performance year 2025 and subsequent performance years, ACOs would be scored on all required measures in the APP Plus quality measure set.

In the CY 2025 PFS proposed rule, we proposed that the policies related to MIPS performance category scoring in the APP at § 414.1367(c) would apply to Shared Savings Program ACOs that report the APP Plus quality measure set for the purpose of meeting the Shared Savings Program's quality performance standard (89 FR 61859).[538] Specifically, we proposed that the APP scoring policies at § 414.1367(c)(1) for the calculation of the ACO's MIPS Quality performance category, § 414.1367(c)(2) for the calculation of an ACO's MIPS Cost performance category, § 414.1367(c)(3) for the calculation of an ACO's MIPS Improvement activities performance category, and § 414.1367(c)(4) for the calculation of an ACO's MIPS Promoting Interoperability performance category would apply to ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years (89 FR 61859). Additionally, we proposed that the performance category weights described in § 414.1367(d) and methodology used to calculate the final score described in § 414.1367(e) would apply to Shared Savings Program ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years (89 FR 61859).

In the CY 2025 PFS proposed rule (89 FR 61859), we stated that if our proposals are finalized, then in performance year 2025, ACOs would be scored on the required eight measures in the APP Plus quality measure set: five eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. In performance years 2026 and 2027, ACOs would be scored on the required nine measures: six eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. In performance year 2028 and subsequent performance years, ACOs would be scored on the required eleven measures: eight eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. We referred readers to Tables 34, 35, and 36 in the CY 2025 PFS proposed rule for additional detail on the required measures in each performance year. We also referred readers to section IV.A.4.e.(1)(b)(i) of the CY 2025 PFS proposed rule for a discussion of our proposal to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the APP Plus quality measure set.

We solicited comments on this proposal. The following is a summary of the public comments we received on this proposal and our responses. Many of the commenters expressing concern with our proposal shared those concerns in the context of our proposal to require Shared Savings Program ACOs to report the APP Plus measure set. To the extent that those comments overlap with regard to the burden associated with APP Plus quality measure set, those comments and our responses are captured in section III.G.4.b(2)(a) of this final rule.

Comment: We received one comment in support of our proposals related to MIPS performance category scoring in the APP that would apply to Shared Savings Program ACOs that report the APP Plus quality measure set for the purpose of meeting the Shared Savings Program's quality performance standard. However, this commenter and others expressed reservations about the

[537] As described at § 414.1325(a)(2)(i), there are no data submission requirements for administrative claims-based quality measures as performance on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

[538] This discussion describes standards under the APP, which are applicable to APM Entities. We refer throughout to ACOs in lieu of APM Entities as we are discussing the application of APP standards to ACOs participating in the Shared Savings Program, and thus ACOs are the sole relevant type of APM Entity.

proposal to require Shared Savings Program ACOs to report all measures in the APP Plus measure set for purposes of meeting the quality reporting standard.

Response: We thank the commenter for supporting our proposal. As discussed in section IV.A.4.e.(1)(b)(i) of this final rule, we are finalizing as proposed that, for the APP Plus quality measure set, Shared Savings Program ACOs that report the APP Plus quality measure set and MIPS eligible clinicians, groups, and APM Entities that choose to report the APP Plus quality measure set, will be required to report on all measures in the APP Plus quality measure set, as applicable. Specifically, in § 414.1335(b), we are finalizing to establish the data submission criteria for the APP Plus quality measure set, which would require the reporting of all measures within the APP Plus quality measure set, except for administrative claims-based quality measures. Under § 414.1380(b)(1), for performance year 2025 and subsequent performance years, ACOs would be scored on all required measures in the APP Plus quality measure set.

We refer readers to section IV.A.4.e.(1)(b)(i) of this final rule for a discussion of our final policy to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the APP Plus quality measure set. We are finalizing as proposed that the policies related to MIPS performance category scoring in the APP at § 414.1367(c) will apply to Shared Savings Program ACOs that report the APP Plus quality measure set for the purpose of meeting the Shared Savings Program's quality performance standard. Specifically, we are finalizing that the APP scoring policies at § 414.1367(c)(1) for the calculation of the ACO's MIPS Quality performance category, § 414.1367(c)(2) for the calculation of an ACO's MIPS Cost performance category, § 414.1367(c)(3) for the calculation of an ACO's MIPS Improvement activities performance category, and § 414.1367(c)(4) for the calculation of an ACO's MIPS Promoting Interoperability performance category will apply to ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years. Additionally, we are finalizing that § 414.1367(d) for the performance category weights and § 414.1367(e) for the calculation of the final score will apply to Shared Savings Program ACOs that report the APP Plus quality measure set in performance year 2025 and subsequent performance years.

Based on the policies finalized in section III.G.4.b.(2)(b) of this final rule, in performance year 2025, ACOs will be scored on the required six measures in the APP Plus quality measure set: four eCQMs/MIPS CQMs/Medicare CQMs, the CAHPS for MIPS survey, and one administrative claims-based measure. In performance year 2026, ACOs will be scored on the required eight measures: five eCQMs/MIPS CQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. In performance year 2027, ACOs will be scored on the required nine measures: six eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. Beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for Quality ID: 487 Screening for Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later, ACOs will be scored on the required eleven measures: eight eCQMs/Medicare CQMs, the CAHPS for MIPS survey, and two administrative claims-based measures. For Quality ID: 487 Screening for Social Drivers of Health or Quality ID: 493 Adult Immunization Status to be incorporated into the APP Plus quality measure set in performance year 2028, the eCQM specification for the measure must be published on the eCQI resource center by May 2027, and the measure would be required to be reported by ACOs in early 2029. We refer readers to Tables 38, 39, 40, and 41 in section III.G.4.f of this final rule for additional detail on the required measures in each performance year.

(b) Establishing a Complex Organization Adjustment for Virtual Groups and APM Entities

To account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs, in section IV.A.4.f.(1)(b)(iii) of the CY 2025 PFS proposed rule, we proposed to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year (89 FR 61859). A Virtual Group and an APM Entity would receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Each reported eCQM may not score more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each measure submitted at the individual measure level.

Since Shared Savings Program ACOs are APM Entities, this proposal would be applicable to Shared Savings Program ACOs reporting the APP Plus quality measure set beginning in performance year 2025. We refer readers to section IV.A.4.f.(1)(b)(iii) of the CY 2025 PFS proposed rule for discussion of our proposal to establish the Complex Organization Adjustment for Virtual Groups and APM Entities (89 FR 62080 through 62083). Under our proposal as described in section III.G.4.f of the CY 2025 PFS proposed rule, the APP Plus quality measure set for Shared Savings Program ACOs would include eight measures (five eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance year 2025 (Table 34); nine measures (six eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2026 and 2027 (Table 35); and eleven measures (eight eCQMs/Medicare CQMs, two administrative claims measures, and the CAHPS for MIPS Survey measure) in performance years 2028 and subsequent performance years (Table 36).

We solicited public comment on the proposal to implement a Complex Organization Adjustment for Virtual Groups and APM Entities, including ACOs in the Shared Savings Program. We refer readers to section IV.A.4.f.(1)(b)(iii) of this final rule for summaries of the comments and our responses.

As discussed in section IV.A.4.f.(1)(b)(iii) of this final rule, we are finalizing as proposed our proposal to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS payment year to account for the organizational complexities faced by Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs. A Virtual Group and an APM Entity will receive one measure achievement point for each submitted eCQM that meets the case minimum requirement at § 414.1380(b)(1)(iii) and the data completeness requirement at § 414.1340. Each reported eCQM may not score

more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment will be added for each measure submitted at the individual measure level. Since Shared Savings Program ACOs are APM Entities, this policy will be applicable to Shared Savings Program ACOs reporting the APP Plus quality measure set beginning in performance year 2025. We refer readers to section IV.A.4.f.(1)(b)(iii) of this final rule for discussion of our policy to establish the Complex Organization Adjustment for Virtual Groups and APM Entities.

As the Adult Universal Foundation measures are phased into the APP Plus quality measure set, ACOs that participate in the Shared Savings Program will be required to report on a larger measure set relative to other eCQM reporters. Under our policy finalized in section III.G.4.f of this final rule, the APP Plus quality measure set for Shared Savings Program ACOs will include six measures (four eCQMs/MIPS CQMs/Medicare CQMs, one administrative claims-based measure, and the CAHPS for MIPS Survey measure) in performance year 2025 (Table 39); eight measures (five eCQMs/MIPS CQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) in performance years 2026 (Table 40); nine measures (six eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) in performance years 2027 (Table 41); and eleven measures (eight eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for Quality ID: 487 Screening for Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later (Table 42).

(c) Scoring Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

In the CY 2024 PFS final rule, we finalized our proposal to establish new benchmarks for scoring ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies (88 FR 79110). As historical Medicare CQM data would not be available, we finalized that for performance years 2024 and 2025, we will score Medicare CQMs using performance period benchmarks. We also finalized that, for performance year 2026 and subsequent performance years, when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we will score Medicare CQMs using historical benchmarks.

A few commenters noted in our proposal in the CY 2024 PFS proposed rule (88 FR 79109 through 79110) their concern about ACOs being compared only to other ACOs that report Medicare CQMs since the Medicare CQMs would be available only to Shared Savings Program ACOs. One commenter stated their preference to have their quality performance compared to all other participants on these measures, while another commenter stated that CMS should stop measuring ACOs against each other and instead measure ACOs on a national standard so that all ACOs can pass and do not lose out on savings due to arbitrary quality decile cut points. In our response to these comments, we stated that given that benchmarks are specific to each collection type and that we proposed to establish Medicare CQMs as a new collection type for only Shared Savings Program ACOs, only ACO data will be available to benchmark Medicare CQMs. Additionally, the health equity adjustment would be applicable to Medicare CQMs for purposes of determining shared savings payments/losses. The application of the health equity adjustment would help improve performance when ACOs deliver high quality care to underserved patient populations. For these reasons, we stated in the CY 2025 PFS proposed rule that it is appropriate to establish benchmarks for Medicare CQMs that are consistent with MIPS benchmarking policies (89 FR 61860). ACOs that prefer to be compared to clinicians at large may do so by reporting eCQMs or MIPS CQMs, for which CMS calculates a benchmark using data reported by MIPS eligible clinicians reporting under the chosen collection type.

In performance year 2022, ACOs had a higher average performance on quality measures they were required to report in order to share in savings compared to other similarly sized clinician groups not in the Shared Savings Program.[539] This includes statistically significant higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer screening; tobacco screening and smoking cessation; and depression screening and follow-up.[540] In shifting to Medicare CQMs, ACO performance would be benchmarked against other ACOs only reporting Medicare CQMs. Since ACOs are high performers relative to comparably sized MIPS groups, benchmarking Medicare CQMs using only ACO data would lower some ACOs' MIPS measure achievement points on those measures. In other words, high-performing ACOs could earn lower measure achievement points relative to comparable MIPS groups because the Medicare CQM benchmarking pool is comprised of higher-than-average performance data–in effect, creating a ''tournament approach'' to scoring Medicare CQMs wherein ACOs must compete with other ACOs to earn measure achievement points. As we stated in the CY 2025 PFS proposed rule, this could be particularly disadvantageous for ACOs that serve a high proportion of underserved populations because, while ACOs that report eCQMs and/or Medicare CQMs and serve a high proportion of underserved populations are eligible for health equity adjustment points, ACOs must score in the top or middle thirds of ACO measure performers to earn health equity adjustment points (89 FR 61860).

As described in section III.G.4.b.(2)(b) of the CY 2025 PFS proposed rule, for performance year 2025 and subsequent performance years, we proposed to streamline the collection types available for Shared Savings Program ACOs reporting the APP Plus quality measure set to the eCQM and Medicare CQM collection types (89 FR 61860). Therefore, as discussed in section IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule, we proposed to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS (89 FR 61860). Our proposal in section IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule would expand the use of flat benchmarks to Medicare CQMs in

[539] Centers for Medicare & Medicaid Services (2023). *Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care. [Press release]. https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-18-billion-2022-and-continues-deliver-high.*

[540] *Id.*

their first two performance periods in MIPS (89 FR 61860). The use of flat benchmarks would allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that ACOs with high quality performance on a measure are not penalized as low performers. As discussed in section IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule, we proposed to add § 414.1380(b)(1)(ii)(F) to incorporate this proposal (89 FR 61860). The use of historical benchmarks, when data are available, is consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii), allow ACOs to know benchmarks prior to start of the performance year, and create opportunities for improvement.

Table 30 in the CY 2025 PFS proposed rule (89 FR 61861), which is the same as the following Table 33, lists the Medicare CQMs in the APP Plus quality measure set that would be eligible for flat benchmarks in performance year 2025 through performance year 2029 under our proposal.

TABLE 33: Proposed Medicare CQMs Eligible for Flat Benchmarks in Performance Year 2025 through 2029

Performance Year	Quality #
2025	001, 134, 236, 112, 113
2026	112, 113, 305
2027	305
2028	487, 493
2029	487, 493

As discussed in the CY 2025 PFS proposed rule, a quality performance benchmark is the performance rate an ACO must achieve to earn the corresponding quality points for each measure (89 FR 61861). Flat benchmarks assign a performance rate range to each decile. In flat benchmarks for non-inverse measures, any performance rate at or above 90 percent would be in the top decile; any performance rate between 80 percent and 89.99 percent would be in the second highest decile, and so on. For inverse measures, this would be reversed—any performance rate at or below 10 percent would be in the top decile; any performance rate between 10.01 percent and 20 percent would be in the second highest decile, and so on. The number of measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

For non-inverse measures, better quality performance is indicated by a higher performance rate. For example, Quality #: 001 Controlling High Blood Pressure is a non-inverse measure that measures the percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period. Better quality performance on this measure is demonstrated by having a higher percentage of patients whose blood pressure was adequately controlled. Table 31 in the CY 2025 PFS proposed rule (89 FR 61861), which is the same as the following Table 34, lists the flat benchmarks for a non-inverse Medicare CQM under our proposal described in section IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule.

TABLE 34: Flat Benchmarks for a Non-Inverse Medicare CQM in its First Two Performance Periods in MIPS in Performance Year 2025 and Subsequent Years

Decile	Performance Rate Range
1	< 10.00
2	10.00 – 19.99
3	20.00 – 29.99
4	30.00 – 39.99
5	40.00 – 49.99
6	50.00 – 59.99
7	60.00 – 69.99
8	70.00 – 79.99
9	80.00 – 89.99
10	>= 90.00

For example, if an ACO reports a non-inverse Medicare CQM in its first two performance periods in MIPS in performance year 2025 and earns a performance rate of 55.25 percent, then the ACO would score in the 6th decile on that measure.

For inverse measures, better quality performance is indicated by a lower performance rate. This is reflected in flat benchmark such that lower quality performance rates are found in higher deciles. For example, Quality #: 001

Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) is an inverse quality measure that measures the percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c >9.0 percent during the measurement period. Better quality performance on this measure is demonstrated by having a lower percentage of patients whose HbA1c was >9.0 percent. Table 32 in the CY 2025 PFS proposed rule (89 FR 61862), which is the same as the following Table 35, lists the flat benchmarks for an inverse Medicare CQM under our proposal described in section IV.A.4.f.(1)(c)(i) of the CY 2025 PFS proposed rule.

TABLE 35: Flat Benchmarks for an Inverse Medicare CQM in its First Two Performance Periods in MIPS in Performance Year 2025 and Subsequent Years

Decile	Performance Rate Range
1	99.00 – 90.01
2	90.00 – 80.01
3	80.00 – 70.01
4	70.00 – 60.01
5	60.00 – 50.01
6	50.00 – 40.01
7	40.00 – 30.01
8	30.00 – 20.01
9	20.00 – 10.01
10	<= 10.00

For example, if an ACO reports an inverse Medicare CQM in its first two performance periods in MIPS in performance year 2025 and earns a performance rate of 12.25 percent, then the ACO would score in the 9th decile on that measure. In performance year 2025, Quality #: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) is the only inverse Medicare CQM.

There are scoring scenarios in which ACOs would earn higher measure achievement points under flat benchmarks compared to those they would earn under performance period benchmarks. Most notable are scenarios in which ACOs have a tight distribution of performance rates on a measure. For example, a non-inverse measure for which a performance rate of 90.00 percent is in the 8th decile. In this example, an ACO that reported a performance rate of 90.00 percent would be scored in the 8th decile when the hypothetical performance period benchmark is applied. Using the flat benchmarks described in Table 34 of this final rule, an ACO that reported a performance rate of 90.00 percent would be scored in the 10th decile, resulting in greater measure achievement points than under the hypothetical performance period benchmarks described in this example. For more details on the calculation of measure achievement points, we refer readers to the ''APM Performance Pathway (APP) Toolkit'' which is updated for each performance year and posted in the QPP Resource Library.

We solicited comment on our proposal to score ACOs reporting Medicare CQMs using flat benchmarks in their first two performance periods in MIPS. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to score ACOs reporting Medicare CQMs using flat benchmarks. Commenters noted that flat benchmarks will make Medicare CQM scoring more predictable and is fair. One commenter noted that flat benchmarks would allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Another commenter stated that flat benchmarks would avoid ''tournament'' approach that is typically found in a group of high performers and allow the opportunity for improvements without penalizing high performers.

One commenter supported flat benchmarking for the first two performance years for Medicare CQMs and stated that it will be a difficult transition for ACOs to progress from the CMS Web Interface attestation method to CQM/eCQM reporting and sees that Medicare CQM flat benchmarking will remove uncertainty from ACO attestation to Medicare CQMs as they will no longer have to rely on benchmarking based upon the performance year.

Response: We thank commenters for their support of our proposal. As discussed in section IV.A.4.f.(1)(c)(i) of this final rule, we are finalizing our proposal with modification to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS. As we stated in the CY 2025 PFS proposed rule (89 FR 61860), the use of flat benchmarks would allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years and would also help to ensure that ACOs with high quality performance on a measure are not penalized as low performers.

Comment: One commenter appreciated the proposal to refine Medicare CQMs away from the retrospective curve, but expressed concern that the proposed benchmarks are still too high. The commenter stated that the proposed percentiles would still result in many ACOs falling below the 40th percentile and losing savings when in the accurate sample methodology, they would have succeeded. The commenter recommended that CMS create an adjustment factor to the percentiles based on the experienced drop in eCQMs, MIPS CQMs, and Medicare CQMs reported in 2023 and

2024 compared to Web Interface reporting. The commenter also stated that their testing shows a drop in accuracy for Medicare CQMs that will cost ACOs millions of dollars in shared savings and noted that while they appreciate CMS' proposals in this area, CMS should adjust benchmarks to account for the observed drop in accuracy.

Response: We thank the commenter for their feedback. As described in our proposal, there are scoring scenarios in which ACOs would earn higher measure achievement points under flat benchmarks compared to those they would earn under performance period benchmarks (89 FR 61862). Most notable are scenarios in which ACOs have a tight distribution of performance rates on a measure. For example, a non-inverse measure for which a performance rate of 90.00 percent is in the 8th decile. In this example, an ACO that reported a performance rate of 90.00 percent would be scored in the 8th decile when the hypothetical performance period benchmark is applied. Using the flat benchmarks described in Table 34 of this final rule, an ACO that reported a performance rate of 90.00 percent would be scored in the 10th decile, resulting in greater measure achievement points than under the hypothetical performance period benchmarks described in this example, which would have resulted in a score in the 8th decile.

In response to the commenter's suggestion that CMS create an adjustment factor to the percentiles based on the experienced drop in eCQMs, MIPS CQMs, and Medicare CQMs reported in 2023 and 2024 compared to CMS Web Interface reporting, we note that section 1899(b)(3)(C) of the Act directs that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. Applying an adjustment factor to downwardly adjust benchmarks across collection types is not consistent with our intent to improve quality of care furnished by ACOs over time. Additionally, consistent with the goal of supporting ACOs in their transition to all payer/all patient eCQMs/MIPS CQMs, in the CY 2024 PFS final rule, we finalized that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when calculating shared savings payments (88 FR 79110). The health equity adjustment upwardly adjusts the MIPS quality performance score for ACOs that report eCQMs/MIPS CQMs/Medicare CQMs, are high performing on quality, and serve a higher proportion of underserved beneficiaries.

Comment: Many commenters recommended that flat benchmarks for Medicare CQM be made permanent rather than for two years because ACOs are high performers compared to non-ACO MIPS clinicians and only comparing ACOs against each other will make benchmarks very high and more difficult to achieve. One commenter recommended that CMS consider extending the flat benchmark scoring policies for Medicare CQMs beyond each measure's first two performance periods.

Response: In response to comments that flat benchmarks be applied to Medicare CQMs permanently or beyond the first two performance periods, we believe that the baseline period data, which will be available to establish historical benchmarks is consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii). As we stated in the CY 2025 PFS proposed rule (89 FR 61860), the use of historical benchmarks, when data are available, allow ACOs to know benchmarks prior to start of the performance year and create opportunities for improvement. Also, as discussed in the CY 2024 PFS final rule, since Medicare CQMs would be subject to MIPS scoring policies, the application of MIPS benchmarking policies to Medicare CQMs is both logical and necessary for implementation of the new collection type (88 FR 79180).

Comment: Several commenters requested clarification on whether flat benchmarks will apply to Medicare CQMs retroactively for the 2024 performance year. Some commenters recommended that CMS retroactively apply this policy for the 2024 performance period. Another commenter recommended the use of flat benchmarks for performance years 2024 and 2025 since historical Medicare CQM data will not be available until 2026.

Response: We did not propose to retroactively apply flat benchmarks to Medicare CQMs in performance year 2024. Shared Savings Program ACOs will have the option to report quality data via the APP using the CMS Web Interface or eCQM/MIPS CQM/Medicare CQM collection types in performance year 2024. The option to report using one or more of four collection types in performance year 2024 will allow ACOs to select the submission method that is most appropriate and advantageous for their situation and technological capabilities. For performance year 2024, we will score Medicare CQMs using performance period benchmarks as finalized in the CY 2024 PFS final rule (88 FR 79110).

We note in section III.G.4.b.(2)(b) of this final rule that, after considering public comments, we are finalizing with modification our proposal to not include the MIPS CQM collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set. Specifically, we are finalizing the inclusion of MIPS CQM collection type for ACOs reporting the APP Plus quality measure set for performance years 2025 and 2026. The MIPS collection type will not be available for ACOs reporting the APP Plus quality measure set beginning in performance year 2027. We recognize flat benchmarks may provide more assurance to ACOs than the extension of the MIPS CQMs and as such, after considering public comments, we are finalizing in section IV.A.4.f.(1)(c)(i) of this final rule that, beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type will be scored using flat benchmarks for their first two performance periods in MIPS.

Comment: Many commenters recommended that CMS release performance data on Medicare CQMs publicly for ACOs to better understand performance.

Response: The Shared Savings Program releases performance year ACO-level financial and quality performance data annually on *https://data.cms.gov.* We anticipate updating the public use files with Medicare CQM performance data when the data are available.

After consideration of public comments and as discussed in section IV.A.4.f.(1)(c)(i) of this final rule, we are finalizing as proposed to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS.

Table 36 lists the Medicare CQMs in the APP Plus quality measure set that will be eligible for flat benchmarks beginning in performance year 2025 through performance year 2028, or the performance year that is one year after the eCQM specifications become available for Quality #: 487 Screening for Social Drivers of Health and Quality #: 493 Adult Immunization Status, whichever is later, under the policies being finalized in this final rule.

Medicare CQM versions of Quality #: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), Quality #: 134 Preventive Care and Screening: Screening for Depression and Follow-up Plan, and Quality #: 236 Controlling High Blood Pressure will be scored using a flat benchmark in performance years 2025. Medicare CQM version of Quality #: 112 Breast Cancer Screening will be scored using a flat benchmark in performance years 2025 and 2026. Medicare CQM version of Quality #: 113 Colorectal Cancer Screening will be scored using a flat benchmark in performance years 2026 and 2027. Medicare CQM version of Quality #: 305 Initiation and Engagement of Substance Use Disorder Treatment will be scored using a flat benchmark in performance years 2027 and 2028. Quality #: 487 Screening for Social Drivers of Health and Quality #: 493 Adult Immunization Status will be eligible for flat benchmarks for two years beginning with performance year 2028 or the performance year that is one year after the eCQM specifications become available for these measures, whichever is later.

TABLE 36: Medicare CQMs Eligible for Flat Benchmarks in Performance Years 2025 through 2028

Performance Year	Quality #
2025	001, 134, 236, 112
2026	112, 113
2027	113, 305
2028	305, 487*, 493*

*Quality #: 487 Screening for Social Drivers of Health and Quality #: 493 Adult Immunization Status will be eligible for flat benchmarks for 2 years beginning with performance year 2028 or the performance year that is 1 year after the eCQM specifications become available for these measures, whichever is later.

We are also finalizing as proposed (1) the flat benchmarks, as listed in Table 31 of the CY 2025 PFS proposed rule (89 FR 61861) and Table 34 of this final rule, for a non-inverse Medicare CQM, and (2) the flat benchmarks, as listed in Table 32 of the CY 2025 PFS proposed rule (89 FR 61862) and Table 35 of this final rule, for an inverse Medicare CQM under our final policy described in section IV.A.4.f.(1)(c)(i) of this final rule.

(3) Changes to Regulation Text

As discussed in sections III.G.4.c.(2)(a), III.G.4.c.(2)(b), and III.G.4.c.(2)(c) of the CY 2025 PFS proposed rule (89 FR 61858 through 61862), we proposed to establish scoring rules to calculate the MIPS Quality performance category score for ACOs reporting the APP Plus quality measure set for performance year 2025 and subsequent performance years. We stated that we believe that these proposed scoring rules would incentivize the reporting of eCQMs in the APP Plus quality measure set while continuing to support ACOs that report Medicare CQMs as they build the infrastructure, skills, knowledge, and expertise necessary to aggregate patient data to report digital quality measures. We are finalizing these policies as proposed. We refer readers to sections IV.A.4.e.(1)(b)(i), IV.A.4.f.(1)(b)(iii), and IV.A.4.f.(1)(c)(i) of this final rule for changes to the regulation text at 42 CFR part 414.

d. Extending the eCQM Reporting Incentive for Meeting the Shared Savings Program Quality Performance Standard

(1) Background

In the CY 2023 PFS final rule, we extended the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025 (87 FR 69836 through 69838). We originally adopted this incentive in the CY 2022 PFS final rule to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance years 2022 and 2023 (86 FR 65269). We finalized an update to the incentive for performance year 2024 such that:

- If an ACO reports the three eCQMs/MIPS CQMs, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQMs/MIPS CQMs, and:
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP measure set and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining five measures in the APP measure set, the ACO will meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable.

We received a few comments on our proposal in the CY 2023 PFS proposed rule to extend the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 suggesting that we extend the incentive beyond 2024 to facilitate the national shift towards eCQMs. In our response in the CY 2023 PFS final rule (87 FR 69836), we stated that ''We are not extending the incentive beyond performance year 2024 at this time because this policy is intended to align with the timeline for sunsetting of the CMS Web Interface reporting option at the end of performance year 2024. We will continue to monitor the impact of this policy as we gain more experience with ACOs reporting eCQMs/MIPS CQMs and may revisit the policy in future rulemaking.''

(2) Revisions

We are committed to continuing to support ACOs in the transition to the use of the all payer/all patient eCQM collection type for quality measure reporting and to digital quality measurement reporting. As described in section III.G.4.b.(2)(a) of the CY 2025 PFS proposed rule, for performance year 2025 and subsequent performance years, we proposed to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section IV.A.4.c.(3) of CY 2025 PFS proposed rule (89 FR 61862). We stated that the APP Plus quality measure set would incrementally grow to comprise

of 11 measures, consisting of six measures from the existing APP quality measure set and five additional measures from the Adult Universal Foundation measure set not already included in the existing APP quality measure set, and would be incrementally incorporated into the APP Plus quality measure between the CY 2025 performance period/2027 MIPS payment year and CY 2028 performance period/2030 MIPS payment year. We also proposed to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs (while not making available the MIPS CQM as an available collection type for Shared Savings Program ACOs under the APP Plus quality measure set) (89 FR 61863).

As discussed in the CY 2025 PFS proposed rule, the Shared Savings Program continues to hear from ACOs and other interested parties about the challenges with reporting on all payer/all patient measures and meeting data management requirements given their muti-practice/multi EHR structure, the challenges to aggregate data with the health IT infrastructure in use by ACOs and current state of interoperability (89 FR 61863). Shared Savings Program quality reporting data over the past two performance years indicate that ACOs have been slow to report eCQMs. In performance year 2021, 5 of 475 ACOs reported eCQMs under the APP. In performance year 2022, among ACOs that reported quality data under the APP, 24 out of 482 reported eCQMs with 7 of these ACOs reporting a combination of eCQMs and MIPS CQMs.[541] We encourage ACOs, especially those ACOs serving large, underserved populations, to leverage interoperability and digital data more fully and to more quickly transition to eCQMs. As such, we proposed to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years to support ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track (89 FR 61863).

Specifically, we proposed that for performance year 2025 and subsequent performance years, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

As proposed, the eCQM reporting incentive would apply only to those ACOs that report all quality measures in the APP Plus quality measure set that have eCQM collection type for an applicable performance year and meet the data completeness requirement for all such measures. Under the proposal, the reporting incentive would not apply to ACOs that report the APP Plus quality measure set using a combination of eCQMs/Medicare CQMs or report only Medicare CQMs. We stated that we would further assess the need for the eCQM reporting incentive in the future as ACOs continue the transition to adopting the eCQM collection type and may make refinements as needed in future rulemaking. We included the available collection types for each measure in the APP Plus quality measure set for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years, which are displayed in Tables 34, 35, and 36 of the CY 2025 PFS proposed rule, respectively (89 FR 61866 through 61868). We included the measure type in these tables for each measure in the APP Plus quality measure set to provide ACOs with a list of the outcome measures for purposes of identifying outcome measures that qualify for the eCQM reporting incentive.

We solicited comments on our proposal to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of our proposal to extend the eCQM reporting incentive. These commenters agreed that extending the eCQM reporting incentive will encourage Shared Savings Program ACOs to transition to using all payer/all patient MIPS CQM and eCQM collection types for quality measure reporting and to digital quality measurement reporting. One commenter stated that extending the incentive would help to mitigate some challenges related to the adoption of the MIPS CQM and eCQM collection types. Another commenter noted that it allowed for a more gradual adoption of the eCQM framework.

Response: We thank commenters for their support.

Comment: Some commenters were concerned that the reporting incentive does not fully offset the costs and challenges faced by ACOs in adopting all payer/all patient collection types. One commenter suggested that Shared Savings Program ACOs would be unable to take advantage of the reporting incentive due to infrastructure problems encountered when reporting quality measures using the eCQM collection type. One commenter was concerned that ACOs comprised of independent, resource limited provider groups practicing in nontraditional settings would not be able to take advantage of the incentive and suggested that incremental incentives for the partial reporting of eCQMs over the course of three or more years is a more realistic motivator to change quality reporting behavior.

Response: We acknowledge the commenters' concerns regarding the challenges that ACOs face in building infrastructure to meet data management and eCQM reporting requirements. Our stated intent for the MIPS CQM and eCQM reporting incentive, which we first finalized in the CY 2022 PFS final rule (86 FR 65269), was to encourage ACOs to begin the transition to the use of eCQM and MIPS CQM collection types when reporting quality measures. We note that in performance year 2023, all ACOs that successfully reported eCQMs/MIPS CQMs met the criteria for the eCQM/MIPS CQM reporting incentive and thus met the Shared Savings Program's quality performance standard.

For performance year 2025 and subsequent performance years, we are finalizing that an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable: If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the MIPS data completeness requirement for all eCQMs/MIPS CQMs; achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set; and achieves a quality performance score equivalent to

[541] Counts based on internal analysis of ACOs' quality reporting in performance year 2022 and 2021.

or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

We believe that the increased number of quality measures that will be phased into the APP Plus quality measure set over time will afford ACOs expanded opportunities to satisfy the reporting incentive criteria. For instance, the number of eCQMs/MIPS CQMs in the APP Plus quality measure set will increase from four in performance year 2025 to five in performance year 2026. Once MIPS CQMs are removed from the APP Plus quality measure set in performance year 2027, the number of eCQMs in the APP Plus quality measure set will increase from five to six in performance year 2027. Once all of the eCQMs are incorporated into the APP Plus quality measure set, there will be 8 eCQMs. For these reasons, we believe that the eCQM/MIPS CQM reporting incentive incentives and supports ACOs to surmount commenters' eCQM challenges. We also believe that several of our other finalized policies address the concerns that interested parties mentioned regarding these challenges. In particular, we are finalizing in section III.G.4.b.(2)(b) of this final rule to make available the MIPS CQM collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for performance years 2025 and 2026. We disagree with the commenter's suggestion that incremental incentives over three or more years for the partial reporting of eCQMs are the best approach to incentivize eCQM reporting. We note that ACOs that are not yet ready to report eCQMs may report quality via other collection types. For instance, ACOs may report via the CMS Web Interface or the MIPS CQM/Medicare CQM collection types in performance year 2024, the MIPS CQM/Medicare CQM collection types in performance years 2025 and 2026, and the Medicare CQM collection types in performance year 2027 and subsequent performance years.

Comment: Several commenters suggested that the eCQM reporting incentive apply to Shared Savings Program ACOs that report quality measures using any collection type or a combination of the Medicare CQM, MIPS CQM and eCQM collection types.

Response: As discussed in section III.G.4.b.(2)(b) of this final rule, we are finalizing our original proposal with modification to make MIPS CQMs available as a collection type for ACOs reporting the APP Plus quality measure set for two additional years (that is, performance years 2025 and 2026). We originally adopted the reporting incentive in the CY 2022 PFS final rule to encourage ACOs to begin the transition to eCQM/MIPS CQM reporting in performance years 2022 and 2023 (86 FR 65269). In the CY 2023 PFS final rule, we extended the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures are required beginning in performance year 2025 (87 FR 69836 through 69838).

In order to continue to align the reporting incentive with the MIPS CQM collection type, we believe that it would be appropriate to extend the reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026, similar to how the reporting incentive has applied to ACOs reporting MIPS CQMs between performance years 2022 and 2024. However, we are declining to modify our proposal to apply the reporting incentive to Shared Savings Program ACOs that use the Medicare CQM collection type to report quality measures. As we previously stated in the CY 2024 PFS final rule ''the incentive is for all payer/all patient eCQM/MIPS CQM reporting. Since Medicare CQMs would include only Medicare FFS beneficiaries, Medicare CQMs are not a form of all payer/all patient reporting. As such, they are not included in the eCQM/MIPS CQM reporting incentive'' (88 FR 79105).

Regarding the application of the reporting incentive to Medicare CQMs, we stated in the CY 2024 PFS final rule (88 FR 79105) that ''[a]s stated in the CY 2024 PFS proposed rule (88 FR 52423), we did not propose to add Medicare CQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(A)(2) for performance year 2024. The incentive is for all payer/all patient eCQM/MIPS CQM reporting. Since Medicare CQMs would include only Medicare FFS beneficiaries, Medicare CQMs are not a form of all payer/all patient reporting. As such, they are not included in the eCQM/MIPS CQM reporting incentive.'' We note that the alternative quality performance standard and the health equity adjustment, both of which we finalized in the CY 2023 PFS final rule (87 FR 69831 and 69838, respectively), would be applicable to ACOs that report Medicare CQMs when those ACOs are otherwise eligible for scaled savings/losses.

Comment: One commenter suggested that the threshold for the incentive should require use of the eCQM collection type for reporting at least 3 of the 4 quality measures with this collection type in the proposed APP Plus quality measure set for the 2025 performance year.

Response: We previously heard from ACOs and other interested parties that the components of implementing an interoperable system are the same regardless of the number of quality measures reported using the MIPS CQM and/or eCQM collection types (86 FR 65260). As such, we are declining to modify the reporting incentive criteria to require the use of the eCQM collection type for reporting at least 3 of the 4 quality measures with this collection type in the proposed APP Plus quality measure set for the 2025 performance year.

After consideration of public comments, we are finalizing our proposal to extend the reporting incentive to ACOs reporting eCQMs in performance year 2025 and subsequent performance years. We are also finalizing to extend this reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026 to further support ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track.

(3) Changes to Regulation Text

In the CY 2025 PFS proposed rule, we proposed to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years to support ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track (89 FR 61863).

Specifically, we proposed that for performance year 2025 and subsequent performance years, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the

remaining measures in the APP Plus quality measure set.

We proposed to add paragraphs (a)(5)(i)(B)(*1*) and (*2*) to § 425.512 to incorporate our proposal to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years into the regulation text (89 FR 61863).

We are finalizing our proposal with modifications. Specifically, for performance years 2025 and 2026, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

Additionally, we are finalizing that, for performance year 2027 and subsequent performance years, an ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 for all eCQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

For performance years 2025 and 2026, the reporting incentive will apply only to those ACOs that report all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year and meet the data completeness requirement for all of the eCQMs/MIPS CQMs. The reporting incentive would not apply to ACOs that report a combination of eCQMs/MIPS CQMs/Medicare CQMs or report only Medicare CQMs. Similarly, for performance year 2027 and subsequent performance years, the reporting incentive will apply only to those ACOs that report all of the eCQMs in the APP Plus quality measure set applicable for a performance year and meet the data completeness requirement for all of the eCQMs. The reporting incentive would not apply to ACOs that report a combination of eCQMs/Medicare CQMs or report only Medicare CQMs.

In addition, we are finalizing to add paragraphs (a)(5)(i)(B)(*1*) and (*2*) to § 425.512 to incorporate the policy to extend the eCQM/MIPS CQM reporting incentive to performance years 2025 and 2026, and we are adding new paragraphs (a)(5)(i)(C), (a)(5)(i)(C)(*1*) and (*2*) to § 425.512 to extend the eCQM reporting incentive to performance year 2027 and subsequent performance years into the regulation text.

e. Summary of Final Policies

In Table 33 of the CY 2025 PFS proposed rule (89 FR 61864 through 61865), we summarized the proposed changes to § 425.512(a)(5) to reflect the changes we proposed to the quality reporting requirements and quality performance standard for performance year 2025 and subsequent performance years. In Tables 37 and 38 of this final rule, we summarize the policies we are finalizing related to the quality reporting requirements and quality performance standard for performance year 2025 and subsequent performance years.

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TABLE 37: Final APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for Shared Savings ACOs for Performance Years 2025 and 2026

	Performance Year 2025	Performance Year 2026
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report the **4** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 1 claims-based measure.	ACOs are required to report **5** eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the 4 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 4 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 3 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 5 measures in the APP Plus quality measure set. **Alternative quality performance**	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or 2. Reporting the 5 eCQMs/MIPS CQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 5 eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 7 measures in the APP Plus quality measure set. **Alternative quality performance**

	Performance Year 2025	Performance Year 2026
	standard used to determine shared savings using the sliding scale methodology: An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1of the 3 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the 4 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	**standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the 5 eCQMs /MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

TABLE 38: Final APP Plus Quality Measure Set Reporting Requirements and Quality Performance Standard for Shared Savings ACOs for Performance Year 2027 and Performance Year 2028 and Subsequent Performance Years

	Performance Year 2027	Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specifications become available for Quality IDs: 487 and 493, whichever is later
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report **6** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.	ACOs are required to report **8** eCQMs/Medicare CQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey. CMS will calculate 2 claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1. ACOs that achieve a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or	**Quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:** 1 ACOs that achieve a health equity adjusted quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

	Performance Year 2027	Beginning with Performance Year 2028 or the performance year that is one year after the eCQM specifications become available for Quality IDs: 487 and 493, whichever is later
	2. Reporting the **6** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 6 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **8** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the **6** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.	2. Reporting the **8** eCQMs in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for all 8 eCQMs, and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining **10** measures in the APP Plus quality measure set. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** An ACO that fails to meet the criteria above but meets the alternative quality performance standard by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's health equity adjusted quality performance score. If an ACO (1) does not report any of the **8** eCQMs /Medicare CQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible to share savings and will owe maximum shared losses, if applicable.

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f. APP Plus Quality Measure Set

(1) Background

The APP quality measure set for performance year 2024 and subsequent performance years was finalized in the CY 2024 PFS final rule (88 FR 79112 through 79114). In that final rule, for performance year 2024 and subsequent performance years, we also finalized the addition to the APP quality measure set of the Medicare CQM collection type for Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Quality #: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality #: 134) and Controlling High Blood Pressure (Quality #: 236).

(2) Revisions

As described in section III.G.4.b.(2)(a) of the CY 2025 PFS proposed rule, for performance year 2025 and subsequent performance years, we proposed to require Shared Savings Program ACOs to report the APP Plus quality measure set as proposed in section IV.A.4.c.(3) of the CY 2025 PFS proposed rule (89 FR 61865). The proposed APP Plus quality measure set would comprise of eleven measures, consisting of six measures from the APP quality measure set and five newly proposed measures from the Adult Universal Foundation measure set that would be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028. We also proposed to focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs (89 FR 61865).

The proposed APP Plus quality measure set for Shared Savings Program ACOs for performance year 2025, performance years 2026 and 2027, and performance year 2028 and subsequent performance years are displayed in Tables 34, 35, and 36 of the CY 2025 PFS proposed rule, respectively (89 FR 61866 through 61868). In these tables, we also included the measure type for each measure in the APP Plus quality measure set to provide ACOs with a list of the outcome measures for purposes of qualifying for the eCQM reporting incentive, as described in section III.G.4.d. of the CY 2025 PFS final rule. As discussed in the CY 2025 PFS proposed rule, this information is also relevant to the alternative quality performance standard under which ACOs that fail to meet the quality performance standard to qualify for the maximum sharing rate, but that achieve a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set, may be eligible to share in savings on a sliding scale, as discussed in the current § 425.512(a)(4)(ii) (89 FR 61866).

We received public comments on the proposed APP Plus quality measure set and refer readers to section IV.A.4.c.(2) for a summary of the comments we received and our responses. The final APP Plus quality measure set for Shared Savings Program ACOs for performance year 2025 and subsequent performance years are displayed in Tables 39 through B–42 of this final rule.

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TABLE 39: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2025

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM/MIPS CQM reporting incentive and the alternative quality performance standard.

TABLE 40: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2026

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM/MIPS CQM reporting incentive and the alternative quality performance standard.

TABLE 41: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2027

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral health	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

TABLE 42: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs Beginning with Performance Year 2028 or the Performance Year that is one year after the eCQM Specifications become available for Quality IDs: 487 and 493, whichever is later

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome^
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Chronic Conditions	Intermediate Outcome^
112	Breast Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Behavioral health	Process
487	Screening for Social Drivers of Health	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Equity	Process
493	Adult Immunization Status	eCQM/Medicare CQM	APM Entity/Third Party Intermediary	Wellness and Prevention	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM reporting incentive and the alternative quality performance standard.

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g. Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey Request for Information

We solicited public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. During the 2023 CAHPS for MIPS Web Mode Field Test,[542] we found that adding the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration resulted in an increased response rate. We thank commenters for their comments in response to this request for information. This Request for Information is also discussed at IV.A.4.e.(1)(e)(i) of this final rule.

5. Providing the Option of Prepaid Shared Savings

a. Background

In the CY 2023 PFS final rule (87 FR 69782 through 69805), CMS finalized a new payment option for eligible Shared Savings Program ACOs entering agreement periods beginning on or after January 1, 2024, to receive advance shared savings payments. This payment option is referred to as advance investment payment (AIP) and the payments themselves are referred to as advance investment payments.

These payments are intended to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by reducing the barriers to participation in the Shared Savings Program by supporting investments in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries. Accordingly, advance investment payments must be spent on one of the following categories: increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health (§ 425.630(e)(1)).

Advance investment payments are only available to ACOs newly entering the Shared Savings Program in their first agreement period (§ 425.630(b)(1)). Many commenters on the CY 2023 PFS final rule (87 FR 69782 through 69805) suggested that CMS should expand access to advance investment payments by expanding the eligibility criteria to include currently participating ACOs as well as high revenue ACOs. While we do not believe that it is appropriate to expand the eligibility criteria for advance investment payments at this time, as CMS still needs time to assess the impact of the new payment option, there is persuasive evidence that investment in staffing, healthcare infrastructure, and accountable care for underserved beneficiaries could be valuable for all ACOs, not just those that are new to the program. Investment in care coordination for beneficiaries reduces costs and improves the quality of care received.[543] [544] [545] Investment in health information technology can be leveraged to empower individuals, address patients' full range of health needs, promote healthy behaviors, and facilitate better health outcomes for individuals, families, and communities.[546] Additionally, there is evidence that investment in services not currently covered by Medicare may improve beneficiary health and reduce avoidable health care utilization costs over time, including coverage of

[542] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2893/2023_CAHPS_for_MIPS_WebMode_Field_Test.pdf.*

[543] Breckenridge ED, Kite B, Wells R, Sunbury TM. Population Health Management. Effect of Patient Care Coordination on Hospital Encounters and Related Costs. September 26, 2019. Available at *https://doi.org/10.1089/pop.2018.0176.*

[544] Elliott MN, Adams JL, Klein DJ, et al. Journal of General Internal Medicine. Patient-Reported Care Coordination is Associated with Better Performance on Clinical Care Measures. September 20, 2021. Available at *https://link.springer.com/article/10.1007/s11606-021-07122-8.*

[545] Figueroa JF, Feyman Y, Zhou X, et al. Hospital-level care coordination strategies associated with better patient experience. BMJ Quality & Safety. April 4, 2018. Available at *https://qualitysafety.bmj.com/content/27/10/844.*

[546] The Office of the National Coordinator for Health Information Technology. 2020–2025 Federal Health IT Strategic Plan. Available at *https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf.*

dental,[547] [548] [549] hearing,[550] [551] and vision [552] care.

Furthermore, we have come to understand that, for beneficiaries, the benefits of receiving services from providers associated with ACOs—such as improvements in quality and coordinated care—may not be immediately apparent. By encouraging ACOs to invest in new services that beneficiaries otherwise would not receive, like hearing, vision and dental services, the benefits of receiving care from providers who are part of an ACO would become more tangible. This would encourage beneficiaries to receive care from providers participating in an ACO and may ultimately result in improved quality and efficiency of care for beneficiaries.

For ACOs that are currently participating in the Shared Savings Program and that reinvest their earned shared savings payments in activities that reduce costs and improve quality of care, it could be more valuable to gain access to those shared savings payments early in and/or throughout each performance year, instead of waiting months after the end of each performance year when any earned shared savings payments are distributed. Currently, CMS completes the financial reconciliation calculations for each ACO during the summer after the end of each performance year, which allows time for claims runout and other necessary data to become available. CMS compares the updated historical benchmark to an ACO's assigned beneficiaries' per capita expenditures during the performance year to determine whether the ACO may share in savings or losses, if owed. CMS then notifies the ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. These payments are generally distributed to ACOs in the early Fall following the end of each performance year. This is the sole payment CMS makes to an ACO in the Shared Savings Program and generally an ACO's sole source of revenue. Distributing prepaid shared savings during a performance year would allow ACOs to invest these payments in additional services for assigned beneficiaries, staffing, and healthcare infrastructure earlier and reap the benefits from that investment earlier.

The CMS Innovation Center tested a number of strategies for providing more experienced ACOs with advances of funding during each performance year. One of the innovations was the infrastructure payments available in the Next Generation ACO model, a CMS Innovation Center model that was intended for more experienced ACOs.[553] Most Next Generation ACOs (82 percent) that participated in the Next Generation ACO model in 2018 had prior experience as Medicare ACOs before starting in the model, and the majority (56 percent) previously participated in the Shared Savings Program.[554] ACOs selecting the infrastructure payment option received $6 per assigned beneficiary per month to support ACO Activities, which was later recouped during financial settlement following each performance year. The model defined ACO Activities as activities related to promoting accountability for the quality, cost, and overall care for the population of beneficiaries assigned to the Next Generation ACO, including managing and coordinating care; encouraging investment in healthcare infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty of the ACO under the terms of the Next Generation ACO model. Examples of these activities included, but were not limited to, providing direct patient care in a manner that reduces costs and improves quality; promoting evidence-based medicine and patient engagement; reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing and improving clinical and administrative systems for the ACO; meeting the quality performance standards; evaluating health needs; communicating clinical knowledge and evidence-based medicine; and developing standards for beneficiary access and communication, including beneficiary access to medical records. In interviews performed as part of the CMS Innovation Center's evaluation of the model, Next Generation ACO leaders described using these funds to support upfront operating costs and healthcare infrastructure and clinical process enhancements such as new staff, health information technology, data analytic capacity, population health management, or care coordination.[555]

Despite these ACOs' prior experience as Medicare ACOs and the meaningful investments many had made in their own healthcare infrastructure and providers, they still found value in access to funding during the performance year. Almost all Next Generation ACOs used the funds to develop workflows informed by data analytics and clinical staff input. Most Next Generation ACOs also reported using the funds to support care management, such as acquiring tools and developing healthcare infrastructure to support care coordination. Leaders from many Next Generation ACOs described how the payments facilitated new processes for seamless patient care handoffs between health care providers, enabled the creation of better workflows for scheduling follow-up visits, and supported provision of screenings and assessments. Data from a clinician survey suggested that the payments were likely helpful in improving the delivery or coordination of care, with 63 percent of providers agreeing that additional resources to support practice changes made their day-to-day work

[547] Schenkein HA, Loos BG. Inflammatory mechanisms linking periodontal diseases to cardiovascular diseases. Journal of Clinical Periodontology. April 30, 2013. Available at *https://doi.org/10.1111/jcpe.12060.*

[548] Teeuw WJ, Gerdes VE, Loos BG. Effect of periodontal treatment on glycemic control of diabetic patients: a systematic review and meta-analysis. Diabetes Care. February 2010. Available at *https://pubmed.ncbi.nlm.nih.gov/20103557/.*

[549] Allareddy V, Rampa S, Lee MK, Allareddy V, Nalliah RP. Hospital-based emergency department visits involving dental conditions: Profile and predictors of poor outcomes and resource utilization. The Journal of the American Dental Association. November 19, 2014. Available at *https://doi.org/10.14219/jada.2014.7.*

[550] Choi JS, Adams ME, Crimmins EM, Lin FR, Ailshire JA. Association between hearing aid use and mortality in adults with hearing loss in the USA: a mortality follow-up study of a cross-sectional cohort. The Lancet Healthy Longevity. January 3, 2024. Available at *https://doi.org/10.1016/S2666-7568(23)00232-5.*

[551] Reed NS, Altan A, Deal JA, et al. Trends in Health Care Costs and Utilization Associated with Untreated Hearing Loss Over 10 Years. *JAMA Otolaryngology—Head and Neck Surgery.* November 8, 2018. Available at *https://jamanetwork.com/journals/jamaotolaryngology/fullarticle/2714049.*

[552] Lipton BJ, Decker SL. The effect of health insurance coverage on medical care utilization and health outcomes: Evidence from Medicaid adult vision benefits. Journal of Health Economics. November 11, 2015. Available at *https://doi.org/10.1016/j.jhealeco.2015.10.006.*

[553] Refer to ''Next Generation ACO Model'' available at *https://www.cms.gov/priorities/innovation/innovation-models/next-generation-aco-model.*

[554] NORC at the University of Chicago. Next Generation Accountable Care Organization Model Third Evaluation Report. September 2020. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport.*

[555] NORC at the University of Chicago. Evaluation of the Next Generation Accountable Care Organization (NGACO) Model—Final Report. January 2024. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2024/nextgenaco-sixthevalrpt.*

easier.[556] Separately, the ACO Investment Model (AIM), a model run by the CMS Innovation Center which informed development of the advance investment payments, gave participating ACOs upfront and quarterly funding to spend on ACO start-up costs. These ACOs primarily invested in staffing and healthcare infrastructure including care management, ACO administration, health IT and data analysis,[557] and these ACOs generated an estimated net aggregate reduction in spending by Medicare of $381.5 million after accounting for Medicare's payment of AIM funds and participating ACOs' earned shared savings.[558]

Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act so long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We are interested in building on experience from the Next Generation ACO model, and we agree, in part, with comments on the CY 2023 PFS final rule that encouraged CMS to expand AIP to additional ACOs. While we do not believe it is appropriate to expand the eligibility criteria for AIPs at this time as explained earlier in this section, we agree with commenters that additional ACOs could benefit from expanded access to performance year funding that encourages investment in staffing, healthcare infrastructure, and additional services for beneficiaries. Prepaid shared savings would be required to be spent at least partially on direct beneficiary services, improving the quality of care beneficiaries receive.

Consequently, under the authority provided to the Secretary by section 1899(i)(3) of the Act, we proposed to provide prepaid shared savings to certain ACOs that meet the eligibility criteria described in section III.G.5.b of this final rule (§ 425.640(b)). Such payments would be made under the standards we proposed to establish in new § 425.640. This new payment option would provide prepaid shared savings to ACOs with a history of earning shared savings while participating in the Shared Savings Program. These payments would be distributed on a quarterly basis and would be recouped from shared savings CMS determines the ACO to have earned during the annual financial reconciliation cycle. Prepaid shared savings would be the advance payment of shared savings that are expected to be earned by the ACO and are covered under the Shared Savings Distribution Waiver (80 FR 66726). If the ACO does not earn sufficient shared savings to offset the advanced payment of shared savings during the applicable performance year, CMS may withhold or terminate the ACO's prepaid shared savings under proposed § 425.640(h)(1)(iii).

We have determined that the other payment model CMS has adopted under section 1899(i)(3) of the Act would continue to improve the quality and efficiency of care should this proposal be finalized. Section 1899(i)(3)(A) of the Act requires CMS determine that the other payment model will improve the quality and efficiency of items furnished under the Medicare program. Based on the evidence for direct beneficiary services noted above, our experience administering the Shared Savings Program, and the CMS Innovation Center's experience with AIM and infrastructure payments in the Next Generation ACO model, we have determined that allowing ACOs access to funding earlier than currently available, in the form of prepaid shared savings, would allow ACOs to more rapidly achieve the benefits of investing in staffing, healthcare infrastructure, and direct beneficiary services. Improvement in these areas would improve the quality and efficiency of beneficiary care, therefore meeting the standard of section 1899(i)(3)(A) of the Act. As we explained earlier in this section, ACOs have expenditures throughout the PY, particularly when implementing care coordination and beneficiary management strategies, and having access to their shared savings early can help ensure the ACO has adequate funding to perform these services throughout the year.

Section 1899(i)(3)(B) of the Act requires CMS to determine that prepaid shared savings, when implemented in combination with existing modifications made to the Shared Savings Program payment model specified in section 1899(d) of the Act, will not result in additional program expenditures. The addition of prepaid shared savings meets this standard in part because the eligibility criteria for prepaid shared savings have been selected to only permit ACOs that CMS estimates are most likely to earn shared savings to receive payments. Additionally, any payments the ACO would receive under this proposal must be repaid to CMS, and CMS would be protected by the ACOs' repayment mechanisms in the event that an ACO does not earn shared savings or cannot otherwise repay the amount owed to CMS. Based on this design, we estimate that there would be no additional program expenditures stemming from the implementation of prepaid shared savings under this proposal. Please review section VI of this final rule for a more complete discussion of the financial impact of the Shared Savings Program payment model, including the findings necessary to demonstrate compliance with section 1899(i)(3)(B) of the Act.

We intend to periodically reassess whether a payment model established under section 1899(i)(3) of the Act, including the payment of prepaid shared savings, continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries without resulting in additional program expenditures. If we determine that the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act (for example if the payment model results in net program costs), we would undertake additional notice and comment rulemaking to adjust our payment methodology to assure continued compliance with the statutory requirements.

b. Eligibility

To ensure that prepaid shared savings are provided only to ACOs that are well-positioned to use prepaid shared savings to improve the quality and efficiency of care to their assigned beneficiaries while minimizing the risk of an ACO being unable to repay prepaid shared savings, we proposed to limit the availability of prepaid shared savings to those ACOs that have a track record of success in the Shared Savings Program (89 FR 61596, 61871). This approach is also consistent with our compliance with section 1899(i)(3)(B) of the Act as such ACOs are most likely to be able to repay the upfront funding through earned shared savings.

We proposed to establish the eligibility criteria for prepaid shared savings in § 425.640(b). CMS must determine that an ACO meets all of the following criteria for the ACO to be

[556] NORC at the University of Chicago. Next Generation Accountable Care Organization (NGACO) Model Evaluation Third Evaluation Report. 2020. Available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport.*

[557] Abt Associates, Evaluation of the Accountable Care Organization Investment Model, AIM Implementation and Impacts over Two Performance Years (September 2019), page 55. Available at *https://www.cms.gov/priorities/innovation/aim-second-annrpt.pdf.*

[558] Abt Associates, Evaluation of the Accountable Care Organization Investment Model, Final Report (September 2020), page 39. Available at *https://innovation.cms.gov/data-and-reports/2020/aim-final-annrpt.*

eligible to receive prepaid shared savings during an agreement period:

- The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years.
- The ACO must have received a shared savings payment for the most recent performance year that:

(A) Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and

(B) CMS has conducted financial reconciliation.

- The ACO must have a positive prior savings adjustment as calculated per § 425.658 at application disposition for the agreement period in which they would receive prepaid shared savings.
- The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation.
- If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.
- The ACO is participating in Levels C–E of the BASIC track or the ENHANCED track during the agreement period in which they would receive prepaid shared savings.
- The ACO has in place an adequate repayment mechanism in accordance with § 425.204(f) that can be used to recoup outstanding prepaid shared savings.
- During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:

(A) Met the quality performance standard as specified under § 425.512; and

(B) Has not been determined by CMS to have avoided at-risk beneficiaries as specified under § 425.316(b)(2).

We proposed these eligibility criteria so that only ACOs with a record of meeting the quality performance standard, not avoiding at-risk beneficiaries, and recent success in earning shared savings would receive prepaid shared savings. This is for the protection of both CMS and the ACOs, as CMS does not want to overestimate an ACO's ability to earn future shared savings and burden an ACO with debt that the ACO would not be able to repay. As we explained in the proposed rule (89 FR 61596, 61871 and 61872), our experience administering the Shared Savings Program leads us to determine that ACOs with prior success in the program—that is, ACOs with a record of meeting the quality performance standard, not avoiding at-risk beneficiaries, and recent success in earning shared savings—are well positioned to identify beneficiary needs and invest prepaid shared savings to improve beneficiary care and are therefore most likely to benefit from prepaid shared savings. These ACOs would also be reasonably confident that they would be able to repay CMS through their earned shared savings and would therefore be comfortable spending the funding they receive. Accordingly, CMS would only permit ACOs that are currently participating in the Shared Savings Program, that have earned shared savings in the most recent performance year for which financial reconciliation has been completed, and that have a positive prior savings adjustment at application disposition to receive prepaid shared savings, as they would possess the history of success that would provide us with a more reasoned expectation that they would continue to earn shared savings in the future. New ACOs would not be eligible for prepaid shared savings, as they would not have a recent performance history that we could use to predict future performance.

Many new ACOs are eligible to receive advance investment payments, which are not available to ACOs currently participating in the Shared Savings Program. Advance investment payments are more tailored to the needs of a new ACO as there is more flexibility in the use of funding, and advance investment payments do not need to be repaid in the event that the ACO does not earn shared savings.

Additionally, ACOs that did not meet the quality performance standard as specified under § 425.512, or were subject to a pre-termination action from CMS after determining that the ACO had avoided at-risk beneficiaries, as specified under § 425.316(b)(2), in the agreement period preceding the agreement period in which the ACO would receive prepaid shared savings, would be prohibited from participating in the prepaid shared savings payment option, as these compliance issues could prevent an ACO from earning shared savings that would be used to repay the prepaid shared savings.

CMS also proposed to limit participation in the prepaid shared savings payment option to ACOs that have fully repaid all shared losses they may owe and any advance investment payments they may have received in a prior agreement period, and to ACOs that participate in a two-sided risk track (Levels C–E of the BASIC track or the ENHANCED track), as these tracks require a repayment mechanism in accordance with § 425.204(f), which could be used to recoup prepaid shared savings. CMS also proposed these criteria, in part, to limit participation to ACOs that were most likely to be able to repay any prepaid shared savings they received. Similarly, if the ACO had received prepaid shared savings in a current or previous agreement period, they must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS had completed financial reconciliation before they would be able to renew their participation in prepaid shared savings for another agreement period. For example, if an ACO were in the fifth year of its 5-year agreement period during which the ACO had been receiving prepaid shared savings, and is in the process of renewing for a new agreement period, CMS would ensure that the ACO had fully repaid the prepaid shared savings received from the first four performance years of the ACO's current agreement period through earned shared savings before the ACO would be approved to receive prepaid shared savings in a new agreement period. As CMS intends to provide prepaid shared savings to ACOs if they improve and maintain performance and continue to see success in the program on an annual basis, ACOs that are not initially eligible would have the option to participate in the prepaid shared savings payment option in future years if they demonstrate a more recent history of success in the program and meet the other eligibility criteria. These criteria would also provide an additional incentive for ACOs to improve their performance in the program. CMS would also continue to review the eligibility criteria over time and may expand eligibility in future years if we determine that doing so is in the interests of the Shared Savings Program, participating ACOs, and their beneficiaries, and that all requirements under section 1899(i)(3) of the Act are satisfied. Additionally, to standardize timelines for payment, spending, and recoupment of prepaid shared savings, ACOs would only be eligible for prepaid shared savings if they renew or early renew to begin a new agreement period. The proposed policies for the calculation, spending and recoupment of prepaid shared savings allow for up to 5 years for ACOs to receive, spend, and repay the funding through earned

shared savings. We proposed to create a new paragraph in § 425.100(e) to establish that an ACO may receive prepaid shared savings if it meets the criteria under § 425.640(b). We proposed in § 425.640(b) to specify the eligibility criteria for an ACO to receive prepaid shared savings.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally expressed appreciation for CMS's efforts to offer experienced ACOs prepaid shared savings for the purpose of encouraging investment in staffing, healthcare infrastructure, and additional services for beneficiaries. Additionally, most commenters supported the eligibility criteria for prepaid shared savings, noting that the proposed criteria would help ensure that experienced ACOs receiving prepaid shared savings are in good standing in the Shared Savings Program and are likely to generate sufficient earned shared savings to repay CMS.

Response: We agree with commenters that the implementation of the new prepaid shared savings payment option will support experienced ACOs with upfront funding for the purpose of encouraging investment in staffing, healthcare infrastructure, and additional services for beneficiaries. We also agree that our proposed eligibility criteria for prepaid shared savings will help ensure that ACOs that receive prepaid shared savings have a track record of success that establishes confidence in the ACOs' ability to generate future shared savings, while also limiting risks of providing prepaid shared savings to ACOs that fail to comply with Shared Savings Program requirements or are unable to generate sufficient shared savings to repay CMS.

Comment: Another commenter encouraged CMS to distribute prepaid shared savings to eligible hospitals, noting that upfront investments are important for enabling essential, safety net hospitals to implement the transition to value-based payments.

Response: Pursuant to section 1899 of the Act, CMS is unable to distribute prepaid shared savings to entities other than ACOs participating in the Shared Savings Program. However, participation in the Shared Savings Program, and the prepaid shared savings payment option specifically, are beneficial tools for caring for underserved populations and helping close gaps in care. We note in particular that, as explained in greater detail below, prepaid shared savings are intended to support ACOs in providing direct beneficiary services, which should benefit underserved populations.

Comment: Several commenters disagreed with the requirement that ACOs begin a new agreement period to receive prepaid shared savings. Commenters shared concerns about being subject to benchmark rebasing if they early renew to begin a new agreement period to comply with this eligibility requirement and believe this may negatively impact ACO participation in the payment option. Commenters encouraged CMS to allow ACOs to opt in to prepaid shared savings mid-agreement period.

Response: We thank commenters for expressing their concerns related to the impact that recalculating an ACO's historical benchmark (benchmark rebasing) may have on ACOs that early renew so that they can participate in the payment option. However, generally requiring ACOs to begin a new agreement period is important for ensuring that ACOs are given adequate time to earn shared savings so that they can repay prepaid shared savings to CMS. CMS will demand repayment of any unspent prepaid shared savings, as well as any outstanding balance of prepaid shared savings, at the end of each agreement period in which an ACO receives prepaid shared savings, as noted in the new § 425.640(e)(3) and (g)(3). It is important for ACOs to have sufficient time to adjust to develop experience receiving, spending, and complying with program requirements related to prepaid shared savings, and repaying these funds through earned shared savings before they must be repaid directly to CMS. ACOs may not have sufficient time to develop this experience if they begin receiving prepaid shared savings mid-agreement period. As we explained in the CY 2025 PFS proposed rule (89 FR 61871), CMS aims to extend this payment option to the ACOs most likely to earn shared savings, to ensure that the addition of prepaid shared savings meets the standard set by section 1899(i)(3) of the Act, which requires CMS to determine that prepaid shared savings will improve the quality and efficiency of items and services furnished under the Medicare program and, when implemented in combination with existing modifications made to the Shared Savings Program payment model specified in section 1899(d) of the Act, not result in more program expenditures than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

ACOs will be able to renew and apply to receive prepaid shared savings on an annual basis, so if an ACO does not wish to early renew to participate, the ACO will be able to wait until it is prepared to renew in order to begin participating in this payment option. However, there is a very large cohort of ACOs renewing for a new agreement period in 2025 that we expect will meet the eligibility requirements under § 425.640(b) and be interested in participating in this payment option. Allowing these ACOs to begin receiving prepaid shared savings in 2026, without renewing again, would encourage program participation and more rapid investment in staffing, healthcare infrastructure and direct beneficiary services. These ACOs will still have four out of five performance years available to develop experience receiving, spending, and complying with program requirements related to prepaid shared savings, and giving these ACOs a one-time exception to participate with a slightly shorter timeline would not negatively impact our obligation under section 1899(i)(3)(B) of the Act to ensure that this payment option does not negatively impact program expenditures. These ACOs were not able to consider the finalized prepaid shared savings policy when they renewed for the 2025 performance year, and as this payment option will be available on an annual basis moving forward this will not be an issue in future performance years.

Accordingly, CMS is making a one-time exception to allow these ACOs to elect to begin receiving prepaid shared savings in 2026, without renewing again. These ACOs will still be required to meet the other eligibility requirements under § 425.640(b), including having a positive prior savings adjustment when they renew for an agreement period beginning in PY 2025 and ensuring they have in place an adequate repayment mechanism to support the repayment of prepaid shared savings in accordance with § 425.204(f). These ACOs will only receive prepaid shared savings beginning in 2026; CMS will not distribute any payments of prepaid shared savings for performance year 2025. These ACOs will also be required to fully pay back the funding they receive by the end of their agreement period in 2029, giving them four years to receive, use, and repay prepaid shared savings.

Furthermore, we note that we have taken steps through prior rulemaking, such as through establishment of a prior savings adjustment and the inclusion of the Accountable Care Prospective Trend (''ACPT'') in a three-way blended update factor, to improve the accuracy

of ACO financial benchmarks for ACOs entering a second or subsequent agreement period. Currently participating ACOs that early renew for a new agreement period beginning on or after January 1, 2026, will be subject to these financial benchmarking policies in accordance with § 425.652.

Comment: Several commenters suggested that CMS expand eligibility to more ACOs, including ACOs that are new to the Shared Savings Program or do not have a history of earning shared savings, as they believe additional ACOs could benefit from prepaid shared savings and improve the care their beneficiaries receive.

Response: While we understand that some commenters believe additional ACOs may benefit from receiving prepaid shared savings, CMS is not expanding the prepaid shared savings eligibility criteria to new ACOs or those without a demonstrated history of earning shared savings. As we explained in the proposed rule (89 FR 61871–61872), we are obligated to protect the Medicare Trust Funds. To do so, we determine that we would not distribute prepaid shared savings to ACOs lacking a demonstrated track record of success generating shared savings, in order to avoid or mitigate the risk of providing ACOs with advances of shared savings they may not be able to repay.

Some ACOs that are new to the Shared Savings Program may be eligible to participate in the advance investment payment option, which provides similar upfront funding for new ACOs serving underserved beneficiaries.

After consideration of public comments, we are finalizing our proposal to establish a new section of the regulations at § 425.640 with provisions on the option to receive prepaid shared savings payments. We are also finalizing paragraph (a) of § 425.640, as proposed, to describe the purpose of the payment option: prepaid shared savings provide an additional cash flow option to ACOs with a history of earning shared savings that will encourage their investment in activities that reduce costs for the Medicare program and beneficiaries and improve the quality of care provided to their assigned beneficiaries.

We are finalizing the proposed prepaid shared savings eligibility criteria under § 425.640(b) with modifications to allow ACOs that renewed to enter an agreement period beginning on January 1, 2025, the option to elect to participate in prepaid shared savings starting with performance year 2026 without renewing again. Specifically, within § 425.640(b)(1), we specify the criterion that the ACO must meet either of the following conditions: (i) The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years; or (ii) The ACO was a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2025, and applied to receive prepaid shared savings in accordance with paragraph (c)(2) of this section starting with the performance year beginning on January 1, 2026. Otherwise, we are finalizing as proposed the remaining eligibility criteria listed in new § 425.640(b)(2) through (8). We are also finalizing our proposal, without modification, to specify in a new paragraph in § 425.100(e) that an ACO may receive prepaid shared savings if it meets the criteria under § 425.640(b).

c. Application Procedure & Contents

We proposed to establish the process for an ACO to apply for prepaid shared savings in § 425.640(c). Specifically, we proposed that an ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. The application cycle for prepaid shared savings would be conducted as part of, and in conjunction with, the Shared Savings Program application process under § 425.202, with instructions and timelines published on the Shared Savings Program website. We proposed the initial application cycle to apply for prepaid shared savings would be for a January 1, 2026, start date. In the CY 2025 PFS proposed rule (89 FR 61596, 61872), we explained that we intended to provide further information regarding the process, including the application contents and specific requirements such as the deadline for submitting applications and all supplemental application information that would be required, through guidance. The prepaid shared savings application procedure would also include a process by which CMS provides an applicant with feedback and an opportunity to clarify or revise their application.

We will provide preliminary information to the applicant ACO about its eligibility to receive prepaid shared savings during the Phase 1 application cycle requests for information, and a final determination about its eligibility to receive prepaid shared savings at the time of final application dispositions. For example, for ACOs applying in 2025 for an agreement period beginning in 2026, we will provide preliminary information identifying whether an ACO is likely to earn shared savings in the 2024 performance year and have a positive prior savings adjustment as calculated per § 425.658 at application disposition.

We proposed at § 425.640(d)(1) that an ACO would be required to submit a spend plan as part of its application for prepaid shared savings. We proposed that the plan must describe how the ACO would spend the prepaid shared savings during the first performance year of the agreement period during which the ACO would receive prepaid shared savings, including the breakdown of how the funding would be spent consistent with the allowable uses as described in section III.G.5.d of this final rule and information about: (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings. ACOs must also include their communication strategy for informing both CMS and any impacted beneficiaries if the ACO will no longer be providing any direct beneficiary services (as described in section III.G.5.d of this final rule) that had previously been provided by the ACO using prepaid shared savings. This communication strategy must include when and how the ACO intends to notify CMS and the impacted beneficiaries, as well as any available alternatives for impacted beneficiaries to access similar services. ACOs would be able to limit the distribution of direct beneficiary services to subgroups of assigned beneficiaries including those with specific medical conditions or specific socioeconomic needs. ACOs would be required to attest that they will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings. ACOs would have flexibility to alter their use of prepaid shared savings from their submitted spend plans during each performance year but would be required to ensure than any changes to proposed spending aligns with the restrictions on spending discussed in section III.G.5.d of this final rule. CMS will review mid-year changes of the use of prepaid shared savings at the end of each performance year. CMS would also be able to review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of § 425.640(d) and (i).

As discussed in greater detail in section III.G.5.f of this final rule, we will reserve the right to withhold or terminate an ACO's ability to receive the prepaid shared savings if it is not in compliance with the requirements of the Shared Savings Program codified in part 425 of our regulations, under § 425.640(h)(1)(i). In addition, by

certifying the application under § 425.202(a)(2), the ACO certifies that the information contained in the application, including information related to the intended use of prepaid shared savings, is accurate, complete, and truthful.

We proposed at § 425.640(d) that we would review the information submitted in the ACO's prepaid shared savings application to determine whether an ACO meets the criteria for prepaid shared savings and would approve or deny the application accordingly. We will review the ACO's Shared Savings Program renewal application simultaneously with the prepaid shared savings application.

As discussed in section III.G.5.g of this final rule, we also proposed to update our public reporting requirements under § 425.308 by adding new paragraph (b)(10) to require an ACO to publicly report its spend plan. We proposed to require that the ACO post on its dedicated public reporting web page: (1) the total amount of prepaid shared savings received from CMS for each performance year; (2) the ACO's spend plan; and (3) an itemization of how the prepaid shared savings were actually spent during each performance year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries, and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under § 425.640(d)(2) (if applicable), and such other information as may be specified by CMS. Additionally, we proposed that the ACO would report the same information as indicated in the ACO's publicly reported spend plan to CMS under § 425.640(i) to facilitate efficient monitoring. This would help ensure that CMS efficiently obtains information in a consistent manner from all ACOs receiving prepaid shared savings and thereby support CMS's monitoring and analysis of the use of prepaid shared savings. CMS will also make this data publicly available through a public use file. Further, we expect to use the submitted data as the template that ACOs can use to populate their public reporting web page early in each performance year to minimize administrative burden for ACOs. We also intend to use the information submitted to CMS to generate a public use file that can be used to quickly review the use of prepaid shared savings across all participating ACOs.

We proposed to add § 425.640(c) and (d) to establish standards for the contents of an application to be determined eligible for prepaid shared savings as well as the procedures for filing such an application.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the inclusion of the prepaid shared savings payment option in the Shared Savings Program annual application process, noting that ACOs would be required to submit supplemental application information, including a spend plan detailing how the ACO intends to use prepaid shared savings. A few commenters encouraged CMS to publish application guidance in advance of the 2026 Medicare Shared Savings Program application cycle to give ample time for interested ACOs to prepare.

Response: We appreciate the commenters' support of our proposal to include the prepaid shared savings application as part of the Shared Savings Program application process. CMS intends to provide ACOs with additional guidance on applying to receive prepaid shared savings in advance of the 2026 Medicare Shared Savings Program application cycle in order to give ACOs time to prepare their spend plans and additional application materials.

Comment: A few commenters requested that CMS reconsider the current application requirement of a written spend plan, as it generates additional burden for ACOs. Commenters also suggested that ACOs not be required to include a line item breakdown of the investment of prepaid shared savings in their spend plans, and only report on total spending within the categories of infrastructure, staffing and direct beneficiary services as a way to reduce burden on ACOs.

Response: We understand that submitting a detailed spend plan on the use of prepaid shared savings requires administrative work for participating ACOs. However, detailed spend plans which include information on (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings are important for monitoring that ACOs use prepaid shared savings consistent with the requirements for use and management of prepaid shared savings under § 425.640(e). It is particularly important for us to ensure ACOs use prepaid shared savings consistent with those use and management requirements because prepaid shared savings are advances of shared savings to ACOs prior to ACOs actually earning the shared savings, and should be focused on improving beneficiary outcomes and quality of care, reducing costs, improving ACO efficiency, and improving beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. These requirements will also promote transparency in how ACOs are using prepaid shared savings. That transparency will improve the coordination and quality of care provided by participating ACOs by facilitating their efforts to share information with each other, CMS, and the public about how they effectively used prepaid shared savings to improve the quality and efficiency of the care they provided to their beneficiaries.

After consideration of public comments, we are finalizing the proposed prepaid shared savings application procedures under § 425.640(c) with modifications to allow ACOs that renewed to enter an agreement period beginning on January 1, 2025, the option to elect to participate in prepaid shared savings starting with performance year 2026 without renewing again (as described and for the reasons explained elsewhere in section III.G.5. of this final rule), among other changes. Specifically, within § 425.640(c)(1), we specify the application procedure for an ACO renewing to enter an agreement period beginning on January 1, 2026, or in subsequent years, in accordance with our proposal. That is, for an ACO renewing to enter an agreement period beginning on January 1, 2026, or in subsequent years to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program in the form and manner and by a deadline specified by CMS. The provision we are finalizing in paragraph (c)(1) of § 425.640 includes a modification to correctly reference the application procedures for renewing ACOs at § 425.224 instead of referencing § 425.202 (as proposed). Within § 425.640(c)(2), we specify, for an ACO that renewed to enter an agreement period beginning on January 1, 2025, to obtain a determination regarding

whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application for prepaid shared savings prior to the start of the performance year beginning on January 1, 2026, in the form and manner and by a deadline specified by CMS. We are also finalizing, without modifications, our proposal to specify in § 425.640(d) provisions on the content of the supplemental application ACOs will use to apply to participate in prepaid shared savings, as well as provisions on CMS' review of the supplemental application information. We discuss certain provisions of § 425.640(d) elsewhere in section III.G.5. of this final rule.

d. Allowable and Prohibited Uses of Prepaid Shared Savings

We proposed in § 425.640(e) to specify how an ACO may use prepaid shared savings. Similar to advance investment payments, prepaid shared savings are intended to improve quality and efficiency of items and services furnished to Medicare beneficiaries. In the CY 2025 PFS proposed rule (89 FR 61596, 61873), we recognized that there are many ways to do this, and that the most effective ways would vary by ACO. Our proposal intended to provide ACOs with flexibility to use payments consistent with broad allowable uses. However, as prepaid shared savings would only be available to ACOs that are currently successfully participating in the Shared Savings Program, we stated that we intended to place restrictions on the amount of total annual prepaid shared savings that could be spent on each category of spending. Financially successful ACOs are likely to have already made significant investments in staffing and healthcare infrastructure, as they are necessary for the functioning of an ACO, and we stated that we intended to encourage ACOs receiving prepaid shared savings to invest in direct beneficiary services that are not already offered by the ACO. Direct beneficiary services like vision, hearing and dental, and other services that have a reasonable expectation of improving or maintaining the health or overall function of ACO beneficiaries have the potential to further improve beneficiary outcomes, reduce costs, and improve beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. However, staffing and healthcare infrastructure are still important expenses that can have positive impacts on healthcare costs, ACO efficiency, and the quality of beneficiary care, regardless of an ACO's experience in the Shared Savings Program. Accordingly, we also explained that we intended to allow ACOs to use some of their prepaid shared savings to invest in these areas. For each performance year, ACOs would be permitted to use up to 50 percent of their estimated annual prepaid shared savings on staffing and healthcare infrastructure and up to 100 percent of their estimated annual prepaid shared savings on direct beneficiary services. ACOs would be required to use a minimum of 50 percent of their prepaid shared savings on direct beneficiary services.

We note that under our proposal, an ACO may use prepaid shared savings for staffing, healthcare infrastructure and direct beneficiary services in a manner that complies with the beneficiary incentives provision at § 425.304(a), (b), and newly proposed (d) as discussed in section III.G.5.i of this final rule, and all other applicable laws and regulations. Permitted uses for ''staffing and healthcare infrastructure'' include but are not limited to the following:

- *Staffing.* Examples could include, but are not limited to, hiring physicians, physicians' assistants, nurse practitioners, clinical nurse specialists, nutrition professionals, case managers, licensed clinical social workers, community health workers, patient navigators, health equity officers, psychiatrists, clinical psychologists, therapists, mental health counselors, licensed professional counselors, substance use counselors, peer support specialists, and other behavioral health clinicians, or staff education.
- *Healthcare Infrastructure:* Examples could include, but are not limited to, investments in or improvements to existing case or practice management systems, clinical data registries, electronic quality reporting, health information exchange participation, certified electronic health record technology (CEHRT), health IT to support behavioral health or dental services, IT-enabled screening tools, closed-loop referral tools, audiovisual interpreter technology, or practice physical accessibility improvements. Investments could be made for individual ACO providers/suppliers (as defined in § 425.20) or ACO wide.
- Direct beneficiary services include in-kind items or services provided to an ACO beneficiary that are not otherwise covered by Traditional Medicare but are evidence-based and medically appropriate for the beneficiary based on clinical and social risk factors. Direct beneficiary services can also include cost sharing support including the reduction of beneficiary copay or deductibles for Traditional Medicare beneficiaries. In advance of the application deadline for agreement periods beginning on January 1, 2026, we intend to release additional guidance with more specific information about permitted uses of funding for direct beneficiary services. Permitted uses for direct beneficiary services could include, but are not limited to the following: beneficiary meals, nutrition support, tenancy support and sustaining services, caregiver support services, services to address social isolation, home visits, transportation services, home or environmental modifications like air conditioners, bathroom safety devices, personal emergency response systems or medical alert systems, and vision, hearing or dental care directly provided by ACO providers/suppliers (as defined in § 425.20) or covered under a health insurance plan purchased by the ACO on behalf of the beneficiary. While some of these services are covered in some form by Traditional Medicare, prepaid shared savings funding reserved for direct beneficiary services would only be permitted to be used for those services if the version of the service offered by the ACO is not currently covered by Traditional Medicare and they are evidence-based and medically appropriate for the beneficiary based on clinical and social risk factors. For example, some types of home visits are covered by Traditional Medicare, but an ACO would be able to extend the number of home visits offered to beneficiaries beyond the number covered by Traditional Medicare with prepaid shared savings. Direct beneficiary services would also include cost-sharing support, including the reduction of beneficiary copay or deductibles for Traditional Medicare beneficiaries for Part B primary care services. ACOs would be able to provide cost-sharing support for primary care services (as defined in § 425.20) with respect to which coinsurance applies under Part B.

As discussed in section III.G.5.i of this final rule, we stated that we expect to make a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect direct beneficiary services that are made in compliance with this policy and the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(2). As noted earlier in this rule, ACOs that wish to provide direct beneficiary services to beneficiaries through prepaid shared savings will need to submit a spend plan with information including the

groups of beneficiaries they intend to provide direct beneficiary services, how the direct beneficiary services will be provided to beneficiaries and how such services support the care of beneficiaries, and attest that they will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to how they propose to spend prepaid shared savings. As proposed, ACOs will also be required to report their actual use of prepaid shared savings after the end of each performance year, including which groups of beneficiaries received direct beneficiary services, how such services were provided to beneficiaries, and how these services supported the care of beneficiaries.

Many direct beneficiary services may be provided by staff working for an ACO or its participating providers or suppliers. If a staff member is hired or directed to provide these services, ACOs may use dollars designated for direct beneficiary services to cover the percentage of their salary that aligns with the percentage of time the staff member spends providing direct beneficiary services that are not otherwise covered by Traditional Medicare. This funding may also be used to contract with a community-based organization (CBO) or other external entity to pay their staff to provide direct beneficiary services. Additionally, ACOs should take care to ensure that a direct beneficiary service that is provided to a beneficiary does not impact other Federal, State, or local means-tested benefits a beneficiary is already receiving, and ACOs should provide beneficiaries with any necessary documentation regarding their receipt of the direct beneficiary service. CMS will include additional information in later guidance regarding the approved uses for direct beneficiary services and potential impacts on beneficiary eligibility for other Federal means-tested programs.

We proposed at § 425.640(e)(2) that an ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1). Prohibited uses of prepaid shared savings would include management company or parent company profit, performance bonuses, provision of medical services covered by Traditional Medicare, cash or cash equivalent payments to beneficiaries, and items or activities unrelated to the management and operations of an ACO or care of beneficiaries. Similar to advance investment payments, prepaid shared savings are intended to help an ACO put care processes in place to directly care for the unique needs of the ACO's beneficiary population, not to solely increase profits or to be spent on items unrelated to the management and operations of the ACO or the beneficiaries it serves. Additionally, we proposed that an ACO participating in Levels C–E of the BASIC track or the ENHANCED track may not use any prepaid shared savings to pay back any shared losses that it would have incurred as specified in a written notice from CMS under § 425.605(e)(2) or § 425.610(h)(2), respectively.

To the extent that an ACO is addressing unmet social needs, including food insecurity and transportation problems, through direct beneficiary services, we encourage ACOs to coordinate with a community-based organization (''CBO'') to provide these services. As explained in the CY 2023 PFS proposed rule (87 FR 46102), where we refer to CBO, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, or other non-profits that apply for grants to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Center for Disease Control and Prevention (CDC), Administration for Children and Families (ACF), Administration for Community Living (ACL), or other Federal or State funded grants to provide social services.

Generally, such organizations know the populations they serve and their communities and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health (''SDOH'') or serve as a source from which ACOs can receive information regarding community needs. Because CBOs have developed such an expertise, it would be impactful for ACOs in the delivery of high-quality direct beneficiary services to contract with CBOs in the provision of these services. CMS further encourages ACOs to work with community care hubs, which are community-focused entities supporting a network of CBOs that provide services addressing health-related social needs and centralize administrative functions and operational infrastructure. Working directly with a community care hub can help connect the ACO with multiple smaller CBOs in the provision of direct beneficiary services. If an ACO works with a CBO to provide these types of services and this is reflected in its plan to address the needs of its population, we would consider them to be in compliance with the requirement at § 425.112(b)(2)(iii)(A), which requires an ACO to, in its plan to address the needs of its population, describe how it intends to partner with community stakeholders to improve the health of its population.

We also proposed in § 425.640(f)(6) to allow ACOs receiving prepaid shared savings to request a smaller quarterly payment amount from CMS. For example, if an ACO is eligible for a maximum quarterly prepaid shared savings amount of one million dollars, we would estimate their annual prepaid shared savings to be four million dollars. This allows the ACO to spend up to two million dollars on staffing and healthcare infrastructure and up to their full $4 million payment amount on direct beneficiary services. However, the ACO may request a lower quarterly payment of $500,000 that results in the ACO only receiving two million dollars over the full performance year. This would also reduce the amount the ACO can spend on staffing and healthcare infrastructure, as an ACO may not spend more than 50 percent of the prepaid shared savings received on staffing and healthcare infrastructure. In the event that CMS stops or reduces an ACO's quarterly payments during the performance year below the quarterly payment amount previously requested by the ACO, the reduction does not impact the total maximum amount the ACO is permitted to spend on each category of allowable uses identified at the start of each year, as it would not be appropriate to subject the ACO to mid-year spend plan changes when it may have entered into contracting or other arrangements with staff or suppliers which could impact continuity of care. We would monitor how ACOs are spending these funds and, as necessary, revisit these guidelines in future rulemaking if changes are required.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters agreed that earlier payment of shared savings would help fund ACO initiatives throughout the performance year. Commenters also appreciated CMS' definition of direct beneficiary services as ''in-kind items or services provided to an ACO beneficiary that are not otherwise covered by traditional Medicare but have a reasonable expectation of improving or maintaining the health or overall function of ACO beneficiaries,'' and believe that interpreting ''direct beneficiary

services'' in this manner will help improve beneficiary care. A few commenters specifically supported that the portion of our proposed permitted uses policy allowing ACOs to provide Part B cost sharing support and other services to improve access to quality care for beneficiaries.

Response: We agree with commenters and appreciate their support for the implementation of the prepaid shared savings payment option, including its permitted uses. We note that we have revised the definition of direct beneficiary services to include: in-kind items or services provided to an ACO beneficiary that are not otherwise covered by Traditional Medicare but are evidence-based and medically appropriate for the beneficiary based on clinical and social risk factors. We believe this definition will more appropriately direct funding towards improving beneficiary care and reduce potential impact on any other means-tested benefits a beneficiary may receive.

Comment: Many commenters asserted that the restrictions on the use of prepaid shared savings are unnecessary and likely to negatively impact ACO participation in prepaid shared savings, including by disproportionally discouraging ACOs with the least access to resources from participating. Commenters asked for more flexibility in using prepaid shared savings. Most disagreed with the requirement that ACOs spend at least 50 percent of prepaid shared savings on direct beneficiary services. Some urged CMS to not require a specified minimum amount that must be spent on direct beneficiary services. A few commenters opposed the requirement that ACOs calculate a percentage of staff time spent on ''providing direct beneficiary services that are not otherwise covered by Traditional Medicare'' as unnecessarily burdensome. Other commenters contended that this requirement would take away from the shared savings dollars that ACOs distribute directly to ACO participants, which is a major incentive for ACO participants to join or form ACOs. Some commenters noted they believe that ACOs are best positioned to determine the appropriate use of prepaid shared savings and the level of investment needed toward infrastructure, staffing, and direct beneficiary services.

Response: We understand that commenters would like additional flexibility with respect to the use of prepaid shared savings and that these restrictions may reduce the number of ACOs that ultimately decide to participate in prepaid shared savings. However, the prepaid shared savings policy was developed to improve the quality and efficiency of items and services furnished to Medicare beneficiaries and help close gaps in health equity. The requirement that ACOs spend at least 50 percent of their prepaid shared savings on direct beneficiary services is important for meeting those goals. Direct beneficiary services like vision, hearing and dental, and other services that are evidence-based and medically appropriate for the beneficiary based on clinical and social risk factors, have the potential to improve beneficiary health outcomes, reduce costs, and improve beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. Financially successful ACOs are likely to have already made significant investments in staffing and healthcare infrastructure, as they are necessary for the functioning of an ACO. The restriction on using prepaid shared savings for provider bonuses, in particular, is important for ensuring that prepaid shared savings are used for expenses that directly improve beneficiary care.

We note that participation in prepaid shared savings is voluntary, and an ACO is able to request to receive less than the full amount of prepaid shared savings it is eligible to receive. The limits on the use of prepaid shared savings do not apply to shared savings paid by CMS at financial reconciliation. If an ACO believes it is important to distribute earned shared savings to ACO participants in order to encourage participation in the ACO, it may do so. Each ACO is well-positioned to make its own decisions about the use of its shared savings, both prepaid and earned, and we understand that the permitted uses of prepaid shared savings may not align with the current financial strategy of some ACOs.

Additionally, many direct beneficiary services may be provided by staff working for an ACO or its participating providers or suppliers. As we explained in the CY 2025 PFS proposed rule (89 FR 61596, 61874), if a staff member is hired or directed to provide these services, ACOs may, but are not required to, use dollars designated for direct beneficiary services to cover the percentage of their salary that aligns with the percentage of time the staff member spends ''providing direct beneficiary services that are not otherwise covered by Traditional Medicare,'' instead of fully including those staff expenses under the ''staffing'' category, where ACOs are limited in their ability to use prepaid savings. We understand that ACO staff may split time between multiple functions and proposed this aspect of our permitted uses criteria partly to make it easier for ACOs to categorize and account for the staff time necessary to provide direct beneficiary services not otherwise covered by Traditional Medicare while meeting the requirement that they spend at least 50 percent of their funding on direct beneficiary services.

Comment: Several commenters expressed concern with CMS' proposal to require at least 50 percent of prepaid shared savings be spent on direct beneficiary services not otherwise payable in Traditional Medicare, because they believe it puts doctors in the direct role of supplying insurance benefits to Medicare recipients, akin to serving as a Medicare Advantage plan. A commenter stated that money spent on provision of direct beneficiary services should not be subject to repayment to CMS if the ACO fails to earn sufficient shared savings, and ACOs and participating providers should work within their communities to connect beneficiaries with such services rather than be required to supply supplemental benefits via prepaid shared savings. A commenter also suggested that CMS find more direct ways to expand health insurance benefits available to beneficiaries, including working with Congress to develop Traditional Medicare benefits that better compete with options offered by Medicare Advantage plans.

Response: We disagree with commenters that using prepaid shared savings to pay for direct beneficiary services places providers in a role akin to a health insurer. Prepaid shared savings are an estimate of the shared savings an ACO may earn each performance year, and ACOs may use their earned shared savings to furnish additional services for their beneficiaries, including direct beneficiary services. The prepaid shared savings payment option merely changes the timing of CMS paying a portion of those savings to ACOs that elect this payment option. Participation in this payment option is voluntary, and ACOs control the amount of prepaid shared savings they request to receive, under the maximum amount calculated by CMS, and therefore how much of that funding must be invested into direct beneficiary services under § 425.640(e)(1)(ii). Additionally, as we explained in the proposed rule (89 FR 61870–61871), we are obligated to protect the Medicare Trust Funds, and this policy relies on the authority provided to the Secretary by section 1899(i)(3) of the Act. To protect the Medicare Trust Funds and maintain

compliance with section 1899(i)(3) of the Act, we determined that it would be appropriate for CMS to recoup all prepaid shared savings that ACOs receive, including those spent on direct beneficiary services.

We agree with the commenter that ACOs and providers should work within their communities to connect beneficiaries with currently available resources, including direct beneficiary services that those beneficiaries may need. As explained earlier in this section of this final rule, we also note that ACO staff time used to connect beneficiaries with direct beneficiary services resources in their communities could be paid for with prepaid shared savings under the direct beneficiary services spending category. Additionally, ACOs can contract with CBOs using prepaid shared savings to provide direct beneficiary services, which CMS would encourage because in many instances CBOs have the most experience providing these services that are not otherwise payable by Traditional Medicare. CMS remains interested in working with and hearing from interested parties on ways to improve the care and benefits that beneficiaries receive.

Comment: A few commenters noted concerns with the implementation of direct beneficiary services. One commenter expressed support for policies that increase access to direct beneficiary services for dually eligible beneficiaries (beneficiaries eligible for Medicare and Medicaid) but noted concern about the lack of coordination between the Shared Savings Program and other State and Federal programs, such as Medicaid, and identified possible unintended consequences of reducing the incentive for dually eligible beneficiaries to enroll or remain enrolled in an integrated dual eligible special needs plan (D–SNP). The commenter argued that poor coordination of economic and health related programs will cause significant confusion among beneficiaries and providers, which may result in healthcare access issues for beneficiaries. In addition, the commenter contended that because direct beneficiary services are not payable under Traditional Medicare Part A or B, direct beneficiary services would not be subject to the Medicare appeals process, which may cause additional confusion for beneficiaries if they only receive a direct beneficiary service from a provider associated with an ACO for a limited period of time and believe they should continue to receive the service. The commenter encouraged CMS to provide further clarification on the proposed policies and to provide guidance to providers and beneficiaries on the interaction of direct beneficiary services and services covered by other payers, such as Medicaid. Another commenter suggested that CMS monitor how ACOs use prepaid shared savings on direct beneficiary services.

Response: We appreciate commenters raising this concern. D–SNPs play an important role in serving the special needs of some dual eligible beneficiaries. We agree that beneficiaries, including dually eligible beneficiaries, may find direct beneficiary services attractive We designed the standards governing the use of prepaid shared savings to ensure that the funds are used to improve the quality and effectiveness of beneficiary care while providing ACOs with the flexibility to experiment and determine which direct beneficiary services are most appropriate to offer to their assigned beneficiaries. However, as discussed in the proposed rule (89 FR 61874), ACOs should ensure the direct beneficiary services distributed to beneficiaries do not impact other means-tested benefits received by a beneficiary under Federal, State, or local means-tested programs. This includes benefits received through State Medicaid programs. ACOs should familiarize themselves with the means-tested benefits that their beneficiaries receive under Federal, State, or local means-tested programs, including their eligibility requirements. CMS provides quarterly lists to ACOs with information about beneficiaries including their State of residence and enrollment in Medicaid, which can be used to support this effort. Additionally, under § 425.640(d)(2)(iv), ACOs would be responsible for notifying beneficiaries if a direct beneficiary service supplied by the ACO will no longer be available. ACOs must also share information with the impacted beneficiaries about any available alternatives for accessing similar services (89 FR 61873). ACOs should take care to avoid disrupting current care arrangements if they are not confident they will be able to provide direct beneficiary services to a beneficiary consistently. CMS intends to issue additional guidance to ACOs to support them in avoiding conflicts between their provision of direct beneficiary services and the means-tested benefits received by their beneficiaries under Federal, State, or local means-tested programs.

We have also revised the definition of direct beneficiary services and removed some examples of direct beneficiary services to reduce potential impact on other means-tested benefits a beneficiary may receive.

As both CMS and ACOs gain more experience with prepaid shared savings, we may reexamine these standards. To aid this process, ACOs are required to publicly report their use of prepaid shared savings under § 425.308(b)(10), and CMS will be publicly sharing files with all ACO usage of prepaid shared savings. We appreciate commenters' feedback on how to improve communication in these areas to reduce beneficiary and provider confusion and will consider it in future rulemaking.

Comment: A few commenters asked for clarification on the use of prepaid shared savings, specifically about ''fitness benefits'' that encourage physical activity for beneficiaries and whether prepaid shared savings could be used to support CBO efforts to build infrastructure that will allow them to collaborate with ACOs to effectively provide direct beneficiary services.

Response: CMS appreciates these requests for clarification. ''Fitness benefits'' for beneficiaries could be covered as a direct beneficiary service if the benefit is not otherwise covered by Traditional Medicare and are evidence-based and medically appropriate for the beneficiary based on clinical and social risk factors. Additionally, spending prepaid shared savings to support development of CBO infrastructure that will allow them to collaborate with ACOs could be covered under multiple prepaid shared savings permitted use categories, depending on the type of infrastructure assistance needed and the type of services provided by the CBO.

We intend to release additional guidance with more specific information about permitted uses of funding for direct beneficiary services before the application cycle for Performance Year 2026.

After consideration of public comments, we are finalizing the policy on the use and management prepaid shared savings as proposed, and as specified in new § 425.640(e). This includes the requirement that ACOs spend to up to 50 percent of their estimated annual prepaid shared savings on staffing and healthcare infrastructure and up to 100 percent, but not less than 50 percent, of their estimated annual prepaid shared savings on direct beneficiary services. We have also revised the definition of direct beneficiary services in the preamble text to reduce potential impact on any other means-tested benefits a beneficiary may receive.

e. Calculation of Prepaid Shared Savings

As noted in section III.G.5.a of this final rule, we have determined that prepaid shared savings would not result in additional program expenditures. While ACOs will be required to repay the prepaid shared savings they receive through earned shared savings, it is also important for CMS to avoid paying ACOs an amount of prepaid shared savings that they are unlikely to be able to repay through earned shared savings. While prepaid shared savings will be helpful in providing successful ACOs with additional cash flow that would encourage their investment in activities that could potentially reduce ACOs' costs and improve the quality of care that ACOs provide to their beneficiaries, overpaying ACOs might result in a level of outstanding debt for some ACOs that could disrupt their operations and potentially their participation in the Shared Savings Program as well as generate unnecessary financial risk for CMS. Our proposed policies on the calculation and distribution of prepaid shared savings payments are intended to balance the benefit for the ACOs of receiving funding earlier with the risk of overpayment both for CMS and the ACO, while helping to ensure that prepaid shared savings do not result in additional program expenditures.

We proposed a new § 425.640(f) to provide an ACO that CMS determines meets the eligibility criteria described in section III.G.5.b of this final rule with a prepaid shared savings payment for each quarter of an agreement period that they are determined to be eligible for prepaid shared savings equal to the maximum quarterly payment amount calculated pursuant to the methodology outlined in § 425.640(f)(2) (as further explained elsewhere in this section), unless the ACO elects to receive a lesser amount as described in § 425.640(f)(6) (as further explained in section III.G.5.d. of this final rule) or the payment is withheld or terminated under § 425.640(h). If an ACO's quarterly payment is withheld or terminated (as further explained in section III.G.5.f.(2) of this final rule), we will not provide ACOs with additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed. We proposed that under new § 425.640(f), CMS will notify in writing each ACO of its determination of the amount of prepaid shared savings. The notice would inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of our regulations. If CMS does not make any prepaid shared savings payments, the notice would specify the reason(s) why and inform the ACO of its right to request reconsideration review in accordance with the standards specified in subpart I of our regulations. Thus, prior to each quarterly payment, we propose to provide the ACO with the notice described above in the form of a report that shows our calculation of the ACO's quarterly prepaid shared savings amount. We proposed to coincide the timing of these notices with the timing of existing report packages sent to ACOs for informational purposes, in December (after initial assignment prior to a given performance year), May (after quarter 1 assignment for a given performance year), and August (after quarter 2 assignment for a given performance year). Accordingly, notice regarding the first and second quarterly payments that an eligible ACO would receive in a given performance year would be provided in December of the immediately preceding year. Subsequent notices regarding the third and fourth quarterly payments that an eligible ACO would receive in a given performance year would then be provided in May and August, respectively, of that performance year.

We also proposed a new § 425.640(f)(2) to specify the calculation of an ACO's maximum quarterly prepaid shared savings payment. To calculate this payment, we proposed calculating a prepaid shared savings multiplier, adjusting it by several factors explained later in this section, and then multiplying one-fourth of the adjusted multiplier by an ACO's assigned beneficiary person years. We proposed to calculate the prepaid shared savings multiplier as the simple average of per capita savings or losses generated by the ACO during the two most recent performance years that have been financially reconciled at the time of the ACO's renewal application disposition, which constitute benchmark year (BY) 1 and BY2 of the agreement period in which the ACO may receive prepaid shared savings (''current agreement period,'' hereafter). That is, we would exclude BY3 from the calculation of an ACO's average per capita savings or losses because the performance year that constitutes BY3 of the ACO's current agreement period would not have been financially reconciled at the time of the ACO's application disposition. Accordingly, the per capita savings for each performance year would be determined as the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. For purposes of calculating the simple average of per capita savings or losses generated by the ACO during the two most recent performance years that have been financially reconciled, we would use all savings generated during each of the 2 performance years in the prepaid shared savings multiplier, not just savings that met or exceeded the ACO's minimum savings rate (MSR) for that prior performance year.

Under new § 425.640(f)(2)(iii), we proposed to apply a proration factor to the prepaid shared savings multiplier to account for situations where an ACO's assigned beneficiary population is larger in BY1 and BY2 when calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, as compared to the ACO's assigned beneficiary population when the ACO was reconciled for the performance years that constitute BY1 and BY2 of the current agreement period. Mathematically, to apply this proration factor we would calculate the ratio between: (1) the ACO's average assigned beneficiary person years for the 2 performance years that constitute BY1 and BY2 for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods, which would occur if the ACO early renews immediately before the current agreement period) and (2) the average assigned beneficiary person years in BY1 and BY2 for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period. Increases in the size of the ACO's assigned beneficiary population during the current agreement period would therefore result in a ratio less than 1, while decreases in the assigned beneficiary population would result in a ratio greater than 1. This ratio would be capped at 1 to avoid increasing the adjusted prepaid shared savings multiplier if the average number of beneficiaries assigned to the ACO across the 2 benchmark years of its current agreement period is lower than the average number of beneficiaries assigned during the 2 performance years that constitute BY1 and BY2. Prorating for growth in assignment would ensure that the prepaid shared savings amount does not exceed the amount of cumulative savings generated by the ACO during the performance years that constitute BY1 and BY2 for its current agreement period.

It is necessary to calculate a proration factor at the start of the ACO's current agreement period to account for several

possible circumstances in which the ACO's assigned beneficiary population may be different in BY1 and BY2 when calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, as compared to the ACO's assigned beneficiary population when the ACO was reconciled for the performance years that constitute BY1 and BY2 of the current agreement period. Specifically, changes in the size of the ACO's assigned beneficiary population at the start of the ACO's current agreement period could be due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E.

Additionally, these circumstances could potentially arise after the start of the ACO's current agreement period. In turn, changes in the size of the ACO's assigned beneficiary population could potentially occur throughout the course of the current agreement period. Therefore, we proposed in new § 425.640(f)(3)(ii) that for the second and each subsequent performance year during the term of the current agreement period, we would redetermine this proration factor.

In addition to pro-rating the prepaid shared savings multiplier, we also proposed to adjust it in two ways. First, under new § 425.640(f)(2)(iv), we will apply a sharing rate scaling factor of ½ (or 50 percent). This sharing rate scaling factor would be similar to the scaling factor we apply under § 425.658(c)(1)(i) when calculating the prior savings adjustment, applicable to agreement periods beginning on or after January 1, 2024, as finalized in the CY 2023 final rule (refer to 87 FR 69899 through 69915). As with the prior savings adjustment calculation, it is important to consider a measure of the sharing rate used in determining the shared savings payment the ACO earned in the applicable performance years under the agreement period immediately before it would receive prepaid shared savings. Consistent with the prior savings adjustment scaling factor, 50 percent represents an appropriate multiplier in this context because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track.

Second, under new § 425.640(f)(2)(v)(A), we will apply a financial risk scaling factor equal to ⅔. The purpose of the financial risk scaling factor would be to mitigate financial risk to the Medicare Trust Funds and to ACOs by reducing the possibility that an ACO's prepaid shared savings payments exceed the ACO's actual earned shared savings. The rationale for a financial risk scaling factor of this magnitude is that it enables us to account for a scenario in which an ACO earned zero per capita savings in the performance year that constitutes BY3 of the current agreement period, which is necessarily excluded from the calculation of an ACO's average per capita savings or losses for purposes of the prepaid shared savings multiplier because, as mentioned previously, the performance year that constitutes BY3 of the ACO's current agreement period will not have been financially reconciled at the time of the ACO's application disposition. Thus, by multiplying an ACO's average per capita savings or losses across BY1 and BY2 by a financial risk scaling factor equal to ⅔, we would impose a downward reduction on the prepaid shared savings multiplier by assuming that it would have been possible, in principle, for an ACO to have not earned any per capita savings in the performance year that constitutes BY3 of the current agreement period. By doing so, we are reducing the probability of distributing excessive prepaid shared savings. As discussed previously, it is important to avoid distribution of excessive prepaid shared savings because doing so could result in several undesirable outcomes, such as ACOs accruing debt to CMS that they are unable to repay, which could disruption the ACOs' operations and participation in the Shared Savings Program.

Consistent with calculations of the prior savings adjustment (refer to § 425.658), the positive regional adjustment (refer to § 425.656), and the proposed health equity benchmark adjustment (refer to section III.G.7.b of this final rule), we proposed under new § 425.640(f)(2)(v)(B), to cap the pro-rated, adjusted prepaid shared savings multiplier at 5 percent of national per capita FFS expenditures for Parts A and B services in order to ensure that the amount of prepaid shared savings that an ACO receives does not exceed an amount that the ACO is able to repay through earned shared savings. Specifically, we proposed to calculate the cap as 5 percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2. Consequently, under new § 425.640(f)(2)(v), the pro-rated, adjusted, and capped prepaid shared savings multiplier that would ultimately be used to calculate a given maximum quarterly prepaid shared savings payment would be equal to the lesser of (A) the pro-rated, adjusted prepaid shared savings multiplier or (B) 5 percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries.

To calculate a given maximum quarterly prepaid shared savings payment, we proposed under new § 425.640(f)(4), to multiply one-fourth of the pro-rated, adjusted, and capped prepaid shared savings multiplier (to account for four quarterly payments) by the ACO's assigned beneficiary person years for the latest available assignment list for a given performance year within the current agreement period. Varying the maximum quarterly payment to reflect the latest available assigned beneficiary person years is similar to how we calculate the AIP quarterly payment calculation (refer to § 425.630(f), CY 2023 PFS final rule (87 FR 69797)), for which we use the latest available assignment list to calculate the quarterly advance investment payment amount. We proposed to use the latest available beneficiary assigned person years for the maximum quarterly prepaid shared savings payment because an ACO's assigned beneficiary person years change over the course of a performance year and over the course of an agreement period. Because later assignment lists more closely reflect the final assignment list that will be used for calculating shared savings and losses for a given performance year within the current agreement period, later assignment lists are more likely than earlier assignment lists to facilitate calculation of quarterly prepaid shared savings payment amounts that closely align with the earned shared savings or losses that an ACO actually generates in the contemporaneous performance year. Using the latest available assigned beneficiary person years mitigates a financial risk that an ACO experiencing declining person years over the course of a performance year could receive excessive prepaid shared savings. As mentioned previously, overpaying prepaid shared savings could result in ACOs accruing a level of debt to CMS that they are unable to repay through earned shared savings which could, in turn, disrupt ACOs' operations and participation in the Shared Savings Program.

We proposed to use assigned beneficiary person year values that CMS provides to ACOs in annual and quarterly informational reports. For

ACOs under preliminary prospective assignment with retrospective reconciliation, Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on the most recent data available (§ 425.400(a)(2)(i)). Assignment is updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described in §§ 425.402 and 425.404 (§ 425.400(a)(2)(ii)). ACOs under preliminary prospective assignment with retrospective reconciliation receive an assigned beneficiary person years value based on the most recent 12 or 24 months of data, as applicable, in annual and quarterly informational reports. For ACOs under prospective assignment, Medicare FFS beneficiaries are prospectively assigned to an ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described in §§ 425.402 and 425.404 (§ 425.400(a)(3)(i)). Each quarter, CMS excludes any prospectively assigned beneficiaries that meet the exclusion criteria under § 425.401(b). ACOs under prospective assignment receive a year-to-date assigned beneficiary person years value with each quarterly report package. For ACOs under prospective assignment, we would annualize the quarterly year-to-date assigned beneficiary person years values for use in the maximum quarterly prepaid shared savings payment calculation. For example, a year-to-date person years value of 1,500 with quarter 1 informational reports would be annualized by multiplying 1,500 by 4. A year-to-date person years value of 3,000 with quarter 2 information reports would be annualized by multiplying 3,000 by 2.

We further proposed to account for circumstances when an ACO was not reconciled for the performance year that constitutes BY1 in the calculation of average per capita prior savings and the proration factor. For instance, ACOs that renew their agreement periods early or are re-entering may not be reconciled for one or more of the years preceding the start of their current agreement period depending upon the timing of the expiration or termination of their prior agreement period and the start of their current agreement period. We proposed under new § 425.640(f)(2)(i), that if an ACO was not reconciled during one of the 2 performance years that constitute BY1 or BY2 of its current agreement period, the ACO would receive zero savings or losses for the BY corresponding to the performance year that was not financially reconciled in the calculation of the prepaid shared savings multiplier. CMS has no way to determine whether the ACO would have generated savings or losses during a performance year for which it was not reconciled. We believe this is appropriate because it enables us to obtain a more conservative prediction of the ACO's financial performance for a given performance year within the current agreement period than we will be able to obtain if we were to exclude the BY corresponding to the performance year that was not financially reconciled from the calculation of the prepaid shared savings multiplier. Excluding this year entirely from the calculation of average per capita prior savings would unduly increase the weight on the other year included in the prepaid shared savings multiplier calculation. This would be problematic in a case where the ACO's financial performance in the BY corresponding to the performance year that was financially reconciled is atypically high because it would upwardly bias the prediction of the ACO's financial performance for a given performance year within the current agreement period. Thus, by imputing zero savings or losses for a BY corresponding to a performance year that was not financially reconciled in the calculation of the prepaid shared savings multiplier, we are reducing the probability of overpredicting the financial performance of the ACO for a given performance year within the current agreement period and, in turn, the probability of distributing excessive prepaid shared savings. As mentioned previously, excessive distribution of prepaid shared savings could result in several undesirable outcomes, such as ACOs accruing debt to CMS that they are unable to repay, which could disrupt the ACOs' operations and participation in the Shared Savings Program.

In contrast, we determined that it would also be appropriate to exclude a year for which the ACO was not reconciled when calculating the proration factor. The purpose of the proration factor is to account for situations where an ACO's assigned beneficiary population calculated at financial reconciliation for the 2 performance years that constitute BY1 and BY2 of the ACO's current agreement period (numerator) is smaller than the ACO's assigned beneficiary population identified for those same years using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period (denominator). If an ACO was not reconciled for one of the 2 performance years that constitute BY1 and BY2 of the current agreement period, it would naturally have zero assigned beneficiary person years determined at financial reconciliation for such year, which would factor into the numerator of the proration factor if such year was considered. However, the ACO would have positive beneficiary counts in the 2 performance years that constitute BY1 and BY2 of the current agreement period generated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, which would factor into the denominator of the proration factor if such year was considered. Thus, if the numerator and the denominator were both calculated as averages over 2 years, incorporating a year for which the ACO was not reconciled in the calculation of the proration factor would artificially decrease the proration factor and lead to a smaller pro-rated average per capita prior savings for the ACO. Alternatively, if the numerator were calculated in a manner that excludes a performance year for which the ACO was not reconciled (that is, calculated in a manner that includes only the year for which the ACO was reconciled from among the 2 performance years that constitute BY1 and BY2 of the current agreement period) and the denominator was calculated as an average that included both of the 2 performance years that constitute BY1 and BY2 of the current agreement period, then the direction of the impact on the proration factor would depend on whether the number of assigned beneficiaries calculated using an ACO's current certified ACO participant list and assignment methodology in the benchmark year for which the ACO was not reconciled exceeds the number of assigned beneficiaries in the other benchmark year, and by how much. Therefore, we see no compelling reason to include a performance year immediately preceding the start of an ACO's current agreement period for which the ACO was not reconciled in the numerator or the denominator of the proration factor. Excluding such a year would ensure that the proration factor compares average person years determined for prior performance years at financial reconciliation (numerator) to average person years for those performance years determined using the ACO's current certified ACO participant

list and assignment methodology (denominator) across a consistent set of years preceding the start of the ACO's current agreement period.

We also proposed to account for certain circumstances where there could be changes to the values used in calculating the prepaid shared savings multiplier as a result of issuance of a revised initial determination of financial performance under § 425.315.

To account for these situations and for the need to recalculate the proration factor as described elsewhere in this section, we proposed to specify in new § 425.640(f)(3) when CMS would recalculate the prepaid shared savings multiplier during the current agreement period. For the first performance year in the current agreement period, the ACO's prepaid shared savings multiplier will be recalculated for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the current agreement period, the ACO's prepaid shared savings multiplier will be recalculated due to redetermining the proration factor for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years that constitute BY1 or BY2 and that are used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315.

The specific computations involved in arriving at the maximum prepaid shared savings payment amount for a given ACO in a given quarter are described below.

- *Step 1:* Calculate a prepaid shared savings multiplier as the average per capita savings across the performance years that constitute BY1 and BY2 of the ACO's current agreement period. First, calculate the total per capita savings amount for each applicable performance year by subtracting assigned beneficiary expenditures from total benchmark expenditures and divide the difference by assigned beneficiary person years. Then, sum the resulting quotients and divide by 2. The per capita savings or losses would be set to zero for a performance year if the ACO was not reconciled for the performance year.
- *Step 2:* Apply a proration factor to the prepaid shared savings multiplier calculated in Step 1. The proration factor is equal to the ratio of the ACO's average assigned beneficiary person years for the 2 performance years that constitute BY1 and BY2 for the ACO's current agreement period (regardless of whether these performance years occurred over one or multiple prior agreement periods) and the ACO's average assigned beneficiary person years in BY1 and BY2 for the ACO's current agreement period calculated using the ACO's certified ACO participant list and assignment methodology for a given performance year within the current agreement period, capped at one. If the ACO was not reconciled for the performance year that constitutes BY1, the person years from that year (or years) will be excluded from the averages in the numerator and the denominator of this ratio. This ratio will be redetermined for each performance year during the agreement period in the event of any changes to the number of average person years in the benchmark years as a result of changes to the ACO's certified ACO participant list, a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E.
- *Step 3:* Adjust the pro-rated prepaid shared savings multiplier calculated in Step 2. First, apply a shared savings scaling factor by multiplying the pro-rated prepaid shared savings multiplier by 0.50. Then, multiply the resulting value by ⅔ to apply a financial risk scaling factor.
- *Step 4:* Cap the pro-rated, adjusted prepaid shared savings multiplier at 5 percent of national per capita FFS expenditures for Parts A and B services in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2.
- *Step 5:* Multiply one-fourth of the pro-rated, adjusted, and capped prepaid shared savings multiplier by the assigned beneficiary person years derived from the ACO's latest available assignment list. The resulting product will serve as the ACO's total maximum prepaid shared savings payment for the applicable quarter. As discussed previously, an ACO's latest available assignment list is updated quarterly. For ACOs under preliminary prospective assignment with retrospective reconciliation, assignment is updated quarterly based on the most recent 12 or 24 months of data, as applicable, under the methodology described at §§ 425.402 and 425.404 (§ 425.400(a)(2)(ii)). For ACOs under prospective assignment, assignment is updated quarterly to exclude any prospectively assigned beneficiaries that meet the exclusion criteria under § 425.401(b) (§ 425.401(b)). Thus, consistent with the methodology that we apply in the case of advance investment payments, quarterly variations in an ACO's assignment list will translate to variations in the maximum quarterly total prepaid shared savings payments that an ACO may receive in any given quarter, in order to help ensure that the payments accurately reflect the attributes of the ACO's assigned beneficiary population throughout the current agreement period.

Table 43 presents a hypothetical example to demonstrate how the prepaid shared savings calculation would work in practice.

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TABLE 43: Calculation of Maximum Quarterly Prepaid Shared Savings Payment

Step 1: Calculate prepaid shared savings multiplier	Per capita savings generated in the 2 performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022 PY 2019: $350 PY 2020: $400 Multiplier: Simple average of the per capita savings across BY1 and BY2 ($350 + $400) / 2 = $375
Step 2: Pro-rate the prepaid shared savings multiplier	Assigned person years from the performance years that constitute BY1 and BY2 for the ACO's current agreement period beginning January 1, 2022: PY 2019: 6,000 PY 2020: 7,000 Assigned person years for BY1 and BY2 of current agreement period (determined using certified ACO participant list for the current performance year of PY 2022): BY 2019: 8,000 BY 2020: 7,500 Proration factor: Ratio between the ACO's average person years in the performance years that constitute BY1 and BY2 and the average person years in BY1 and BY2, excluding years for which the ACO was not reconciled, capped at 1. Apply the proration factor to the prepaid shared savings multiplier: [(6,000 + 7,000)/2] / [(8,000 + 7,500)/2] x $375 = $314.52
Step 3: Adjust the pro-rated prepaid shared savings multiplier for financial risk and sharing rate	Shared savings scaling factor: (0.5) Financial risk scaling factor: (2/3) Apply the shared savings scaling factor and the financial risk scaling factor to the pro-rated prepaid shared savings multiplier: $314.52 x (0.5) x (2/3) = $104.84
Step 4: Cap the pro-rated, adjusted prepaid shared savings multiplier	National assignable per capita FFS expenditures for assignable beneficiaries in BY2: $10,000 Cap: 5 percent of national assignable per capita FFS expenditures for assignable beneficiaries in BY2 0.05 * $10,000 = $500
Step 5: Determine the maximum prepaid shared savings payments for the applicable quarter	Assigned beneficiary person years derived from the ACO's latest available assignment list: 8,500. Total prepaid shared savings payments for the applicable quarter: Product of one-fourth of the pro-rated, adjusted, capped prepaid shared savings multiplier and the assigned beneficiary person years derived from the ACO's latest available assignment list. ($104.84/4) x 8,500 = $222,785

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The ACO's maximum quarterly prepaid shared savings payments would set a ceiling on the amount of quarterly prepaid shared savings that an ACO could receive from CMS for each quarter. ACOs will be able to request to receive an amount of funding under this maximum amount. Prior to each performance year, ACOs would notify CMS of the amount of prepaid shared savings they want to receive in the first quarter under the maximum quarterly prepaid shared savings amount and the first quarterly payment will be used to determine the total amount of prepaid shared savings the ACO will use to budget for that performance year. We proposed in new § 425.640(f)(5) that for the purposes of determining the amount of prepaid shared savings permitted to be allocated to the uses specified in § 425.640(e), the estimated annual prepaid shared savings amount can be calculated by multiplying the first quarterly payment amount the ACO will receive in each performance year by four. This allows the ACO to calculate the total amount of funding they are permitted to spend on each allowable use at the start of each performance year. If an ACO's maximum quarterly payments decrease over the performance year and result in the ACO receiving less than the estimated annual prepaid shared savings amount, the

ACO would not be subject to compliance actions solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings it received during that PY on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the originally estimated annual prepaid shared savings amount on staffing and healthcare infrastructure. For example, if an ACO is eligible for a maximum quarterly prepaid shared savings payment of $300,000 for quarter 1 of a performance year, but only wishes to receive $250,000 for quarter 1 of a performance year, their estimated annual prepaid shared savings amount would be $1,000,000. This allows the ACO to spend up to $500,000 on staffing and healthcare infrastructure, or up to the full amount of $1,000,000 on direct beneficiary services. If an ACO has a reduction in assigned beneficiaries and is only eligible for a maximum quarterly prepaid shared savings payment of $200,000 for quarters 2, 3 and 4, this results in an actual total of $850,000 in received prepaid shared savings for the performance year. However, the ACO would still be permitted to spend up to $500,000 on staffing and healthcare infrastructure in that performance year, as that is 50 percent of the original estimated amount and we do not want to change budget maximums retroactively for an ACO.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed policy for the calculation of the quarterly payments and the use of an ACO's latest available assignment list to reflect changes to the ACO's assigned population during the agreement period. One commenter encouraged CMS to provide ACOs with preliminary estimated prepaid shared savings amounts during the annual Medicare Shared Savings Program application cycle to inform development of their spend plan.

Response: We appreciate the commenters' support. CMS does intend to share preliminary information about prepaid shared savings amounts with ACOs during the application cycle, which they can use to inform development of their spend plan.

Comment: One commenter suggested that an ACO receiving prepaid shared savings should have the option to elect to receive a smaller payment amount than the maximum quarterly payment calculated by CMS, or to elect to have prepaid shared payments withheld and later resumed.

Response: We agree with commenters that ACOs should have the flexibility to determine the amount of prepaid shared savings they receive below the maximum calculated quarterly payment, as well as the ability to elect to have these payments withheld and later resumed. Under § 425.640(f)(6), we proposed to offer ACOs flexibility to request a smaller quarterly payment amount from CMS. Under § 425.640(h)(1)(vii), CMS may withhold an ACO's prepaid shared savings during an agreement period upon request of the ACO. Under § 425.640(h)(3), if CMS withholds a quarterly payment, the ACO will not receive additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed. The ACO may later request to resume quarterly payments if it meets all other requirements for receiving quarterly payments.

After consideration of public comments, we are finalizing the proposed prepaid shared savings payment and payment methodology provisions under § 425.640(f) with modifications to specify the application of the provisions to ACOs that renewed to enter an agreement period beginning on January 1, 2025, and applied and were approved to participate in prepaid shared savings starting with performance year 2026 without renewing again. Specifically, under § 425.640(f)(1)(i) we specify that an eligible ACO entering an agreement period beginning on January 1, 2026, or in subsequent years will receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless the payment is withheld or terminated pursuant to § 425.640(h). Under § 425.640(f)(1)(ii), we specify that an eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, and for the remainder of its agreement period, unless the payment is withheld or terminated pursuant to § 425.640(h). The ACO will not receive additional or catch-up payments for performance year 2025. That is, these ACOs will only receive quarterly prepaid shared savings for the 4 years that would remain in their agreement period as of January 1, 2026. We specify in § 425.640(f)(1)(iii), in accordance with our proposal, that if an ACO's quarterly payment is withheld or terminated pursuant to paragraph § 425.640(h), the ACO will not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed.

Regarding the steps involved in the calculation of prepaid shared savings payment amounts, ACOs that renewed to enter an agreement period beginning on January 1, 2025, and participate in prepaid shared savings starting with performance year 2026 without renewing again will be subject to the same methodology that applies to all other ACOs that participate in the payment option, consistent with proposed § 425.640(f)(2) through (f)(6). For example, for a given ACO that renewed in 2025 and participates in the payment option starting with performance year 2026 without renewing again, we will calculate both the prepaid shared savings multiplier and the proration factor by reference to the two performance years that constitute BY1 and BY2 of the agreement period during which the ACO receives prepaid shared savings: 2022 and 2023, respectively. Similarly, we will cap the pro-rated, adjusted prepaid shared savings multiplier for these ACOs at 5 percent of national per capita FFS expenditures for Parts A and B services for assignable beneficiaries identified for the 12-month calendar year corresponding to 2023, or BY2. We are finalizing without modification our proposed methodology described at new § 425.640(f)(2) through (f)(6).

f. Duration, Frequency and Withholding or Termination of Prepaid Shared Savings Payments

(1) Duration and Frequency

We anticipate that the vast majority of ACOs receiving prepaid shared savings will fully repay the amount they receive of prepaid shared savings from their earned shared savings on an annual basis. This will allow CMS to distribute prepaid shared savings to ACOs continually, throughout an agreement period in which the ACO is deemed eligible to participate, without withholding prepaid shared savings under § 425.640(h). We proposed at § 425.640(f)(1) that ACOs would receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless withheld or terminated under § 425.640(h). However, we also proposed at § 425.640(h)(3) that if CMS withholds or terminates a quarterly payment under paragraph (h), the ACO will not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed. As discussed later in this section, prepaid shared savings payments will generally be withheld from ACOs when we have information that the ACO may not generate sufficient earned shared

savings to repay the prepaid shared savings in current or future performance years or has other Shared Savings Program compliance issues. Once prepaid shared savings payments are withheld, if an ACO earns shared savings in a future year, then prepaid shared savings can resume at the time of the next scheduled quarterly payment, but catch-up payments would not be provided. This protects CMS from distributing payments that the ACOs may not be able to repay and the ACOs from accumulating more debt than they can repay through earned shared savings. An ACO will be notified if CMS is willing to resume prepaid shared savings payments and will have the ability to elect to resume payments as well as select the payment amount they would like to receive under the maximum quarterly payment, if desired.

(2) Withholding and Termination

To ensure orderly administration of the Shared Savings Program, including protection of the Medicare Trust Funds, we intend to monitor the performance of ACOs receiving prepaid shared savings and proposed that we may withhold or terminate quarterly prepaid shared savings payments under a variety of specified circumstances. Many of the circumstances under which we proposed that CMS may withhold to terminate the payments directly relate to circumstances under which we will be concerned that the ACO has not or will not meet the standards for the use of prepaid shared savings, such as an ACO's failure to comply with the requirements of § 425.640. Other circumstances address situations where it becomes apparent that the ACO is likely to lack the ability to repay prepaid shared savings to CMS. For example, we proposed that CMS may withhold or terminate the payments if CMS predicts that the ACO will not generate sufficient earned shared savings to repay the prepaid shared savings in future performance years or has other Shared Savings Program compliance issues. These predictions will be based on a rolling 12-month window of beneficiary claims data or year-to-date beneficiary claims data, depending on whether an ACO selects prospective assignment or preliminary prospective assignment with retrospective reconciliation. We proposed that CMS may also withhold quarterly payments if an ACO fails to earn enough shared savings in a performance year to fully repay the prepaid shared savings the ACO received during that performance year, to avoid the ACO accruing debt they will be unable to repay. As noted earlier in this section, an ACO will be notified if CMS determines the ACO is sufficiently likely to earn additional shared savings such that CMS could resume prepaid shared savings payments, in which case the ACO will have the ability to elect to resume payments and select the payment amount it would like to receive. Additionally, while unspent funds received for a performance year must be reallocated in the spend plan for the ACO's next performance year as noted at § 425.640(e)(3), if an ACO fails to spend a majority of the prepaid shared savings received in a performance year, we may withhold future quarterly payments until the ACO spends the funding already received and reports this spending to CMS through an updated spend plan. An ACO may also request that CMS withhold future quarterly payments until the ACO is ready for payments to resume. ACOs that elect to have CMS withhold their prepaid shared savings payments will have the ability to later elect to resume payments as well as select the payment amount they would like to receive. If an ACO has unspent funding at the end of their agreement period, that funding must be repaid to CMS under § 425.640(e)(3).

Accordingly, we proposed at § 425.640(h)(1) that CMS may withhold or terminate prepaid shared savings during an agreement period if:

- The ACO fails to comply with any of the prepaid shared savings requirements of § 425.640;
- The ACO meets any of the grounds for ACO termination set forth at § 425.218(b); [559]
- The ACO fails to earn sufficient shared savings from a performance year to repay the prepaid shared savings they received during that performance year;
- CMS determines that the ACO is not expected to earn shared savings in a performance year during the agreement period in which the ACO received prepaid shared savings, based on a rolling 12-month window of beneficiary claims data or year-to-date beneficiary claims data;
- The ACO falls below 5,000 assigned beneficiaries;
- The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or
- The ACO requests that CMS withhold a future quarterly payment.

Additionally, we proposed at § 425.640(h)(2) that CMS must terminate an ACO's prepaid shared savings during an agreement period if:

- The ACO fails to maintain an adequate repayment mechanism in accordance with § 425.204(f); or
- The ACO fails to meet the quality performance standard as specified under § 425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2).

We further proposed under § 425.640(h)(4) that CMS may immediately terminate an ACO's prepaid shared savings under § 425.640(h)(1) and (2) without taking any of the pre-termination actions set forth in § 425.216.

In general, if an ACO is complying with the Shared Savings Program and prepaid shared savings requirements but is not achieving, or is not predicted to achieve, success in earning shared savings, CMS may withhold payments while the ACO works to improve its financial performance. For example, if an ACO is eligible to receive quarterly prepaid shared savings payments in an agreement period beginning in 2026 but does not earn shared savings during 2025 reconciliation that occurs in mid-2026, the ACO's quarterly payments will be withheld until the ACO earns shared savings in a future performance year reconciliation. Similar to our rationale for the eligibility requirement described at § 425.640(b)(2), we believe that recent past performance in earning shared savings provides information on the ACO's potential to earn future shared savings, and we will not distribute prepaid shared savings to ACOs that have not earned sufficient shared savings in their most recent reconciled performance year to repay the prepaid shared savings they received during that performance year.

Additionally, if CMS, through its financial monitoring of ACOs, predicts that an ACO would not earn shared savings in its current performance year, quarterly prepaid shared savings may be withheld until the ACO generates earned shared savings in the future. We expect that immediate termination of prepaid shared savings during an agreement period, without a possibility of resumption of payments during that agreement period, would be invoked only in cases of serious noncompliance with the requirements of § 425.640, including deliberately spending prepaid shared savings on a prohibited use, or when the ACO's actions or inaction poses a risk of harm to beneficiaries or negatively affects their access to care.

[559] Under §§ 425.216 and 425.218, CMS can terminate an ACO's participation agreement or take pre-termination actions (such as requesting a corrective action plan) if CMS determines that an ACO is not in compliance with the requirements of Part 425 of our regulations.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Two commenters appreciated that CMS would generally only immediately terminate prepaid shared savings in cases of serious noncompliance with the requirements of § 425.640 or when the ACO's actions or inaction poses a risk of harm to beneficiaries or negatively affects their access to care. Other commenters encouraged CMS to provide more clarity around what would trigger CMS's concern that an ACO may be unable to fully repay prepaid shared savings payments and offer more flexibility to work with ACOs before withholding or terminating prepaid shared payments.

Response: CMS will primarily review claims data based on a rolling 12-month window or year-to-date data, depending on whether an ACO selects prospective assignment or preliminary prospective assignment with retrospective reconciliation, to determine if an ACO is expected to earn adequate shared savings to repay CMS. For example, if CMS determines that it is likely that an ACO will not earn sufficient shared savings to repay CMS, CMS may withhold or terminate quarterly payments. CMS intends to release additional guidance on prepaid shared savings in advance of the PY 2026 annual application and change request cycle. ACOs will have access to the same financial indicators and quarterly reports reviewed by CMS in order to track their own financial performance. We refer commenters to additional discussion elsewhere in this section of this final rule explaining when CMS may withhold or terminate prepaid shared savings payments and the flexibilities that ACOs would have with respect to these issues.

Comment: One commenter requested additional clarity around situations where an ACO is not able to repay prepaid shared savings through earned shared savings, or if CMS determines that prepaid shared savings have been used inappropriately. They note that there is not a clear pathway to refute these determinations and warn against withholding or terminating quarterly prepaid shared savings payments too quickly. They requested a clearer pathway for an ACO to refute these determination and recoup payments which have been withheld or terminated.

Response: In response to the commenter who requested a pathway for ACOs to refute prepaid shared savings determinations and recoup payments which have been withheld or terminated, we note that Subpart I of 42 CFR part 425 details the reconsideration review process for the Shared Savings Program. For an ACO that is unable to repay prepaid shared savings through earned shared savings, the options for repayment would depend on where the ACO is in the agreement period. For ACOs not in the final performance year of their agreement period, they will be able to carry forward any unpaid balance of prepaid shared savings to a subsequent performance year and repay them through future earned shared savings during the agreement period, under § 425.640(g)(1). CMS will only immediately require an ACO to repay prepaid shared savings if the ACO is at the end of its agreement period, or if the ACO or CMS terminates its participation agreement mid-agreement period, under § 425.640(g)(3). Under § 425.640(g)(3), if an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If an ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of the notification, CMS would recoup that amount from the ACO's repayment mechanism established under § 425.204(f).

Additionally, if an ACO fails to earn sufficient savings to repay prepaid shared savings in a performance year, CMS may withhold additional quarterly payments to an ACO during the agreement period until prepaid shared savings are repaid, under § 425.640(h)(1), in order to avoid burdening an ACO with more debt than it is able to repay. While the ACO would not receive quarterly payments until it earns sufficient shared savings to repay all prepaid shared savings it received, CMS would not recoup earned shared savings in excess of any outstanding prepaid shared savings. If prepaid shared savings are resumed during an agreement period, catch-up payments would not be provided.

In the event that CMS determines an ACO has used prepaid shared savings for a prohibited use under § 425.640(e)(2) or failed to spend the funding in accordance with § 425.640(e)(1)(i) and (ii), CMS may immediately terminate prepaid shared savings during an agreement period (§ 425.640(h)(4)).

After consideration of public comments, we are finalizing the proposed policies on the duration and frequency of prepaid shared savings under 425.640(f)(1) with modifications to specify that for ACOs that renewed to enter an agreement period beginning on January 1, 2025, and applied and were approved to participate in prepaid shared savings starting with performance year 2026 without renewing again, they will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, and for the remainder of its agreement period, unless the payment is withheld or terminated pursuant to paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025. We are finalizing without modification our proposed policy on withholding or termination of prepaid shared savings payments at new § 425.640(h).

g. Monitoring ACO Eligibility for and use of Prepaid Shared Savings

To provide CMS with a clear indication of how ACOs intend to spend prepaid shared savings, help provide adequate protection to the Medicare Trust Funds, and prevent funds from being misdirected or appropriated for activities that do not fall within the parameters set forth within proposed § 425.640(e), we proposed at § 425.316(f)(1) to monitor ACOs receiving prepaid shared savings for compliance with § 425.640(e) and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings under § 425.640(h)(1) and (h)(2). In the proposed rule, we explained that for the first performance year of the current agreement period, we would monitor the ACO's use of prepaid shared savings by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against the actual spending as reported by the ACO, including any expenditures not identified in the spend plan. ACOs would be required to submit a revised spend plan with updated anticipated spending annually, as well as annually report their actual expenditures to CMS and on their public reporting web page as noted in §§ 425.308(b)(10) and 425.640(i), and we would similarly monitor the ACO's use of prepaid shared savings during the current agreement period using the updated spend plan and those reports. The reported annual spending must include any expenditures of prepaid shared

savings on items not identified in the spend plan. In the event that an ACO uses prepaid shared savings for uses not permitted by § 425.640(e), we would require them to reallocate the funding to a permitted use and may take compliance action as specified at §§ 425.216, 425.218 or withhold or terminate payments as specified at § 425.640(h)(1) and (2).

Similar to the policy for advance investment payments (§ 425.630), we additionally believe that transparency of information in the healthcare sector facilitates more informed patient choice and offers incentives and feedback that help improve the quality and lower the cost of care and improve oversight with respect to program integrity. As CMS has discussed in previous final rules, improved transparency supports a number of program requirements. In particular, increased transparency is consistent with and supports the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it. Therefore, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's use of prepaid shared savings to be available to the public. Making this information available would provide both Medicare beneficiaries and the general public with insight into the use of prepaid shared savings by an ACO.

Accordingly, we proposed to modify § 425.308 to require that an ACO publicly report information annually regarding prepaid shared savings on its public reporting web page. Specifically, under new § 425.308(b)(10), we proposed that, for each performance year, an ACO would be required to report (in a standardized format specified by CMS) its spend plan, the total amount of prepaid shared savings received from CMS, and an itemization of how any prepaid shared savings were actually spent during each year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under § 425.640(d)(2), and such other information as may be specified by CMS.[560] We proposed that this itemization must include expenditures not identified or anticipated in the ACO's submitted spend plan, and any amounts remaining unspent. We also proposed at § 425.640(i) that ACOs also be required to report this information directly to CMS.

Under this proposal, if CMS determined that an ACO used prepaid shared savings for a prohibited use under § 425.640(e)(2), allocated over 50 percent of their annual maximum prepaid shared savings on staffing and healthcare infrastructure as at § 425.640(e)(1)(i), or failed to spend at least 50 percent of the annual maximum prepaid shared savings on direct beneficiary services, we would require the ACO to reallocate the funding in compliance with § 425.640(e) and submit an updated spend plan demonstrating the reallocation by a deadline specified by CMS and may withhold or terminate the ACO's receipt of prepaid shared savings at § 425.640(h)(1). CMS could also take compliance action as specified at §§ 425.216 and 425.218. If an ACO fails to reallocate prepaid shared savings it received by a deadline specified by CMS, the ACO must repay all prepaid shared savings it received and may be subject to compliance action as specified at §§ 425.216 and 425.218. CMS would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Additionally, we noted that under existing § 425.314, ACOs would be required to retain and provide CMS with access to adequate books, contracts, records, and other evidence to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs' use of prepaid shared savings (for example, invoices, receipts, and other supporting documentation of prepaid shared savings disbursements). To protect the Shared Savings Program and the Medicare Trust Funds, we explained that we would reserve the right under §§ 425.314 and 425.316(a) to audit and monitor ACO compliance with Shared Savings Program requirements, including with respect to prepaid shared savings. We explained that we would conduct audits as necessary to monitor and assess an ACO's use of prepaid shared savings and compliance with program requirements related to such payments.

We received public comments on these proposals. The following is a summary of the comments we received and our response.

Comment: We received a few general comments on the administrative burden associated with participating in the prepaid shared savings payment option including the reporting requirements. Commenters noted that these burdens might negatively impact participation in prepaid shared savings.

Response: We understand that the reporting requirements relating to the use of prepaid shared savings will produce some administrative burden for ACOs. However, these requirements are important for promoting transparency as to ACO's use of prepaid shared savings. These requirements are also important for allowing CMS to monitor that prepaid shared savings are spent consistent with program requirements and support the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it.

After consideration of public comments, we are finalizing without modification the proposed policies on monitoring ACO eligibility for and use of prepaid shared savings under new §§ 425.316(f)(1) and 425.308(b)(10).

h. Recoupment of Prepaid Shared Savings

We anticipate that the vast majority of ACOs receiving prepaid shared savings will fully repay the amount they receive prepaid shared savings from their earned shared savings on an annual basis. However, as prepaid shared savings are an advance of the shared savings payments an ACO is expected to earn, we proposed to recoup prepaid shared savings from ACOs that are unable to fully repay prepaid shared savings through their earned shared savings. This approach will also help ensure that prepaid shared savings will not result in additional expenditures for the Shared Savings Program, as required by section 1899(i)(3)(B) of the Act.

We proposed to add a new § 425.640(g)(1) to recoup prepaid shared savings from earned shared savings, as defined at § 425.20, in each performance year. If there are insufficient shared savings to recoup the prepaid shared savings made to an ACO for a performance year, we would hold paying future prepaid shared savings payments and carry forward the remaining balance owed to subsequent

[560] We note that in a corresponding description in the preamble of the CY 2025 PFS proposed rule (89 FR 61882) we inadvertently misstated some of the proposed regulations text under § 425.308(b)(10), which we have corrected within this description in this final rule.

performance year(s) in which the ACO achieves shared savings.

Under new § 425.640(g)(2), we proposed that in circumstances where the amount of shared savings earned by the ACO is revised upward by CMS for any reason, we would reduce the redetermined amount of shared savings by the amount of prepaid shared savings made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, we proposed that the ACO would not receive a refund of any portion of the prepaid shared savings previously recouped or otherwise repaid, and any prepaid shared savings that are now outstanding due to the revision in earned shared savings must be repaid to CMS upon request.

We proposed under § 425.640(g)(3) that if an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. We will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If an ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of the notification, we would recoup that amount from the ACO's repayment mechanism established at § 425.204(f).

For example, if an ACO received $300,000 in prepaid shared savings payments and earned shared savings of $500,000 for the first performance year, we would recoup $300,000 in prepaid shared savings payments and make $200,000 in reconciliation shared savings payments to the ACO. Alternatively, if an ACO received $300,000 in prepaid shared savings and earned shared savings of $200,000 for the first performance year, we would recoup only $200,000 in prepaid shared savings payment and not make a reconciliation shared savings payment to the ACO. The ACO would have future prepaid shared savings payments placed on hold, and the outstanding balance of $100,000 would be carried forward, to be recouped in a future performance year in which the ACO achieves shared savings. Under a third scenario, if the ACO does not earn sufficient shared savings in all 5 performance years of its agreement period, CMS would recoup the outstanding balance directly from the ACO under new § 425.640(g)(3). If the ACO fails to repay the funding to CMS, we would recoup the outstanding balance from the ACO's repayment mechanism.

Under the new § 425.640(g)(4), we proposed that if an ACO or CMS terminates its participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings received in full. In such a case, we will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If an ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of the notification, we would recoup that amount from the ACO's repayment mechanism established at § 425.204(f). We also proposed edits to § 425.204(f) to incorporate a reference to prepaid shared savings in existing provisions that reference only shared losses to clarify that we would be able to recoup outstanding prepaid shared savings from an ACO's repayment mechanism.[561] If the ACO terminates its participation agreement early in order to renew under a new participation agreement, CMS may also recover the amount owed by reducing the amount of any future shared savings the ACO may be eligible to receive.

In the event the ACO enters into proceedings relating to bankruptcy, whether voluntary or involuntary, we proposed at § 425.630(g)(5) that the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244, or such other address as may be specified on the CMS website for purposes of receiving such notices.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters noted that to protect the fiscal sustainability of the Medicare program, it is imperative that CMS implement a robust recoupment process as planned to avoid unwarranted increases in program spending. Another commenter expressed concern for the financial risks tied to participation in prepaid shared savings option, as the requirement for ACOs to repay prepaid shared savings if they do not earn sufficient savings to repay all of the prepaid shared saving received by the ACO could pose significant challenges. This commenter is concerned that ACOs may be hesitant to elect to participate in the prepaid shared savings option if they are uncomfortable with the risk that they will be unable to repay CMS. This financial obligation could deter participation in the option or create financial instability, even among ACOs that are otherwise performing well. This commenter requested detailed guidelines from CMS on repayment terms, permissible investments of prepaid shared savings, and additional monitoring processes to ensure that the proposal is implemented effectively and transparently. A different commenter recommended that CMS work with ACOs to develop reasonable repayment parameters.

Response: We appreciate commenters' concerns about protecting the Medicare Trust Funds, and we have designed prepaid shared savings eligibility requirements to maximize the chance that participating ACOs should earn sufficient shared savings to repay all upfront funding they receive on an annual basis.

With respect to the other commenter's concern that requiring ACOs to repay prepaid shared savings may deter some ACOs from electing this option, we acknowledge that some ACOs that are eligible to receive prepaid shared savings may opt not to receive them. The policies we adopt to improve the quality and efficiency of care provided to beneficiaries must be consistent with our statutory obligation to not increase program expenditures, as discussed elsewhere in this rule. We have balanced these concerns by providing ACOs with numerous opportunities to repay prepaid shared savings through earned shared savings.

Under § 425.630(g)(1), if an ACO fails to earn sufficient prepaid shared savings, the balance will carry forward until all prepaid shared savings have been recouped by CMS. Under § 425.630(g)(3), if an ACO has an outstanding balance of prepaid shared

[561] In the CY 2025 PFS proposed rule, refer to the proposed amendments to the text of the regulations for § 425.204(f) at 89 FR 62220. We note that we inadvertently mischaracterized some of these proposed changes in the preamble description at 89 FR 61883.

savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, then the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS would provide written notification to the ACO of the amount due and the ACO would have 90 days after the receipt of notification to make repayment. Only if the ACO failed to repay any outstanding amount of prepaid shared savings within 90 days of that written notification, CMS would recoup against an ACO's repayment mechanism established under § 425.204(f). Also, under § 425.630(g)(3), CMS may recover any outstanding amount of prepaid shared savings owed by recouping from any future shared savings the ACO may be eligible to receive in a subsequent agreement period. If an ACO or CMS terminates the ACOs participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings it received in full upon request from CMS (§ 425.640(g)(4)), unless the ACO terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program, in which case CMS may recover the amount owed by recouping from any future shared savings the ACO may be eligible to receive in subsequent agreement periods (§ 425.640(g)(4)(ii)).

ACOs that do not earn sufficient shared savings during an agreement period where they are receiving prepaid shared savings may also have their quarterly prepaid shared savings withheld until they earn sufficient shared savings again, in order to avoid overburdening the ACO with repayment obligations. ACOs are also permitted to request lower quarterly payment amounts, in order to avoid incurring a debt they are uncomfortable repaying to CMS. Additionally, the eligibility requirement for an ACO to have established an adequate repayment mechanism helps protect ACOs from incurring a debt in prepaid shared savings that they may be unable to repay.

CMS intends to provide more detailed guidance for ACOs regarding participation in the prepaid shared savings option, including guidance on repayment processes and permissible uses of prepaid shared savings prior to the 2026 Medicare Shared Savings Program application cycle. However, we note that this is a voluntary payment option and no ACO must participate. CMS appreciates commenters' feedback on the prepaid shared savings recoupment processes and will consider this feedback in future rulemaking.

After consideration of public comments, we are finalizing as proposed our policies on recoupment of prepaid shared savings, as specified under new § 425.640(g). We are also finalizing without modification our proposed amendments to § 425.204(f) to support the requirement for ACOs to have in place an adequate repayment mechanism that CMS can use to recoup outstanding prepaid shared savings (as applicable).

i. OIG Safe Harbor Authority

In section II.G.5.i. of the CY 2025 PFS proposed rule (89 FR 61883 and 61884), we stated that should the proposed policies be finalized, CMS expects to make a determination, that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect patient incentives that may be permitted under the final rule, if issued. Specifically, we stated that we expect to determine that the CMS-sponsored models safe harbor would be available to protect direct beneficiary services provided to beneficiaries through the prepaid shared savings payment option.

We proposed to add a new paragraph (d) to § 425.304 that notes that we have determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the prepaid shared savings program option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth at § 1001.952(ii)(2).

We received no comments on the OIG safe harbor authority in relation to prepaid shared savings and are therefore finalizing as proposed to specify in § 425.304(d) that CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect remuneration furnished in the prepaid shared savings option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth in § 1001.952(ii).

6. Advance Investment Payment Policies

a. Allow ACOs Receiving Advance Investment Payments to Voluntarily Terminate Payments While Continuing Participation in the Shared Savings Program

Beginning January 1, 2024, we implemented a new payment option in the Shared Savings Program, advance investment payments (AIP), and codified AIP requirements at § 425.630. In the CY 2023 PFS final rule (87 FR 69803 through 69805), we discussed policies for termination of advance investment payments from ACOs whose participation agreements are terminated for noncompliance with certain requirements and finalized a recoupment policy in which all advance investment payments must be repaid to CMS within 90 days from the date CMS provided the ACO whose participation agreement was terminated with written notice of the amount due. These regulations are codified at § 425.630(g) and (h).

Currently, there are no regulations that account for an ACO that seeks to voluntarily terminate receipt of advance investment payments from CMS, but that wishes to remain in the Shared Savings Program for the rest of their agreement period. While we expect advance investment payment terminations to be an uncommon occurrence, since advance investment payments are a voluntary payment option, ACOs should be able to decline further participation. To accommodate voluntary terminations of advance investment payments for ACOs that wish to continue participating in the Shared Savings Program, in the CY 2025 PFS proposed rule (89 FR 61884 through 61885), we proposed to modify program regulations at § 425.630(g) and (h). We proposed to allow ACOs who wish to voluntarily terminate receipt of advance investment payments to do so and remain in the Shared Savings Program.

We explained that an ACO may have justified business reasons for terminating receipt of advance investment payments (such as an ACO's desire to participate in a CMS Innovation Center model whose eligibility criteria exclude ACOs that receive AIP), and that CMS wishes to amend its termination policies to account for such a scenario. We also stated that it is the best interest of the Medicare Trust Funds and the Shared Savings Program to allow continued program participation by ACOs that terminate receipt of advance investment payments, especially among ACOs and

ACO participants in, or that serve, underserved communities. Therefore, we proposed new regulations effective January 1, 2025, to allow ACOs to voluntarily terminate receipt of advance investment payments while remaining in the Shared Savings Program. We explained that under this proposal, we would develop an advance investment payment voluntary termination notification process to allow ACOs to voluntarily terminate receipt of these payments, and we would issue guidance regarding this process to participating Shared Savings Program ACOs shortly after publication of the CY 2025 PFS final rule.

We proposed to update § 425.630(g) to state that if an ACO opts to voluntarily terminate from the advance investment payment option, they will be required to return any outstanding advance investment payments to CMS. Upon an ACO notifying CMS that it wants to terminate from the advance investment payment option, we would then provide a written notification to the ACO of the total amount of recoupment due. We would then require the ACO to repay the amount due no later than 90 days after the receipt of such notification. This aligns with how CMS recoups advance investment payments from ACOs whose advance investment payments are involuntarily terminated due to failure to comply with advance investment payment eligibility requirements at § 425.316(e)(3) and with the repayment requirements at § 425.630(g)(4), if an ACO chooses to terminate from the Shared Savings Program.

ACOs that terminate from the advance investment payment option would no longer be monitored for their appropriate use of advance investment payments once the payments are repaid to CMS. As such, ACOs that terminate would no longer be subject to annual reporting requirements for their spend plans once the payments are repaid to CMS. This proposal will allow an ACO additional flexibility to determine its best payment and participation options, making it easier for an ACO receiving advance investment payments to continue their participation in the Shared Savings Program long-term. As noted in the CY 2023 PFS final rule (87 FR 69784), advance investment payments were designed to assist ACOs that face difficulty funding the start-up costs for forming ACOs, caring for beneficiaries in underserved communities, and achieving long term success in the Shared Savings Program. Allowing these ACOs more flexibility would have the effect of supporting continued Shared Savings Program participation among these ACOs, including those serving rural and underserved populations.

We proposed to update § 425.630(g)(5) to state that if an ACO notifies CMS that it no longer wants to participate in the advance investment payment option but does want to continue its participation in the Shared Savings Program, the ACO must repay all outstanding advance investment payments it received. We would provide written notice to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

Additionally, we proposed conforming revisions to § 425.630(h) to clarify that ACOs can voluntarily terminate from the advance investment payment option. Specifically, we proposed to add a paragraph (h)(1)(iv) to read ''Voluntarily terminates payments of advance investment payments but continues its participation in the Shared Savings Program.'' CMS also proposed conforming revisions to § 425.630(h)(1)(ii) and (iii). The proposed changes would be effective beginning January 1, 2025.

b. Recoup Advance Investment Payments When CMS Terminates the Participation Agreement of an ACO

Under current advance investment payment recoupment regulations, there is no clear pathway for CMS to recoup outstanding advance investment payments if CMS terminates an ACO's participation agreement in accordance with § 425.218(b). To address this and reduce the risk to the Trust Funds, in the CY 2025 PFS proposed rule (89 FR 61884 through 61885), we proposed to add new § 425.630(g)(6) to require ACOs to repay any outstanding advance investment payments in the event that CMS terminates the ACO's Shared Savings Program participation agreement.

Upon the termination of their Shared Savings Program participation agreement, the ACO's advance investment payments will cease immediately under § 425.630(h)(1)(ii). We would provide the ACO with written notification of the total amount due for the full recoupment of advance investment payments, and the ACO must pay such amount within 90 days after the receipt of such notification. This approach aligns with how CMS recoups advance investment payments for ACOs under § 425.630(g)(4) if an ACO receiving advance investment payments chooses to voluntarily terminate from the Shared Savings Program. This proposal would protect CMS from not being able to recoup outstanding advance investment payments in the event CMS terminates an ACO's participation agreement in accordance with § 425.218(b).

Specifically, we proposed to add § 425.630(g)(6) to state that if CMS terminates the participation agreement of an ACO that has an outstanding balance of advance investment payments owed to CMS, the ACO must repay any outstanding advance investment payments it received. We would provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification. If an ACO fails to fully repay the advance investment payments they received, we would carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings, including in any performance year(s) in a subsequent agreement period.

We also proposed conforming edits to § 425.630(g)(3) to remove the phrase ''paragraph (g)(4) of this section'' and add in its place the phrase ''paragraphs (g)(4) through (g)(6) of this section.'' If finalized, this proposal would allow CMS to recoup more than the amount of shared savings earned by an ACO in a particular performance year in the event that an ACO or CMS terminates an ACO from the advance investment payment option or the Shared Savings Program as a whole. This proposal would require CMS to renumber regulations at § 425.630(g). Therefore, we proposed a conforming change to redesignate § 425.630(g)(5) as § 425.630(g)(7). If finalized, these proposals would be effective beginning January 1, 2025.

We received public comments on both of these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the proposals and noted that they align with existing AIP and other Shared Savings Program policies. The commenters explained that the proposals would provide clarity for participating ACOs on AIP termination and recoupment policies. Commenters particularly supported the codification of regulations to allow ACOs to terminate their advance investment payments while continuing participation in the Shared Savings Program.

Response: We agree with commenters that these proposals should improve clarity for participating ACOs and align with current AIP and other Shared Savings Program policies.

After consideration of public comments, we are finalizing our proposal, without modification, to

amend § 425.630(g) to specify under § 425.630(g)(5) a policy to allow ACOs receiving advance investment payments to voluntarily terminate from the advance investment payment option while remaining in the Shared Savings Program. We are also finalizing related conforming changes to § 425.630(h) to clarify that ACOs can voluntarily terminate from the advance investment payment option, and that CMS may terminate an ACO's advance investment payments if the ACO does so. Further, we are finalizing our proposal, without modification, to add § 425.630(g)(6), to specify a policy for recouping advance investment payments from ACOs whose participation agreements are terminated by CMS. We are also finalizing as proposed conforming edits and changes to other provisions of § 425.630(g).

7. Financial Methodology

a. Overview

In section III.G.7 of the CY 2025 PFS proposed rule (89 FR 61885 through 61923), we proposed modifications to the financial methodologies used under the Shared Savings Program. We stated that the modifications we proposed would encourage participation in the program by removing barriers for ACOs serving underserved communities [562] as well as provide greater specificity and clarity on how CMS would perform certain financial calculations in the Shared Savings Program. Specifically, we proposed to create a health equity benchmark adjustment (section III.G.7.b of the proposed rule) to potentially provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). We also proposed to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a) (section III.G.7.c. of the proposed rule). We proposed to establish an approach to identify significant, anomalous, and highly suspect (''SAHS'') billing activity in CY 2024 or subsequent calendar years (section III.G.7.d of the proposed rule). We proposed to specify how we would exclude payment amounts from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified as well as from historical benchmarks used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified to mitigate the impact of SAHS billing activity. We sought comment on a financial model that would allow for higher risk and potential reward than currently available under the ENHANCED track while still meeting the requirements for use of our authority under section 1899(i)(3) of the Act, among other considerations for the financial model design (section III.G.7.e of the proposed rule). We also proposed certain modifications for clarity and consistency in provisions of the Shared Savings Program regulations on calculation of the ACO risk score growth cap in risk adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor (section III.G.7.f of the proposed rule).

b. Health Equity Benchmark Adjustment

(1) Background

(a) Summary of Statutory and Regulatory Background on Adjusting the Historical Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Pursuant to this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

Benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years, are specified at § 425.652. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; and CY 2024 PFS final rule, 88 FR 79174 through 79208).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (refer to 87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (refer to 87 FR 69898 through 69915). The modifications to the regional adjustment are designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high-cost beneficiaries. In the CY 2024 PFS final rule (refer to 88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. The prior savings adjustment policy was developed such that a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period. In the CY 2024 PFS final rule (refer to 88 FR 79196 through 79200), we modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315.

(b) Methodology for Determining the Applicability of a Regional Adjustment or Prior Savings Adjustment to the ACO's Historical Benchmark, for Agreement Periods Beginning on or After January 1, 2024

Under the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years, CMS calculates two adjustments to the historical benchmark, a regional adjustment (refer to § 425.656) and a prior savings adjustment (refer to § 425.658). We determine which adjustment is applied

[562] As described in the *CMS Framework for Health Equity* and consistent with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009), the term ''underserved communities'' refers to populations sharing a particular characteristic, including geographic communities that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified in the definition of ''equity.'' See for example CMS Framework for Health Equity 2022–2032, available at *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf*.

to the benchmark, either the regional adjustment, prior savings adjustment, or no adjustment (refer to § 425.652(a)(8) and (c)).

Under the current methodology, the adjustment that will apply in the establishment of benchmarks for ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years, is calculated as follows:

- *Step 1:* Calculate the capped regional adjustment expressed as a single dollar value as specified in § 425.656. CMS calculates the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.656(c)(3), CMS caps the per capita dollar amount for each Medicare enrollment type at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service (FFS) program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

—Under § 425.656(c)(3)(i), for positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

—Under § 425.656(c)(3)(ii), for negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

++ Under § 425.656(d)(1), CMS expresses the regional adjustment as a single value by taking a person year [563] weighted average of the Medicare enrollment type-specific regional adjustment values.

- *Step 2:* For eligible ACOs, calculate the capped prior savings adjustment as specified in § 425.658. Under § 425.658(c)(1), CMS calculates an adjustment to the historical benchmark to account for savings generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more performance years in the Shared Savings Program during this period.
- *Step 3:* Determine the final adjustment to the benchmark, as specified in § 425.652(a)(8). Compare the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

++ Under § 425.652(a)(8)(ii), if an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Under § 425.652(a)(8)(iii), if an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

++ Under § 425.652(a)(8)(iv), if an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

—Under § 425.652(a)(8)(iv)(A), the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

—Under § 425.652(a)(8)(iv)(B), the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.652(a)(8)(v), if an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) Background on Incorporating Health Equity Data Within the Shared Savings Program

Development of a health equity benchmark adjustment builds upon Shared Savings Program policies finalized in the CY 2023 and CY 2024 PFS final rules to advance health equity, including the establishment of the health equity adjustment to an ACO's MIPS quality performance category score (applicable to all ACOs beginning with performance year 2023) (87 FR 69838 through 69857 and 88 FR 79114 through 79117); the availability of advance investment payments to eligible new, low revenue ACOs entering a new agreement period beginning on January 1, 2024, and in subsequent years (87 FR 69782 through 69805 and 88 FR 79208 through 79216); as well as changes to the benchmarking methodology aimed to facilitate participation by ACOs serving medically complex or underserved beneficiaries (87 FR 69915 through 69924 and 88 FR 79185 through 79195).

Further, in a Request for Information in the CY 2023 PFS final rule (87 FR 69977 through 69979), we discussed addressing health equity through benchmarking and summarized related comments. In the CY 2023 PFS final rule (87 FR 69978), we explained our interest in considering how direct modification of benchmarks to account for existing inequities in care can be used to advance health equity. The vast majority of commenters expressed support for exploring methodologies to address health equity via benchmarking changes. Specifically, many of these commenters noted that benchmark adjustments could be an effective tool to redirect resources to ACOs serving underserved communities. Multiple

[563] To calculate person years: We sum the number of Shared Savings Program-eligible months (beneficiaries are only assigned a monthly enrollment status for months in which they are alive on 1st of the month, enrolled in both Parts A and B, and not enrolled in a Medicare Group Health Plan for the month) for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

commenters commented specifically on the health equity benchmark adjustment approach utilized by the ACO Realizing Equity, Access, and Community Health (REACH) Model. Several of these commenters expressed support for using a similar methodology in implementing a health equity benchmark adjustment in the Shared Savings Program. In response, we stated that we will consider these comments in the development of policies for future rulemaking. Based on our experience with adjustments under the current benchmarking methodology, our experience establishing policies to advance health equity in the Shared Savings Program, and the support received for addressing health equity through benchmarking in response to the Request for Information, we explained in the CY 2025 PFS proposed rule that it would be timely to implement a health equity benchmark adjustment (HEBA) into the Shared Savings Program's benchmarking methodology. Implementing a HEBA would ensure benchmarks continue to serve as a reasonable baseline when ACOs serve high proportions of beneficiaries who are members of underserved communities and incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities.

In the CY 2025 PFS proposed rule (89 FR 61887), we explained that a health equity benchmark adjustment is likely to encourage more participation in the Shared Savings Program by ACOs that serve beneficiaries who are members of rural and underserved communities by allowing them to participate with potentially higher benchmarks. That, in turn, would increase the likelihood that they could earn shared savings and increase the amount of those shared savings payments and reduce the financial barriers to forming ACOs that providers who serve underserved communities face. We explained that benchmarks based on historically observed spending could be set too low if they are based on the spending of a population of underserved communities. An ACO serving such communities could be harmed financially if they are successful at improving access to high-value care during the performance period. Additionally, the Congressional Budget Office (CBO) recently reported high start-up costs for providers in rural and underserved communities as a barrier to forming ACOs.[564] We stated in the CY 2025 PFS proposed rule that these providers may want to participate in ACOs but are disincentivized due to steep start-up costs.

We also explained in the CY 2025 PFS proposed rule that a health equity benchmark adjustment would encourage currently participating ACOs to attract more beneficiaries who are members of underserved communities and remain in the Shared Savings Program. Direct increases to benchmarks for ACOs serving higher proportions of beneficiaries who are members of underserved communities would grant additional financial resources to healthcare providers accountable for the care of these populations and may work to offset historical patterns of underspending that influence benchmark calculations.

The ACO REACH Model incorporates a HEBA to test a way to address historical health inequities within CMS ACO initiatives, with the intent of incentivizing ACOs to seek out and form relationships with beneficiaries who are members of underserved communities. The adjustment is intended to mitigate the disincentive for ACOs to serve underserved communities by accounting for historically suppressed spending levels for these populations. It is a critical step towards enabling ACOs to serve underserved communities in a manner that reflects their health needs.[565] Likewise, the Shared Savings Program aims to design a health equity benchmark adjustment that achieves those same goals while aligning the program's benchmarking policies and health equity initiatives. We explained in the CY 2025 PFS proposed rule (89 FR 61887) that the HEBA proposal was informed by CMS' initial experience with the ACO REACH Model, which includes a HEBA, that has been associated with increased participation in ACOs by safety net providers.[566] Increasing access to providers participating in ACOs in rural and other underserved areas remains a priority for CMS to help address inequities in ACO participation and grow accountable care.

(2) Revisions

As described in the CY 2025 PFS proposed rule (89 FR 61887 through 61892), relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we proposed a HEBA applicable to ACOs in agreement periods beginning on January 1, 2025, and in subsequent years. The proposed HEBA would offer a third method of upwardly adjusting an ACO's historical benchmark, in addition to the existing regional adjustment and prior savings adjustment. This upward adjustment to the historical benchmark is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities and receiving lower regional adjustments (§ 425.656) or lower prior savings adjustments (§ 425.658), or receiving neither adjustment. Under proposed § 425.652(a)(8)(ii), an ACO would receive the highest of the positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or health equity benchmark adjustment. If an ACO is not eligible to receive a prior savings adjustment or a HEBA, and the regional adjustment, expressed as a single value, is negative or zero, then the ACO would not receive an adjustment to its benchmark.

By increasing the likelihood that an ACO would earn shared savings and by potentially increasing the amount of shared savings earned, the HEBA is meant to provide a greater financial incentive for ACOs to serve more beneficiaries from underserved communities and to encourage ACOs already serving higher proportions of beneficiaries from underserved communities to enter and remain in the Shared Savings Program. Practices that serve large proportions of beneficiaries who are members of underserved communities that may otherwise see financial risk in joining the program may be incentivized to form an ACO and join the program with a health equity benchmark adjustment policy in place. In addition, currently participating ACOs that may otherwise see risk in attracting additional beneficiaries from underserved communities to their ACOs may be incentivized to do so with a health equity benchmark adjustment policy in place. In the CY 2025 PFS proposed rule, we noted that, if finalized, the proposed prepaid shared savings option (described in section III.G.5 of the CY 2025 PFS proposed rule) would operate synergistically with the proposed HEBA, in that ACOs that have been

[564] Congressional Budget Office (CBO), ''Medicare Accountable Care Organizations: Past Performance and Future Directions,'' April 2024, available at *https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.*

[565] Centers for Medicare & Medicaid Services, ''ACO Realizing Equity, Access, and Community Health (REACH) Model Finance-Focused Frequently Asked Questions'' (Version 1, April 2022), available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-finfaqs.*

[566] See Rawal P., Seyoum S., Fowler E. ''Advancing Health Equity Through Value-Based Care: CMS Innovation Center Update,'' *Health Affairs Forefront,* June 4, 2024. DOI: 10.1377/forefront.20240603.385559. Available at *https://www.healthaffairs.org/content/forefront/advancing-health-equity-through-value-based-care-cms-innovation-center-update.*

successful in earning shared savings while serving larger proportions of beneficiaries from underserved communities would in subsequent years have additional capabilities through prepaid shared savings to address the unmet health-related social needs of the beneficiaries they serve and may have higher benchmarks due to the HEBA.

We proposed to calculate the HEBA as the multiplicative product of the HEBA scaler and the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. We proposed to calculate the HEBA scaler as a measure of the difference between the following two per-capita dollar values:

- 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary, expressed as a single value by taking a person year weighted average of the Medicare enrollment type-specific values: ESRD, disabled, aged/dually eligible for Medicare and Medicaid, and aged/non-dually eligible for Medicare and Medicaid, and
- the higher of the regional adjustment expressed as a single value, the prior savings adjustment, or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment.

We explained that this approach would ensure that the value of the HEBA itself cannot exceed 5 percent of national assignable per capita expenditures expressed as a single value using the ACO's BY3 enrollment proportions, similar to the cap applied to the regional adjustment under § 425.656(c)(3) and the cap applied to the prior savings adjustment under § 425.658(c)(1)(ii).

For this proposed health equity benchmark adjustment, we proposed to identify beneficiaries from underserved communities as those who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. Furthermore, we proposed to determine the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid using the ACO's performance year assigned population. We stated that because a higher proportion of assigned beneficiaries who are enrolled in Medicare Part D LIS or dually eligible would result in a higher HEBA, using the performance year assigned population is expected to incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities while accounting for changes in the ACO's population over the agreement period.

We proposed to provide ACOs with a preliminary calculation of the HEBA near the start of their agreement period when final historical benchmarks are determined, using the ACO's BY3 assigned population in this preliminary calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid. Under the proposed approach, we would then update the calculation when the ACO's historical benchmark is updated at the time of financial reconciliation for the performance year to reflect the ACO's performance year-assigned population in the calculation of the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

In the CY 2025 PFS proposed rule, we proposed (89 FR 61888) that ACOs with a proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid of less than 20 percent would be ineligible for a HEBA.[567] We explained our belief that imposing this threshold of 20 percent would reinforce that the HEBA is intended for ACOs serving higher proportions of beneficiaries who are members of underserved communities. Based on data from PY 2023, the average proportion of ACO-assigned beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid was roughly 15 percent. Thus, ACOs meeting the threshold of 20 percent are serving a larger-than-average proportion of beneficiaries from underserved communities. We explained that absent such a threshold, an ACO with a lower-than-average regional adjustment or prior savings adjustment (and therefore a larger HEBA scaler) that is providing care for relatively few beneficiaries from underserved communities may receive a sizable HEBA, which would reward the ACO despite it not serving a significant proportion of beneficiaries from underserved communities. This would not support the purpose of the HEBA, which is to provide a greater financial incentive for ACOs to serve more beneficiaries from communities and encourage practices already serving higher proportions of beneficiaries from underserved communities to enter and/or remain in the Shared Savings Program.

We explained in the CY 2025 PFS proposed rule (89 FR 61889) that under this proposed approach, simulation analysis based on 456 ACOs using historical benchmark data from 2023 indicated that 20 ACOs would receive a HEBA greater than either the prior savings adjustment or regional adjustment. With the HEBA applied, the average increase to historical benchmarks among these 20 ACOs would be $230 per capita, which corresponds to an increase of 1.57 percent to their historical benchmarks on average.

Tables 44 through 46 present hypothetical examples to demonstrate how the HEBA would work in practice.

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[567] The health equity adjustment to an ACO's MIPS quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117) has established a similar 20 percent threshold. ACOs with an underserved multiplier of less than 20 percent are not eligible to receive a health equity adjustment (§ 425.512(b)).

TABLE 44: ACO with a HEBA Greater Than the Regional Adjustment and Prior Savings Adjustment

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.60
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $100 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $100 = $400
Step 3: Calculate HEBA	Product of the proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid and the HEBA Scaler: 0.60 x $400 = $240
Step 4: Determine Final Adjustment to Benchmark	Highest of regional adjustment expressed as a single value, prior savings adjustment, or HEBA: Highest of $200, $100, or $240 = $240 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $240 = $92,240 Disabled: $13,000 + $240 = $13,240 Aged/dual: $19,000 + $240 = $19,240 Aged/non-dual: $10,000 + $240 = $10,240

TABLE 45: ACO with a HEBA Less Than the Regional Adjustment and Prior Savings Adjustment

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.25
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $300 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $300 = $300
Step 3: Calculate HEBA	Product of the proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid and the HEBA Scaler: 0.25 x $300 = $75
Step 4: Determine Final Adjustment to Benchmark	Highest of regional adjustment expressed as a single value, prior savings adjustment, or HEBA: Highest of $200, $300, or $75 = $300 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $300 = $92,300 Disabled: $13,000 + $300 = $13,300 Aged/dual: $19,000 + $300 = $19,300 Aged/non-dual: $10,000 + $300 = $10,300

TABLE 46: ACO Ineligible for the HEBA

Calculation Step	Description of Calculation and Example
Step 1: Calculate Proportion of Assigned Beneficiaries Who Are Enrolled in the Medicare Part D LIS or Dually Eligible for Medicare and Medicaid	Proportion of PY-assigned beneficiaries enrolled in Medicare Part D LIS or dually eligible for Medicare and Medicaid: 0.10
Step 2: Calculate HEBA Scaler	5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value: $600 Prior savings adjustment: $200 Regional adjustment expressed as single value: $300 Difference between 5 percent of the national per capita expenditures for assignable beneficiaries in BY3 expressed as a single value and the higher of prior savings adjustment and regional adjustment expressed as a single value: $600 – higher of $200 or $300 = $300
Step 3: Calculate HEBA	Step not applicable as ACO has a proportion of assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid less than 0.20 and is ineligible for a HEBA as a result.
Step 4: Determine Final Adjustment to Benchmark	Higher of regional adjustment expressed as a single value or prior savings adjustment: Higher of $200 or $300 = $300 Per capita historical benchmark expenditures by enrollment type after adjustment: ESRD: $92,000 + $300 = $92,300 Disabled: $13,000 + $300 = $13,300 Aged/dual: $19,000 + $300 = $19,300 Aged/non-dual: $10,000 + $300 = $10,300

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We proposed to implement the changes described in this section through revisions to § 425.652 and the addition of § 425.662. Specifically, within § 425.652, which sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we proposed revisions to § 425.652(a)(8). As proposed, this revised provision would describe how we would determine and apply the adjustment to an ACO's benchmark, if any, based on a comparison of the ACO's regional adjustment expressed as a single value, prior savings adjustment, and the proposed health equity benchmark adjustment. Furthermore, we proposed to amend § 425.652 by redesignating paragraphs (a)(9)(v) and (vi) as paragraphs (a)(9)(vi) and (vii), respectively, and to specify in a new paragraph (a)(9)(v) the adjustments made to the health equity benchmark adjustment for the first performance year during the term of the agreement period and in the second and each subsequent performance year during the term of the ACO's agreement period, if applicable. We also proposed conforming changes in newly redesignated § 425.652(a)(9)(vi), specifying that CMS redetermines the adjustment to benchmark in accordance with § 425.652(a)(8), to list the HEBA along with the regional adjustment and prior savings adjustment. In the proposed new section of the regulation at § 425.662, we describe the calculation of the HEBA. We also proposed to make conforming changes to § 425.658(d), which describes the applicability of the prior savings adjustment, to include consideration of the HEBA in addition to the regional adjustment, in determining the adjustment (if any) that would be applied to the ACO's benchmark. We sought comment on these proposals.

In combination with the proportion of ACO-assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid, we also solicited comment on the use of the Area Deprivation Index (ADI) to identify beneficiaries from underserved communities for purposes of determining eligibility for and the amount of any health equity benchmark adjustment. For example, similar to how the ADI is used in the underserved multiplier as part of the calculation of the health equity adjustment to an ACO's MIPS Quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117), we stated that we were considering taking the higher of either the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85 or the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS

or dually eligible for Medicare and Medicaid to determine eligibility for and the amount of any health equity benchmark adjustment. We stated that CMS would explore how best to incorporate geographic parameters into Shared Savings Program benchmark adjustments, informed by the current use of the ADI in other health equity provisions of the Shared Savings Program. We explained that CMS would also consider learnings from the Innovation Center's ACO REACH Model, which is testing the use of the ADI as a component of the model's HEBA. We stated that by considering the ADI in addition to the proportion of ACO-assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid, the HEBA would more closely align with existing Shared Savings Program policies to advance health equity, such as the health equity adjustment to an ACO's MIPS Quality performance category score (87 FR 69838 through 69857 and 88 FR 79114 through 79117) and the calculation of the amount of quarterly advance investment payments made available to eligible new, low revenue ACOs (87 FR 69782 through 69805 and 88 FR 79208 through 79216).

In the CY 2025 PFS proposed rule (89 FR 61892), we also explained that recent analyses have found that the ADI weights 2 variables (median home value and median income) higher relative to the weights associated with the other 15 variables in the index, which may have limited contributions in determining the ADI. In many indexes, variables are standardized to the same range for ease of comparison, prior to incorporation into the index. The ADI does not standardize its variables; median home value and median income are measured on their local area dollar-value scales, which are larger than the scales on which the other variables are measured. Some researchers have reported that, without standardization, the ADI overemphasizes the 2 variables (median home value and median income), a finding that may underscore the importance of using standardized values.[568] [569] [570] We solicited comment on considering the ADI for purposes of determining eligibility for and the amount of any health equity benchmark adjustment, and related factors including the calculation of the ADI.

The following is a summary of the public comments we received on the proposal to create a health equity benchmark adjustment, the comment solicitation on the use of ADI for purposes of determining eligibility for and the amount of any health equity benchmark adjustment, and conforming changes to the Shared Savings Program regulations, and our responses.

Comment: The proposed HEBA was generally supported by many commenters. One commenter stated they supported CMS's efforts to address the higher cost and resource utilization associated with dually eligible beneficiaries and those enrolled in Medicare Part D LIS. A few commenters acknowledged the proposed upward adjustment of the HEBA as a positive step towards enhancing health equity in the Shared Savings Program. One commenter appreciated CMS's efforts to implement a HEBA and acknowledged the challenge of developing a methodology to identify underserved beneficiaries for purposes of an ACO benchmark adjustment, noting that the proposed HEBA is a ''starting point'' and ''not necessarily the optimal approach.'' Another commenter supported the proposal to ''incentivize ACOs to treat rural and underserved beneficiaries through the establishment of the HEBA.'' Some of the supportive commenters encouraged CMS to find additional ways to ''support providers caring for underserved beneficiaries.''

The majority of supportive commenters believed that this adjustment will also improve beneficiary access to ACO providers in underserved areas, ''encourage equitable care for all beneficiaries,'' especially for ''dual-eligible beneficiaries who often face compounded health disparities,'' and improve participation in the Shared Savings Program by ACOs serving higher-risk beneficiaries. Commenters characterized the HEBA as a significant step forward in promoting health equity and addressing health disparities faced by dually eligible beneficiaries and those enrolled in Medicare Part D LIS.

Many commenters also supported the HEBA because it would modify current Shared Savings Program financial methodologies to better account for the needs of underserved beneficiaries. One commenter supported the HEBA, noting that ''remedying historical barriers to care among some populations might initially increase costs as these inequities are corrected.'' Other commenters stated that the HEBA would increase resources for ACOs serving underserved beneficiaries without penalizing other ACOs by reducing their benchmarks. Commenters generally characterized the HEBA as a positive step toward ensuring that all ACOs, regardless of size or location, have a fair opportunity to succeed in the Shared Savings Program while advancing equitable healthcare for all beneficiaries.

Response: We thank commenters for their support and agree that the HEBA will address the higher cost and resource utilization associated with dually eligible and LIS beneficiaries, increase beneficiary access to ACO providers in underserved areas, encourage equitable care (including by incentivizing ACOs to treat rural and underserved beneficiaries and better accounting for the needs of those beneficiaries), and improve participation in the Shared Savings Program by ACOs serving higher-risk beneficiaries. We appreciate commenters' support and acknowledge the challenge of developing a methodology to identify underserved beneficiaries for purposes of adjusting ACO benchmarks. We note that the HEBA is a starting point in this regard, and we will continue to refine the HEBA in accordance with learnings from ACO REACH and other CMMI models. We will also continue to evaluate additional ways to support Shared Savings Program ACOs and providers caring for underserved beneficiaries.

Comment: Several commenters, while supportive of CMS's goals to advance health equity, nonetheless expressed opposition to the proposal.

A few commenters expressed concerns that the proposed HEBA ''conflates risk adjustment with the goals of Shared Savings Program benchmarking policy'' and is thus ''unlikely to achieve its stated goals.'' These commenters encouraged CMS to develop policies that advance health equity without impacting benchmark adjustments. As an example, one commenter proposed that CMS implement a HEBA that more closely resembles the HEBA in ACO REACH, which uses a relatively small downward adjustment across many ACOs without a need for a health equity adjustment to

[568] *See* Hannan, EL, et al. The Neighborhood Atlas Area Deprivation Index For Measuring Socioeconomic Status: An Overemphasis On Home Value. *Health Affairs,* vol. 42, no. 5 (May 2023): 702–709. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01406.*

[569] *See* Rehkopf, DH, and Phillips, RL, Jr. The Neighborhood Atlas Area Deprivation Index And Recommendations For Area-Based Deprivation Measures. *Health Affairs,* vol. 42, no. 5 (May 2023): 710–711. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00282.*

[570] *See* Petterson, S. Deciphering the Neighborhood Atlas Area Deprivation Index: the consequences of not standardizing. *Health Affairs Scholar,* volume 1, issue no. 5 (November 2023), qxad063; Available at *https://academic.oup.com/healthaffairsscholar/article/1/5/qxad063/7342005.*

''subsidize'' upward adjustments for a smaller set of ACOs serving higher proportions of underserved beneficiaries. One commenter argued that because there is already a high rate of dually eligible beneficiaries in rural counties, the HEBA does not seem necessary to incentivize ACOs to serve dually eligible beneficiaries in all rural counties. Further, this same commenter suggested the HEBA would provide additional financial support to ACOs without commensurate support to dual eligible special needs plans (D–SNPs) and may make it more difficult for D–SNPs to compete with ACOs for providers in certain counties.

Response: We appreciate the commenters' concerns and recommendations. The Shared Savings Program has implemented policies that advance health equity without impacting benchmarking adjustments through advance investment payments and prepaid shared savings. We refer readers to our discussion of advance investment payments in the CY 2023 final rule at 87 FR 69782 through 69805, and in the CY 2024 final rule at 88 FR 79208 through 79216, as well as our discussion of prepaid shared savings in section III.G.5 of this final rule. Additionally, we explained in the CY 2025 PFS proposed rule (89 FR 61887) that the HEBA proposal was informed by CMS' initial experience with the ACO REACH Model, which includes a HEBA, that has been associated with increased participation in ACOs by safety net providers.[571] In contrast with the ACO REACH Model's HEBA, the Shared Savings Program's HEBA was proposed as an upward adjustment to the historical benchmark; and would not adjust historical benchmarks downward as a result of the proposed HEBA. The Shared Savings Program aims to design a health equity benchmark adjustment that incentivizes ACOs to form relationships with beneficiaries who are members of underserved communities while aligning the program's benchmarking policies and health equity initiatives. In this way, the HEBA would ensure that benchmarks continue to serve as a reasonable baseline when ACOs serve high proportions of beneficiaries who are members of underserved communities. Furthermore, the proposed HEBA is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities—including those residing in rural areas and in other underserved communities—and receiving lower regional adjustments (§ 425.656), lower prior savings adjustments (§ 425.658), or receiving neither adjustment. Increasing beneficiary access to providers participating in ACOs in both rural and other underserved areas remains a priority for CMS to help address inequities in ACO participation in the Shared Savings Program and grow accountable care.

We thank the commenter for their feedback on D–SNPs. We note that providers associated with Shared Savings Program ACOs are not prohibited from providing care in Medicare Advantage networks, and therefore we do not believe that the HEBA will necessarily make it more difficult for D–SNPs to compete with ACOs for providers in certain counties.

Comment: Several commenters suggested that CMS modify the policy to reduce or remove the requirement that at least 20 percent of ACOs' assigned beneficiaries must be enrolled in LIS or dually eligible in order for the ACO to be eligible for the HEBA. These commenters assert that the HEBA, as proposed, is expected to impact relatively few ACOs, and that removing or reducing the 20 percent threshold would significantly increase the number of ACOs eligible for the HEBA. A few commenters suggested eliminating the 20 percent threshold to maximize the HEBA's impact and ensure that value-based care models do not penalize providers caring for higher-risk beneficiaries. One commenter asserted that ''studies show that approximately 49 percent of safety net hospitals participate in a Shared Savings Program ACO, and a quarter of all participating Shared Savings Program ACOs include a Federally Qualified Health Center, thus demonstrating that the proposed methodology would not benefit the majority of ACOs serving dually eligible and LIS-enrolled beneficiaries.''

Several commenters stated that the HEBA as proposed would not go far enough—that the proposed approach considers too narrow of a population of beneficiaries for purposes of determining eligibility, is likely to benefit too few ACOs, would not adequately account for the expense associated with providing care for historically underserved populations, and is unlikely to drive increased or sustained participation in the Shared Savings Program.

Response: We are persuaded by commenters' concerns that the proposed policy considers too narrow of a population of beneficiaries for purposes of determining eligibility, is likely to benefit too few ACOs, and that removing or reducing the 20 percent threshold would increase the number of ACOs eligible for the HEBA while still furthering our policy goals with the HEBA explained in the proposed rule (89 FR 61887. In consideration of public comments, we are finalizing our proposal with modification. Specifically, we are modifying our policy (under § 425.662(b)(3)) to modify the requirement that ACOs must have at least 20 percent of their assigned beneficiaries enrolled in LIS or dually eligible in order to be eligible for the HEBA. We are instead finalizing § 425.662(b)(3) to require that ACOs have at least 15 percent of their assigned beneficiaries enrolled in LIS or dually eligible in order to be eligible for the HEBA.

Based on data for 456 ACOs that participated in the Shared Savings Program in PY 2023, decreasing the HEBA eligibility threshold to 15 percent will increase the number of ACOs estimated to receive a HEBA by 60 percent and, like our proposed 20 percent threshold, will continue to ensure that ACOs with an above-average percent of dually eligible or LIS enrolled beneficiaries are eligible for a HEBA.[572] Increasing the number of ACOs eligible for the HEBA by 60 percent supports the goals of the HEBA described in the CY 2025 PFS proposed rule (89 FR 61888) by increasing the likelihood that an ACO would earn shared savings and by potentially increasing the amount of shared savings earned, which in turn provides a greater financial incentive for ACOs to serve more beneficiaries from underserved communities and encourages ACOs already serving higher proportions of beneficiaries from underserved communities to remain in the Shared Savings Program and attracts new ACOs to join the Shared Savings Program. We will monitor the effect of using the 15 percent eligibility threshold for the HEBA and may revisit this threshold in future rulemaking.

This modification furthers the goals of the original proposal, including to provide greater financial incentives for ACOs to attract and retain underserved beneficiaries, particularly ACOs with smaller or no regional adjustments or prior savings adjustments, while also producing significant savings, as identified in the Regulatory Impact

[571] See Rawal P, Seyoum S, Fowler E. ''Advancing Health Equity Through Value-Based Care: CMS Innovation Center Update'', *Health Affairs Forefront,* June 4, 2024. DOI: 10.1377/forefront.20240603.385559. Available at *https://www.healthaffairs.org/content/forefront/advancing-health-equity-through-value-based-care-cms-innovation-center-update*.

[572] Based on PY 2023 data (for the 456 ACOs that participated in the Shared Savings Program in PY 2023), the average percent of ACO-assigned beneficiaries who are dually eligible or enrolled in LIS is approximately 15 percent.

Analysis Table D–B7, in section VI of this final rule. Removing the threshold entirely as some commenters recommended would result in ACOs that are not serving an above-average proportion of underserved beneficiaries receiving a HEBA, which is not in line with the intent of our HEBA proposal.

Further, we clarify for commenters who suggested that CMS ensure value-based care models do not inadvertently penalize providers caring for higher-risk beneficiaries that the HEBA is an upside-only adjustment to the benchmark, and it will not penalize providers with a downward adjustment. Regarding the commenter's statement that the HEBA, as proposed, would not benefit the majority of ACOs serving dually eligible and LIS-enrolled beneficiaries, we reaffirm that the HEBA as finalized with modifications will benefit ACOs serving an above-average proportion of LIS enrolled or dually eligible beneficiaries. The HEBA is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities and receiving lower regional adjustments or lower prior savings adjustments, or receiving neither adjustment. Regarding commenters' statements that the HEBA does not go far enough, we note that the HEBA as finalized with modifications will increase the number of ACOs estimated to receive a HEBA by 60 percent. We reiterate for commenters that we will monitor the HEBA's impact on ACOs participating in the Shared Savings Program and may consider modifications to the policy as appropriate in future notice-and-comment rulemaking.

Comment: Many commenters suggested that CMS make the HEBA additive, applicable in addition to the regional adjustment and prior savings adjustment to the benchmark, instead of applying only the highest positive adjustment for which the ACO is eligible. According to commenters, doing so would allow the HEBA to increase benchmarks for any ACO that has disproportionate number of assigned beneficiaries from underserved communities, thus allowing more ACOs to benefit from the HEBA and making the Shared Savings Program more appealing to ACOs whose assigned beneficiary population includes a disproportionate number of historically underserved beneficiaries. One commenter emphasized that this change would help to compensate for the lack of risk adjustment in the prior savings adjustment, which especially impacts renewing ACOs with high percentages of complex, high risk assigned beneficiaries.

Response: We thank commenters for their feedback. We disagree with commenters that we should make the HEBA additive, applicable in addition to the regional adjustment and prior savings adjustment to the benchmark. As noted in our proposal (89 FR 61887), our intent is to establish HEBA as a third method of upwardly adjusting an ACO's risk-adjusted historical benchmark, in addition to the existing regional adjustment and prior savings adjustment. This upward adjustment to the historical benchmark is designed to benefit ACOs serving larger proportions of beneficiaries from underserved communities and receiving lower regional adjustments (§ 425.656) or lower prior savings adjustments (§ 425.658), or receiving neither adjustment. We explain in the CY 2025 PFS proposed rule (89 FR 61887) that implementing a HEBA would ensure benchmarks continue to serve as a reasonable baseline when ACOs serve high proportions of beneficiaries who are members of underserved communities and incentivize ACOs to provide coordinated care to beneficiaries who are members of underserved communities. A HEBA is likely to encourage more participation in the Shared Savings Program by ACOs that serve beneficiaries who are members of rural and underserved communities by allowing them to participate with potentially higher benchmarks. That, in turn, would increase the likelihood that they could earn shared savings and increase the amount of those shared savings payments and reduce potential financial barriers to forming ACOs. Furthermore, a health equity benchmark adjustment would also encourage currently participating ACOs to attract more beneficiaries who are members of underserved communities and remain in the Shared Savings Program. However, a majority of existing ACOs already benefit from adjustments to their benchmarks based on the higher of the regional adjustment or prior savings adjustment. A further adjustment for ACOs already benefiting from the existing benchmark adjustment methodology would increase program spending without materially improving the incentive for these ACOs to continue participation. Therefore, we believe the proposal to include the HEBA as a third method of upwardly adjusting an ACO's risk-adjusted historical benchmark, is the appropriate approach to incentivizing ACOs to remain in or join the Shared Savings Program while balancing costs to the Trust Funds, and it would not be appropriate for the HEBA to be additive for ACOs already benefiting from prior savings adjustments or regional adjustments.

With respect to the commenter who stated that making HEBA additive would help ''compensate for the lack of risk adjustment in the prior savings adjustment, which especially impacts renewing ACOs with high percentages of complex, high risk assigned beneficiaries,'' we note that total per capita savings or losses for each performance year during the 3 years prior to the start of the ACO's current agreement (which are used to calculate the prior savings adjustment) are calculated using expenditures that are risk adjusted to reflect severity and case mix in the assigned beneficiary population in the performance year. Further, through recent prior rulemaking (see, for example, 88 FR 79185 and 79195) we have refined the financial methodology to support ACOs serving medically complex, high-costs populations, such as the policy to cap regional risk score growth in an ACO's regional service area when calculating regional trends used to update the historical benchmark at the time of financial reconciliation for symmetry with the cap on ACO risk score growth according to § 425.652(b)(2), and the policy to eliminate negative regional adjustments.

Further, we note for commenters that the prepaid shared savings option finalized in section III.G.5 of this final rule would operate synergistically with the proposed HEBA, in that ACOs that have been successful in earning shared savings while serving larger proportions of beneficiaries from underserved communities would in subsequent agreement periods have additional capabilities through prepaid shared savings to address the unmet health-related social needs of the beneficiaries they serve and may have higher benchmarks due to the HEBA.

Comment: A couple of commenters expressed concerns related to the proposed HEBA, including whether the HEBA's perceived complexity or the proposed cap on an ACO's HEBA equal to 5 percent of the United States Per Capita Costs (USPCC) may limit its impact or overall effectiveness. One commenter expressed concerns that introducing a third potential benchmark adjustment makes setting financial targets related to assigned beneficiary expenditures more difficult and may result in ''negative financial outcomes.'' Another commenter requested clarity related to whether CMS will modify the HCC risk adjustment process if the HEBA proposal is finalized.

Response: We acknowledge the complexity of the HEBA and refer readers to the discussion in the proposed rule (89 FR 61888) detailing how the HEBA is calculated and applied as well as to the Shared Savings Program's Program Guidance & Specifications web page,[573] where we anticipate publishing details on the HEBA calculation in a future version of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications. We also refer readers to the discussion elsewhere in this section of this final rule in which we describe the design of the HEBA, which does not feature a 5 percent cap of the USPCC or a downward adjustment that would introduce unpredictability when setting financial targets. Additionally, we explained that an ACO would receive the highest of the positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or health equity benchmark adjustment. The resulting historical benchmark can be used to set financial targets related to assigned beneficiary expenditures in the same way regardless of which—if any—adjustment was applied to the benchmark.

Additionally, in response to the commenter's request for clarity regarding whether we plan to implement any changes to the HCC risk adjustment process, we note that the HEBA is an upward adjustment to an ACO's historical benchmark that does not change or otherwise impact adjustments for changes in severity and case mix using prospective HCC risk scores when establishing or adjusting the benchmark as described in § 425.652(a)(3), (a)(9), and (a)(10). Accordingly, the finalization of the HEBA policy does not necessitate changes to our HCC risk adjustment methodologies.

Comment: Many commenters supported considering ADI to determine HEBA eligibility and amounts. These commenters stated that using ADI to determine HEBA eligibility and amounts could ''ensure more precise targeting of resources to areas most in need,'' and that, while person-level measures of social vulnerability are the ''gold standard, validated geographic indices such as the ADI are useful proxies.'' One commenter described the ADI as ''a crucial metric for identifying underserved communities.'' A few commenters recognized the shortcomings of currently available metrics, including ADI, for identifying beneficiaries from underserved communities but noted that using all available data on social risk for purposes of determining HEBA eligibility and amounts will ''expand the HEBA's ability to address issues [related to providing care for higher-risk beneficiaries].'' Many other commenters suggested considering metrics such as Medicare enrollment due to disability in combination with the ADI and the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid for the purposes of determining eligibility for and the amount of any HEBA. Another commenter suggested that it may be helpful to use ADI, which is a census block group level measure, to calculate HEBA amounts but noted that it ''may not be applicable to rural areas, for which most measures are available at the county level.''

Several commenters suggested alternatives to the ADI for the purpose of determining HEBA eligibility and amounts. One commenter suggested exploring whether the Social Vulnerability Index [574] or the new standardized area-level measure of socioeconomic deprivation under the ACO REACH Model [575] would be a better metric than ADI when used in combination with the proportion of ACO-assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid for determining HEBA eligibility and amounts in the Shared Savings Program. Additionally, one commenter noted that as CMS considers area-level composite indices of socioeconomic deprivation, such as the ADI, it is critical that those indices are comprised of a variety of unique measures of social vulnerability. One commenter encouraged CMS to consider ACO beneficiary engagement, Patient Reported Outcome Measures, and Patient Reported Experience Measures [576] when deciding an ACO's eligibility for HEBA and the amount of any adjustment. Another commenter emphasized the need for additional measures beyond ADI that are based on analyses of the root causes of historical inequality, such as hypersegregation and redlining, to more reliably design financial policies that promote health equity.

A few other commenters opposed the use of ADI for determining HEBA eligibility and amounts, arguing that ADI can ''underestimate the vulnerability of neighborhoods where housing prices do not reflect broader trends and other specific obstacles to health and healthcare.'' One of these commenters recommended using the Vizient Vulnerability Index,[577] which is more closely associated with average life expectancy than does the ADI. Two additional commenters opposed using the ADI and suggested that CMS continue to monitor and refine the use of ADI for calculating the ACO REACH Model's HEBA.

Response: We appreciate the commenter's feedback and will consider for future rulemaking.

After consideration of public comments, we are finalizing with modifications our proposed changes to the Shared Savings Program regulations to establish the HEBA that applies to ACOs with agreement periods beginning on January 1, 2025, and in subsequent years. We are finalizing our proposal to add a new section of the regulation at § 425.662 describing the calculation of the HEBA. We are finalizing as proposed the provisions of § 425.662, with the exception of § 425.662(b)(3). We are finalizing with modification the provision in § 425.662(b)(3), which specifies that CMS determines the ACO's eligibility for the HEBA based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid, to specify that: (1) an ACO is only eligible for the HEBA if this proportion is greater than or equal to 15 percent, and (2) an ACO with a proportion less than 15 percent is ineligible to receive a HEBA. This reflects a modification from the proposed eligibility threshold of 20 percent.

[573] *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations#Financial_and_Beneficiary_Assignment.*

[574] The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry Social Vulnerability Index is a place-based index, database, and mapping application designed to identify and quantify communities experiencing social vulnerability. See *https://www.atsdr.cdc.gov/placeandhealth/svi/index.html.*

[575] In PY 2025, CMS will remove the National/State blended ADI and replace it with an area-level socioeconomic deprivation measure that uses standardized variables. This will ensure the ADI accurately captures deprivation in areas with high housing values. See *https://www.cms.gov/aco-reach-model-performance-year-2025-model-update-quick-reference.*

[576] Patient-Reported Outcome Measures (PROM) and Patient Reported Experience Measures (PREM) are standardized questionnaires that can be used to capture patients' perspectives of their health and healthcare.

[577] See *https://www.vizientinc.com/what-we-do/health-equity/vizient-vulnerability-index-public-access.*

Further, within § 425.652, which sets forth the methodology for establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years, we are finalizing our proposal to revise § 425.652(a)(8) to describe how we would determine and apply the adjustment to an ACO's benchmark, if any, based on a comparison of the ACO's regional adjustment expressed as a single value, prior savings adjustment, and the health equity benchmark adjustment. Furthermore, we are finalizing our proposal to amend § 425.652 by redesignating paragraphs (a)(9)(v) and (vi) as paragraphs (a)(9)(vi) and (vii), respectively, and to specify in a new paragraph (a)(9)(v) the adjustments made to the health equity benchmark adjustment for the first performance year during the term of the agreement period and in the second and each subsequent performance year during the term of the ACO's agreement period, if applicable. We are also finalizing as proposed conforming changes in newly redesignated § 425.652(a)(9)(vi), specifying that CMS redetermines the adjustment to benchmark in accordance with § 425.652(a)(8), to list the HEBA along with the regional adjustment and prior savings adjustment. We are also finalizing as proposed to make conforming changes to § 425.658(d), which describes the applicability of the prior savings adjustment, to include consideration of the HEBA in addition to the regional adjustment, in determining the adjustment (if any) that would be applied to the ACO's benchmark.

Further, the text of the proposed regulations in the CY 2025 PFS proposed rule (89 FR 62228) included two technical changes to provisions of subpart G of part 425 that were not described in preamble. We proposed to amend § 425.650(a) by removing the reference to ''425.660'' and adding in its place the reference ''425.662.'' This change is necessary to ensure the range of sections specifying the benchmarking methodology for agreement periods beginning on or after January 1, 2024, referenced in § 425.650(a), appropriately includes the new section of the regulations at § 425.662, describing the calculation of the HEBA. As previously described in this section of this final rule, we are finalizing our proposal to add a new section of the regulation at § 425.662 describing the calculation of the HEBA. We received no comments addressing the proposed change in the regulations at § 425.650(a), and we are finalizing this technical change without modification.

Additionally, the text of the proposed regulations in the CY 2025 PFS proposed rule (89 FR 62230) included an amendatory instruction: ''Sections 425.664 through 425.669 are added and reserved.'' There was no corresponding discussion of this proposed change in the preamble. However, our proposed changes specified with the SAHS billing activity proposed rule (which appeared in the July 3, 2024 **Federal Register**, prior to the issuance of the CY 2025 PFS proposed rule, which appeared in the July 31, 2024 **Federal Register**) included the following amendatory instruction: ''Add reserved §§ 425.661 through 425.669 to subpart G'' (refer to 89 FR 55168, including the preamble discussion at 89 FR 55174, and text of the proposed regulations at 89 FR 55179). We finalized this proposed change, among our other proposals, in the SAHS billing activity final rule, which appeared in the September 27, 2024 **Federal Register** (refer to 89 FR 79152, including the preamble discussion at 89 FR 79165, and the text of the regulations at 89 FR 79171). We received no comments addressing this proposed change in the regulations. However, because we already added and reserved sections 425.664 through 425.669 in the SAHS billing activity final rule, we are not finalizing this proposal in this final rule.

c. Reopening ACO Payment Determinations

(1) Background

(a) Statutory Background on Shared Savings Program Financial Calculations

Section 1899(d)(1)(B)(ii) of the Act provides for the calculation and update of ACO benchmarks under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Further, an ACO's benchmark must be reset at the start of each agreement period. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act.

Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models, if the Secretary determines it is appropriate, and if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. As discussed in earlier rulemaking, we have used the authority under section 1899(i)(3) of the Act to adopt alternative policies to the provisions of section 1899(d)(1)(B) of the Act for updating the historical benchmark [578] and calculating performance year expenditures,[579] among other factors.[580] We have also used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models,[581] and to mitigate

[578] Such as using only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures (81 FR 37985 through 37989), calculating the benchmark update using factors based on regional FFS expenditures (81 FR 37977 through 37981), calculating the benchmark update using a blend of national and regional expenditure growth rates (83 FR 68027 through 68030), removing payment amounts for episodes of care for treatment of COVID–19 from expenditures used to calculate the benchmark update (85 FR 27577 through 27582), and calculating the benchmark update using an Accountable Care Prospective Trend/national-regional three-way blended update factor (87 FR 69881 through 69898).

[579] Such as excluding indirect medical education and disproportionate share hospital payments from ACO performance year expenditures (76 FR 67920 through 67922), determining shared savings and shared losses for the 6-month performance years (or performance period) in 2019 using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year or performance period (83 FR 59949 through 59951, 83 FR 67950 through 67956), removing payment amounts for episodes of care for treatment of COVID–19 from performance year expenditures (85 FR 27577 through 27582), and the exclusion of the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals from performance year expenditures (87 FR 69954 through 69956).

[580] Such as allowing for advance investment payments (87 FR 69782 through 69805), and expansion of the criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR as required under section 1899(d)(1)(B)(i) of the Act (87 FR 69946 through 69952).

[581] See earlier rulemaking establishing two-sided models: Track 2 (76 FR 67904 through 67909), Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 and 32772), and the BASIC

shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years.[582]

(b) Background on Shared Savings Program Reopening Policy and Financial Calculation Methodology

Under § 425.315(a)(1), if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error CMS may reopen the initial determination or a final agency determination under subpart I and issue a revised initial determination: (i) at any time in the case of fraud or similar fault as defined in § 405.902; [583] or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year, for good cause.

In accordance with § 425.315(a)(2), good cause may be established when (i) there is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion, or (ii) the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination. Section 425.315(a)(3) specifies that a change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under the Shared Savings Program regulations. CMS has sole discretion to determine whether good cause exists for reopening a payment determination (§ 425.315(a)(4)).

We first adopted a reopening policy in the November 2011 final rule, where we finalized at § 425.314(a)(4) a provision reserving the right for CMS to reopen the initial determination and issue a revised initial determination, if as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or amount of shared losses owed by the ACO has been calculated in error (see 76 FR 67957 through 67958, and 67982). In the June 2016 final rule, we revised the Shared Savings Program regulations, including to remove the provision in § 425.314(a)(4), and further specify the reopening policy in a new section of the regulation at § 425.315 (81 FR 37997 through 38002, and 38013 through 38014). We subsequently revised § 425.315 to apply the policies on reopening determinations to payment determinations for a 6-month performance year or 6-month performance period during CY 2019 (refer to the November 2018 final rule, 83 FR 59958 and 60092, and the December 2018 final rule, 83 FR 67955 through 67967), and to ACOs participating in the BASIC track (refer to the December 2018 final rule, 83 FR 67842 and 68068). In the CY 2023 PFS final rule, we clarified the circumstances in which CMS would exercise discretion to reopen the initial determination of an ACO's financial performance for good cause to correct errors in the determination of MIPS Quality performance category scores that affect the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of shared losses owed by the ACO (see 87 FR 69868 through 69869).

Most recently, in the CY 2024 PFS final rule, we finalized an approach to recalculating the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year following a reopening of ACO shared savings and shared losses calculations (88 FR 79195 through 79200). In the CY 2024 PFS final rule, we also discussed a proposed timing cutoff such that changes to savings or losses for a benchmark year that were finalized after notification to the ACO of the initial determination of shared savings or shared losses for a given performance year would be reflected in the adjusted benchmark applied to any subsequent performance year during the relevant agreement period but would not be retroactively applied to completed performance years in the agreement period (88 FR 79198 through 79200). We stated that we believed it would be appropriate to consider new information that could impact the prior savings adjustment up to the point at which an ACO receives its initial determination. However, we also noted that we would continue to consider the complexities surrounding reopening initial determinations for multiple prior performance years throughout the program's benchmarking and financial reconciliation methodologies and may address this issue in future rulemaking (88 FR 79199). We refer readers to these discussions in past rulemaking for additional details.

In our earlier rulemaking, we did not discuss the specific methodology that would be employed for recalculating an ACO's shared savings or shared losses in the event of a reopening in order to issue a revised initial determination. As additional background, in the following discussion, we summarize the general approach to identification and use of payment amounts from Medicare FFS Parts A and B FFS claims and certain other payment amounts in Shared Savings Program calculations.

Under the Shared Savings Program, providers and suppliers continue to bill for services furnished to Medicare beneficiaries and receive FFS payments under traditional Medicare. CMS uses payment amounts for Parts A and B FFS claims for calculating benchmark and performance year expenditures and determining benchmark update factors as specified in the Shared Savings Program regulations in subpart G. These operations typically require the determination of expenditures for Parts A and B services under the original Medicare FFS program for a specified population of Medicare FFS beneficiaries or the Medicare Parts A and B FFS revenue of ACO participants. The Medicare FFS beneficiary population for which expenditures are determined may differ depending on the specific program operation being performed and may reflect expenditures for the ACO's assigned beneficiaries, assignable beneficiaries, or all Medicare FFS beneficiaries. The applicable Medicare FFS beneficiary population is specified in the regulations governing each program operation.

In calculating expenditures for Medicare FFS beneficiaries used in Shared Savings Program calculations, CMS uses payment amounts included on Parts A and B FFS claims with dates of service in the relevant benchmark or performance year, allowing for a 3-month claims run out, as follows: claim payment amounts identified for inpatient, Skilled Nursing Facility (SNF), outpatient, Home Health Agency (HHA), and hospice claims at any provider; and line item payment amounts identified for carrier (including

track (83 FR 67834 through 67841). We also used our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID–19 from ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track (85 FR 27577 through 27582).

[582] See earlier rulemaking establishing policies for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances (82 FR 60916 and 60917, 83 FR 59974 through 59977).

[583] As defined in § 405.902, ''similar fault'' means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in 42 CFR part 411.

physician/supplier Part B) and Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims. For both Parts A and B claims, CMS excludes payments on denied claims or line items from the calculation, for claims or line items with dates of service within the relevant benchmark year or performance year, processed before the end of the 3-month claims run out period. In calculating expenditure amounts for Medicare FFS beneficiaries under the Shared Savings Program, CMS makes certain adjustments,[584] which if applicable, exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, and take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. We also account for certain population-based payments or other similarly structured payments made under other Medicare shared savings initiatives, specifically the Pioneer ACO Model, Next Generation ACO Model, Vermont All-Payer ACO Model, and ACO REACH Model (as applicable). Population-based payments are a per-beneficiary per month payment amount intended to replace some or all of the FFS payments with prospective monthly payment.[585]

The Shared Savings Program's existing financial methodology does not fully account for actions taken to protect the integrity of the Medicare program, or address the impact of improper payments, including improper payments resulting from fraud or similar fault on program calculations. For instance, demanded overpayment determinations resulting in adjusted claim or line item payment amounts after the 3-month claims run out period, or aggregate amounts that are not linked to specific claims or line items, are not accounted for in Shared Savings Program expenditure calculations. Additionally, under the existing financial methodology for the Shared Savings Program, we lack a means to account for improper payment amounts identified in a settlement agreement between a provider or supplier and the Government or a court's judgment, including pursuant to conduct by individuals or entities performing functions or services related to an ACO's activities. Under the proposed approach described in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule, the term ''improper payment'' for purposes of the Shared Savings Program would include an amount associated with a demanded overpayment determination and certain amounts identified in a settlement agreement or judgment that have the potential to impact program financial calculations. We explained in the CY 2025 PFS proposed rule that since January 2023, we have evaluated several cases where such improper payments may have impacted one or more reconciled performance years for an ACO under the Shared Savings Program, including cases where ACOs reported concerns about alleged fraud or similar fault to CMS. We stated it is thus timely and appropriate to undertake notice and comment rulemaking to establish a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a); to describe factors that we may consider in exercising our discretion to reopen an ACO's payment determination under which we apply the proposed methodology to recalculate the ACO's financial performance; and to propose to establish a process by which an ACO could request a reopening of an initial determination of shared savings or shared losses. Our experience reviewing several cases supported the development of our proposed revisions to Shared Savings Program policies.

(2) Revisions

Section III.G.7.c.(2) of the CY 2025 PFS proposed rule (89 FR 61894 through 61909) included a proposed change to the provision specifying CMS' discretion to reopen payment determinations under § 425.315(a)(4) (described in section III.G.7.c.(2).(a) of the proposed rule). We discussed and solicited comment on the circumstances in which we would exercise our discretion to reopen a payment determination and issue a revised initial determination to account for the impact of identified improper payments on Shared Savings Program calculations (described in section III.G.7.c.(2).(b) of the proposed rule). We proposed modifications to the Shared Savings Program regulations to specify a calculation methodology to account for the impact of identified improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a) (described in section III.G.7.c.(2).(c) of the proposed rule). We also proposed certain adjustments to Shared Savings Program benchmark calculations to account for the impact of identified improper payments, in the event a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's current agreement period, and when CMS has not yet issued an initial determination for a performance year of the ACO's current agreement period (described in section III.G.7.c.(2).(d) of the proposed rule).[586] Lastly, we proposed a process for ACOs to request that CMS reopen a payment determination (described in section III.G.7.c.(2).(e) of the proposed rule), and briefly discussed the role of ACOs in preventing and reporting Medicare fraud (described in section III.G.7.c.(2).(f) of the proposed rule). Our specific proposals are discussed in detail in the following sections.

We proposed that the policy changes discussed in section III.G.7.c. of the CY 2025 PFS proposed rule would be effective January 1, 2025, unless specified otherwise (89 FR 61894). We explained that should the proposed policies be finalized, the policies would apply to reopening requests made on or after January 1, 2025. We also explained that if the proposal to establish a process by which an ACO may request a reopening review was to be finalized, we anticipated continuing to evaluate previously received reopening requests for performance years for which initial determinations were issued prior to January 1, 2025, consistent with the timeframes specified under § 425.315(a)(1). If the proposed recalculation methodology to account for the impact of improper payments were to be finalized, we would consistently apply the methodology in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations upon reopening a payment determination pursuant to § 425.315(a).

The following is a summary of general comments we received on our discussion and proposals regarding reopening ACO payment determinations

[584] The Shared Savings Program's financial models and benchmarking policies, among other program policies, have changed over time as described in earlier rulemaking (refer to section III.G.1.b. of this final rule), and as outlined in the provisions of subpart G.

[585] See for example, Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (Version 11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (refer to Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures).

[586] We refer readers to section III.G.7.c.(2).(d) of this final rule, in which we clarify the applicability of the benchmark adjustment.

and the timing of applicability of the proposed modifications.

Comment: Most commenters addressing the reopening policy proposals and related considerations described in section III.G.7.c of the CY 2025 PFS proposed rule responded favorably to an approach under which CMS would recalculate ACO financial performance and adjust ACO historical benchmarks to account for the impact of improper payments on Shared Savings Program financial calculations, establish a process for ACOs to request reopening, and related considerations in connection with these proposals. Some commenters addressed the specific proposals or policy considerations, including to provide alternative suggestions, or to urge CMS to provide additional information on the approach and transparency into its processes. At least one commenter, which was a supportive commenter, attempted to summarize the proposals, but did so inaccurately.[587]

Some commenters addressing the proposals and related considerations tended to express general support for CMS' proposal to codify a process for reopening payment determinations in instances where improper payments have been identified. Only a few commenters provided detailed explanations of their support. More generally, one commenter explained the approach is responsive to ongoing concerns from ACOs around the negative impact of bad actors on both the Medicare Trust Funds as well as ACOs' ability to succeed in the Shared Savings Program. Another commenter supported proposals to facilitate the reopening of payment determinations to assist in mitigating the negative effects of improper payments. Some commenters stated their belief that the reopening policy could be an opportunity to remove instances of fraud or abuse from ACO performance calculations, and tended to underscore that criminal matters are not often resolved until months or years after a performance year's reconciliation. Some of these commenters further explained that ACOs typically hear about confirmed fraud in their markets years after the performance period ended yet have no recourse for action, and as a result, ACOs are held accountable for patients' total cost of care but have no ability to stop instances of improper payments. One commenter expressed their belief that accounting for the impact of certain improper payments in performance year and benchmark expenditures, among other proposed changes to Shared Savings Program policies described in the CY 2025 PFS proposed rule, will help increase participation in ACOs and enable ACOs to focus more on underserved populations, but did not offer a detailed explanation of how this could occur.

Response: We summarize and respond to commenters' specific concerns and suggestions throughout the rest of this section of this final rule. We appreciate the commenters' support for the proposals in connection with reopening ACO payment determinations. As described throughout this rest of this section of this final rule, we are finalizing our proposals, and note that in the case of the benchmark adjustment we are finalizing a clarification to our proposal, as specified in section III.G.7.c.(2).(d) of this final rule.

As we explained in the CY 2025 PFS proposed rule, the Shared Savings Program's existing financial methodology does not fully account for actions taken to protect the integrity of the Medicare program, or address the impact of improper payments, including improper payments resulting from fraud or similar fault on program calculations. We acknowledge commenters' concerns that ACOs' financial performance can be negatively impacted by confirmed fraud in their markets that is beyond their control yet are held accountable for the related costs, potentially impeding their ability to succeed in the Shared Savings Program. Addressing improper payments in the Medicare program, through the program's reopening authority, would help protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations, and lead to greater beneficiary protections and protection of the Trust Funds.

While ACOs may learn of fraud or abuse in their region, or impacting their assigned beneficiaries, not all instances of such conduct may result in a decision by CMS to reopen the ACO's payment determination and to issue a revised initial determination. CMS retains discretion over whether to reopen payment determinations after identifying improper payments that have the potential to impact Shared Savings Program financial calculations, which may come to our attention through ACO reopening requests, as well as input from program integrity staff and law enforcement agencies. We also caution ACOs of the potential effects on their performance that could result from addressing the impact of improper payments on Shared Savings Program financial calculations. As described in section III.G.7.c.(2).(c). of this final rule, accounting for the impact of improper payments on expenditures could increase or decrease an ACO's amount of shared savings or shared losses. We also reiterate a key point from our discussion in section III.G.7.c.(2).(b) of this final rule, that we are continuing to consider applying an approach under which we differentiate between cases where improper payments originate inside the ACO versus outside the ACO, in deciding whether to reopen the payment determination, in order to strike a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations.

Codifying an approach to account for the impact of improper payments in Shared Savings Program financial calculations, and establishing a process for ACO reopening requests are critical initial steps towards more systemically identifying and addressing improper payments that impact Shared Savings Program calculations.

Comment: Many of the comments on the reopening policies in the CY 2025 PFS proposed rule addressed both the reopening policy proposals and SAHS billing activity proposals, and did not differentiate between these two approaches. For instance, a few commenters expressed support for the reopening policy proposals in conjunction with the proposal to mitigate the impact of SAHS billing activity on Shared Savings Program financial calculations in CY 2024 or subsequent calendar years. One such commenter encouraged CMS to ''streamline the process'' as much as possible (although the commenter did not make clear the process being referred to) and to work with ACOs to ''address SAHS situations as early as possible.''

Some commenters' descriptions generally indicated that the concept of SAHS billing activity was addressed through or included in the reopening policy. For instance, several commenters suggested that CMS hold ACOs ''harmless'' for SAHS billing activity by recalculating expenditures and payment amounts to account for improper payments upon reopening a payment determination and excluding SAHS billing activity from expenditure and revenue calculations for the relevant calendar year, as well as from historical benchmarks. Another commenter stated support for CMS' ''exclusion [of] SAHS billing including

[587] We refer commenters and other readers of this final rule to the summary of the proposals and policy considerations described elsewhere in this section of this final rule to aide their understanding of the proposals.

establishing a process to reopen payment determinations.''

Further, we have summarized and responded to comments addressing the SAHS billing activity policy within section III.G.7.d. of this final rule.

Response: These comments indicate that some commenters may have misunderstood the differences between the SAHS billing activity policy proposal and the reopening policy proposal. Together, the SAHS billing activity policy and the reopening policy provide a comprehensive basis for CMS to adjust payment amounts used in Shared Savings Program financial calculations. Each policy, however, addresses a different type of payment issue. Under the SAHS billing activity policy proposal (refer to section III.G.7.d of this final rule), CMS would proactively adjust Shared Savings Program calculations pursuant to a determination that SAHS billing activity occurred in CY 2024 or a subsequent calendar year. The SAHS policy would address and remove—prior to financial reconciliation for a performance year—large scale, unexplained billing anomalies for all ACOs. By contrast, the reopening process is the mechanism by which CMS would determine whether to reopen a previous initial determination and final agency determination for a performance year, for fraud or similar fault, or good cause, as specified under § 425.315(a), and issue a revised initial determination, which may include accounting for the impact of identified improper payments in recalculating savings or losses under the proposed calculation methodology (refer to section III.G.7.c.(2).(c) of this final rule). CMS may learn of potential inaccuracies in the ACO's previously completed financial reconciliation results through an ACO's submission of a reopening request, and we proposed to establish a related reopening request process (refer to section III.G.7.c.(2).(e) of this final rule).

Further, since the adjustment for SAHS billing activity would occur prior to the issuance of an initial determination, we would not reopen an initial determination to adjust for payment amounts excluded under the SAHS billing activity policy. Those amounts were already excluded in their entirety from all calculations due to the high probability of inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if left in. However, we note that there could be other reasons why CMS would reopen an initial determination which used expenditures adjusted under the SAHS billing policy.

To the extent the commenters' remarks are suggesting that CMS use alternative approaches to address SAHS billing activity, to account for the impact of improper payments on Shared Savings Program financial calculations upon reopening a payment determination, or both, we decline these suggestions at this time. In light of the aforementioned considerations, the adjustment for SAHS billing activity described in section III.G.7.d of this final rule, and the policies for recalculating expenditures and payment amounts to account for improper payments upon reopening a payment determination, each support critical and different functions for improving the accuracy, fairness, and integrity of Shared Savings Program financial calculations. We believe it is timely to finalize proposals in each of these policy areas. As we gain experience with these policies, we may revisit potential interactions between the policies in future notice and comment rulemaking.

Comment: Some commenters addressed the discussion in the CY 2025 PFS proposed rule on the timing of applicability of the policy changes on reopening ACO payment determinations, and in particular the applicability of the policies to reopening requests made on or after January 1, 2025. These commenters requested that CMS apply the policy changes on reopening ACO payment determinations to reopening requests for performance years prior to 2025. Commenters making this suggestion tended to specify that CMS should apply the policy for reopening ACO payment determinations to address other billing activity that ACOs suspect to be SAHS, citing examples impacting CY 2023 that would not be addressed by the rulemaking to address SAHS billing activity for urinary catheters in CY 2023 (see SAHS billing activity proposed rule, 89 FR 55168), or CY 2024. (Related comments are summarized and responded to in section III.G.7.d. of this final rule.) One commenter specified that ACOs had identified ''improper payments'' impacting performance years prior to 2025, including billings for skin substitutes, ventilators, diabetic supplies, and collagen dressings, but did not specify additional details including how the determination was made or the year(s) impacted.

Response: Commenters' suggestions that the policy changes on reopening ACO payment determinations apply to reopening requests for performance years prior to 2025, may reflect confusion over the difference between the effective date for the policies being finalized in this final rule and the timeframes for reopening payment determinations in accordance with § 425.315(a) (as amended by this final rule), and the new process for ACOs to request reopening review under the provisions we are finalizing with this final rule in § 425.315(b) (as described in section III.G.7.c.(2).(e) of this final rule). Under the policies we are finalizing described in section III.G.7.c. of this final rule, ACOs may submit to CMS for consideration reopening requests for performance years prior to PY 2025. CMS will apply the policies established with this final rule beginning on the effective date of the final rule, January 1, 2025. As we specified in the CY 2025 PFS proposed rule, and reiterated in section III.G.7.c.(2).(e) of this final rule, the timing of an ACO's reopening request must be consistent with the timeframes specified in § 425.315(a)(1)(i) and (ii), respectively, either (i) at any time in the case of fraud or similar fault, or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause. Consistent with our statement in the CY 2025 PFS proposed rule (89 FR 61894), with the finalization of the policies on reopening ACO payment determinations in this final rule, we will evaluate previously received reopening requests for performance years for which initial determinations were issued prior to January 1, 2025, consistent with the timeframes specified under § 425.315(a)(1). In recalculating expenditures and payment amounts used in Shared Savings Program financial calculations to account for the impact of improper payments, we will consistently apply the methodology finalized in this section of this final rule, upon reopening a payment determination pursuant to § 425.315(a).

In response to a commenter's assertion that ACOs have identified improper payments impacting performance years prior to 2025, we encourage ACOs, or anyone else suspecting healthcare fraud, waste or abuse to report it to CMS or the Department of Health and Human Services Office of Inspector General (HHS–OIG). Refer to section III.G.7.c.(2).(f) of this final rule entitled ''Preventing and Reporting Medicare Fraud'' for related information. As explained in section III.G.7.c.(2).(e) of this final rule, we anticipate providing additional information on the reopening request process for ACOs through guidance, including the form and manner in which CMS must receive a

reopening request. ACOs seeking to submit a reopening request prior to the issuance of the guidance material on the reopening request process are encouraged to submit detailed information in writing to CMS by email to *SharedSavingsProgram@cms.hhs.gov*. Further, as we described in the CY 2025 PFS proposed rule, and reiterated in section III.G.7.c.(2).(b) of this final rule, the Shared Savings Program will coordinate with program integrity staff and law enforcement agencies to identify and quantify improper payments potentially impacting expenditures used in program calculations that are not otherwise accounted for in Shared Savings Program expenditure calculations.

Although some commenters referred to billing activity that ACOs may suspect to be SAHS billing activity, we wish to reiterate that CMS will have the sole discretion to identify cases of SAHS billing activity for a particular calendar year that warrant adjustment of Shared Savings Program financial calculations, for CY 2024 or subsequent calendar years, in the approach we are finalizing in section III.G.7.d of this final rule. Further, as we describe elsewhere in this final rule, we anticipate this policy to adjust Shared Savings Program calculations to mitigate the impact of SAHS billing activity would be invoked in rare and extreme cases when CMS identifies a code that meets the high bar to be defined as SAHS billing activity. In section III.G.7.d. of this final rule, we summarize and respond to public comments received on the proposals to mitigate the impact of SAHS billing activity on Shared Savings Program financial calculations in CY 2024 or subsequent calendar years.

More generally, in the discussion that follows, we summarize and respond to public comments we received on the remaining proposals and considerations described in section III.G.7.c.(2) of the CY 2025 PFS proposed rule.

(a) Change to Provision Specifying CMS' Discretion To Reopen Payment Determinations

In earlier rulemaking we explained that CMS would have discretion to reopen a payment determination for fraud or similar fault, or good cause, as reflected in the provisions in § 425.315(a)(1) and (4). The latter provision expressly provides that CMS has sole discretion to determine whether good cause exists for reopening a payment determination. In the June 2016 final rule, in restating the discussion of the proposal from the February 2016 proposed rule, we explained that CMS would have discretion to reopen a payment determination at any time in the case of fraud or ''similar fault,'' as defined in § 405.902 (81 FR 37998).

We continue to believe that it is important to maintain CMS' sole discretion in determining whether to reopen a payment determination. We also believe it is important to preserve CMS' flexibility in determining whether reopening is warranted to address the impact of fraud or similar fault on Shared Savings Program calculations, in particular given the potential for various actions to be taken by CMS, law enforcement agencies and courts in response to fraud or similar fault. Thus, we proposed revisions to § 425.315(a)(4) to make clear that CMS has the sole discretion to determine whether to reopen a payment determination in the case of fraud or similar fault, as well as to determine whether good cause exists to reopen a payment determination.

We received no comments directly addressing the proposed revisions to § 425.315(a)(4), as described in this section of this final rule. We are finalizing without modification our proposal to revise § 425.315(a)(4) to make clear CMS' discretion applies to determining whether to reopen a payment determination in the case of fraud or similar fault, as well as to determining whether good cause exists to reopen a payment determination.

(b) Considerations for Reopening a Payment Determination To Account for Improper Payments

In section III.G.7.c.(2).(b) of the CY 2025 PFS proposed rule (89 FR 61895 through 61898), we described factors CMS may consider to inform our decision of whether to reopen an initial determination of an ACO's financial performance pursuant to § 425.315(a)(1)(i) or (ii) to account for the impact of improper payments that affect the determination of whether an ACO is eligible for shared savings or liable for shared losses, and the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO. We solicited comments on these considerations. We also explained that we anticipate revisiting these considerations as we gain experience with processing ACO reopening requests as described in section III.G.7.c.(2).(e) of the proposed rule (89 FR 61907 through 61908), reopening payment determinations and applying the calculation methodology described in section III.G.7.c.(2).(c) of the proposed rule (89 FR 61898 through 61907), and applying the benchmark adjustment described in section III.G.7.c.(2).(d) of the proposed rule (89 FR 61907). We specified that, if appropriate, we may revisit these considerations for exercising our discretion to reopen payment determinations in future notice and comment rulemaking.

As an initial matter, the Shared Savings Program would need to identify improper payments that have the potential to impact program financial calculations. The Shared Savings Program depends on input from the CMS Center for Program Integrity (CPI) and law enforcement agencies (including the Department of Justice) to identify and quantify improper payments potentially impacting expenditures used in program calculations that are not otherwise accounted for in Shared Savings Program expenditure calculations as described in section III.G.7.c.(2).(b) of the CY 2025 PFS proposed rule. This could include: (1) certain demanded overpayment determinations, such as demanded overpayment amounts that result in adjusted claim or line item payment amounts associated with dates of service during a performance year or benchmark year, where the adjustment occurs after the 3-month claims run out period, and demanded extrapolated overpayment amounts which are aggregate amounts that are not linked to specific claims or line items and are not currently accounted for in Shared Savings Program expenditures; [588] and (2) improper payments resulting from conduct by individuals or entities performing functions or services related to an ACO's activities as identified in certain settlement agreements or judgments. In section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule we discussed considerations for identifying these amounts. Further, as discussed in greater detail in section III.G.7.c.(2).(e) of the CY 2025 PFS proposed rule, ACOs can play an important role in identifying for CMS improper payments that may impact Shared Savings Program calculations. ACO reopening requests submitted to CMS may be another means by which the Shared Savings Program becomes aware of improper payments impacting ACO financial calculations; however, CMS would retain discretion over whether to reopen payment determinations after

[588] For additional information on overpayment procedures and overpayment estimation, see, for example, Medicare Program Integrity Manual, Chapter 8—Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c08.pdf.*

reviewing information provided in such requests.

Second, we anticipated needing to perform an initial analysis of whether the improper payments would warrant reopening the ACO's payment determination. This analysis may include a number of factors, such as whether the improper payments meet the requirements for reopening for fraud or similar fault in accordance with § 425.315(a)(1)(i), or for good cause in accordance with § 425.315(a)(1)(ii) and (a)(2). A variety of circumstances could lead CMS, law enforcement agencies or courts to determine whether good cause exists or whether fraud or similar fault has occurred. The timelines associated with the related investigations, and the potential for various actions to be taken in response, can make it challenging to identify a one-size-fits-all approach to addressing the impact of improper payments on Shared Savings Program calculations. We noted that once we are notified of potential improper payments impacting Shared Savings Program calculations, it may take months or years to determine the actual amount of any improper payments impacting an ACO's payment determination, particularly if we are awaiting the conclusion of program integrity and law enforcement investigations, among other possible determinations about the related conduct of providers or suppliers. Additionally, administrative action and judicial action leading to the identification of improper payments may be subject to appeal, and ultimately the amount of the improper payments may be redetermined or otherwise amended.[589] It would further protract the timeline for considering use of improper payments in recalculating ACO financial performance results to await the outcome of any appeal of an improper payment.

We further explained that since there could be a variety of reasons for which CMS seeks to recoup an overpayment amount from a provider or supplier, there are many possible circumstances that could warrant reopening under § 425.315. As an example, we may consider a combination of factors in evaluating whether demanded overpayment determinations would be the basis for reopening for fraud or similar fault under § 425.315(a)(1)(i).[590] For instance, we may consider whether there is ''reliable evidence'' (as defined according to § 405.902, which means evidence that is relevant, credible, and material) of similar fault to warrant reopening a Shared Savings Program payment determination.[591] For purposes of the Shared Savings Program's reopening policy, we may find there is reliable evidence of similar fault when a demanded overpayment determination was issued to a provider or supplier for which CMS has revoked or deactivated their Medicare billing privileges, or for which there is a closed law enforcement investigation, among other possible factors. Although demanded overpayment determinations are subject to appeal, we stated our belief that using these amounts in reopening and recalculating an ACO's financial performance under the Shared Savings Program would allow us to more timely address the impact of improper payments on Shared Savings Program calculations, rather than waiting to consider the outcome of any possible appeal of the amounts (as discussed in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule, 89 FR 61906).

We explained that as part of our initial analysis to evaluate whether to reopen an ACO's initial determination, we may also consider the significance of the improper payments to an ACO's financial calculations by estimating the financial impact of improper payments on an ACO's payment determination. We noted that if we estimate that the improper payments have impacted the dollar amount of earned shared savings, or the amount of shared losses that the ACO owes or has paid to CMS, we anticipate reopening an ACO's payment determination. We described that, when determining whether to reopen an ACO's payment determination, we anticipate considering a combination of factors including:

- The dollar value of improper payments and the number of claims or line items impacted (if applicable).
- How any related impact on performance year expenditures may compare to the impact on the ACO's updated historical benchmark (which could include considering the impact on benchmark year expenditures and factors used to establish, adjust and update the benchmark). In particular, we may consider whether comparing performance year expenditures to the updated benchmark expenditures used in financial reconciliation, once adjusted to account for the estimated impact of the improper payments, would result in a significant change in the amount of shared savings paid to or shared losses owed by the ACO. For purposes of this analysis we may consider the following (restated with a minor corrections for clarity):

++ The minimum savings rate (MSR)/minimum loss rate (MLR) applicable to the ACO for the relevant performance year.

++ Whether the ACO met or exceeded the applicable MSR/MLR with the initial determination.

++ Whether accounting for improper payments would cause a change in the ACO's financial performance compared to its performance under the initial determination, including:

—Causing an ACO to meet or exceed its MSR/MLR when it did not do so under its initial determination, or to no longer meet or exceed the relevant threshold when it did so under its initial determination.

—Causing an ACO that shared in savings or owed shared losses under the initial determination to share in either a higher or lower amount of savings or losses (respectively).

—Causing an ACO to continue to generate savings or losses less than the MSR/MLR threshold, as it did under its initial determination, and therefore the ACO would remain ineligible for shared savings, except in cases where certain low revenue ACOs participating in the BASIC track may qualify for a shared savings payment in accordance with § 425.605(h), and would not be held liable for shared losses.

We noted that the existing reopening authority at § 425.315 and the proposed financial methodology to address improper payments in such a reopening are not intended to address particular instances of low-value improper payments which, in an individual case may be to the benefit of either the ACO

[589] For instance, a provider receiving an initial demand letter for an overpayment may appeal the overpayment by requesting a redetermination, among other actions. See for example, CMS, MLN Fact Sheet, ''Medicare Overpayments'' (MLN006379 October 2023), available at *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/overpaymentbrochure508-09.pdf*. The Medicare Parts A and B appeals process includes multiple levels of appeal. See for example, CMS, MLN Booklet, ''Medicare Parts A & B Appeals Process'' (MLN006562 November 2023), available at *https://www.cms.gov/files/document/mln006562-medicare-parts-b-appeals-process.pdf*.

[590] While this example presumes reopening for fraud or similar fault, there may be additional considerations and complexities around reopening for good cause.

[591] This approach may continue to maintain a degree of alignment between reopening policies under the Shared Savings Program and other Medicare policies. In the February 2016 proposed rule, in which we proposed amending the Shared Savings Program's reopening policy, we referred to the longstanding policy in the Medicare program that a determination may be reopened at any time if it was procured by fraud or similar fault, and as an example referred to 42 CFR 405.980(b)(3) (see 81 FR 5855). In accordance with § 405.980(b)(3), a contractor may reopen an initial determination or redetermination on its own motion at any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

or CMS and in the aggregate are likely have a de minimis net effect on program expenditures in the long run.[592] CMS would be highly unlikely to reopen in such cases under § 425.315. We stated our belief that considering the significance of the potential impact of the improper payments on the ACO's payment determination, in deciding whether to reopen the payment determination, is a key component of striking a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations. We discussed related concerns and considerations elsewhere in the CY 2025 PFS proposed rule. Therefore, we would seek to reopen an ACO's payment determination only in cases where the impact of improper payments warrants disrupting the initial determination.

We discussed, as an example, the case of an initial determination in which we found that an ACO generated savings below its MSR and, therefore, did not qualify for a shared savings payment according to the policies for determining the ACO's eligibility for shared savings applicable to its agreement period under the Shared Savings Program.[593] If, based on an initial analysis, we estimate that the ACO's savings, though higher once adjusted to remove improper payments from performance year expenditure calculations, would still fall below the MSR, it would not be necessary to reopen an ACO's payment determination because the ACO would still not qualify for a shared savings payment. Under such circumstances, we would not reopen the initial determination or proceed with the recalculations described in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule. We anticipated that this particular type of situation could occur in cases where the improper payments at issue are relatively small and the differential between an ACO's generated shared savings and MSR as calculated in the initial determination is relatively large such that recalculating the amounts would not produce a different outcome to the payment determination.

It is also possible that improper payments would have no impact on Shared Savings Program financial calculations as they may consist of claims or payment amounts that were not used in reaching the initial determination of the ACO's financial performance. For instance, if a demanded overpayment determination was for a payment amount on a claim with a HCPCS or CPT code identified as having significant, anomalous, and highly suspect billing activity, and therefore the payment amount was excluded from certain financial calculations used in determining the ACO's financial performance under the proposed adjustment discussed in section III.G.7.d of the CY 2025 PFS proposed rule, we would not include this amount as part of a reopening for the same performance year. As another example, if the demanded overpayment determination was for a claim or line item that was initially paid after the end of the 3-month claims run out period, we would not take into account through the reopening process a payment amount that was not included in Shared Savings Program calculations to begin with. We anticipated improper payments identified in these circumstances would not merit reopening the ACO's initial determination.

We specified that a number of steps would follow after CMS has decided to reopen the initial determination. We would recalculate the ACO's financial performance for a performance year by applying the methodology as described in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule. With this recalculation we would determine the amount of shared savings payment the ACO may be eligible to receive or the amount of shared losses the ACO may owe for the performance year after accounting for the impact of the improper payments. We would issue a revised initial determination to the ACO with the recalculated payment determination for the performance year. We would notify the ACO of savings and losses in accordance with § 425.604(f), § 425.605(e), § 425.606(h), § 425.609(e), or § 425.610(h) (as applicable). Depending on the outcome of the recalculation as specified in the revised initial determination, we would engage in payment activities and recoupment activities, as needed. As explained in earlier rulemaking, we anticipated considering ways to minimize program disruptions for ACOs that could result from one or more reopenings (see for example, 81 FR 38001 through 38002; see also, 87 FR 69868 through 69872). We noted that CMS may require considerable time after deciding to reopen an initial determination before it can complete the aforementioned process for a variety of reasons. For example, additional time may be necessary for CMS or other agencies to ascertain the precise amount of improper payments that affected the initial determination.

In reopening a payment determination, we noted that improper payments may impact either performance year expenditures, the ACO's updated historical benchmark used in determining the ACO's financial performance (including calculation of benchmark expenditures and factors used to establish, adjust and update the ACO's historical benchmark), or both. The recalculation of the ACO's financial performance may have varying effects on the ACO's payment determination for the performance year. In some scenarios, the recalculation may change the determination of whether the ACO earned shared savings or owes shared losses, or may change the amount of any shared savings earned or shared losses owed. It is also possible that we may observe there is no impact on the amount of shared savings earned or amount of shared losses owed by the ACO, once we have performed the recalculation of the ACO's financial performance.

Under the Shared Savings Program's benchmarking methodology, there are potential interactions between performance of an ACO under the program for a performance year during an agreement period and resetting the ACO's benchmark for a subsequent agreement period. Specifically, an ACO's performance year may correspond to a benchmark year of its subsequent agreement period, such that improper payments impacting expenditures for Medicare FFS beneficiaries used to determine performance year expenditures may similarly impact expenditures for the same period used to establish the ACO's historical benchmark. For instance, for ACOs that have participated in the Shared Savings Program over multiple agreement periods, improper payments may impact the amount of a prior savings adjustment to the historical benchmark (if applicable).[594] We noted

[592] *See, for example,* 81 FR 38000 and 38001.

[593] This example assumes a one-sided model ACO with an MSR based on the number of beneficiaries assigned to the ACO, or a two-sided model ACO with an MSR/MLR greater than zero.

[594] Refer to § 425.658 specifying calculation of the prior savings adjustment applicable to ACOs in agreement periods beginning on January 1, 2024, and in subsequent years. Refer to § 425.603(b)(2) specifying an additional adjustment is made to the historical benchmark to account for the average per capita amount of savings generated during the ACO's previous agreement period, implemented for renewing ACOs entering a second agreement period in 2016. See the discussion in the CY 2023 PFS final rule, in which we finalized the prior savings adjustment applicable for agreement periods beginning on January 1, 2024, and in subsequent years, and provided background on, and a description of, the prior savings adjustment that

Continued

the complexity around some related interactions in regard to recalculating the prior savings adjustment, as discussed in CY 2024 PFS rulemaking (see 88 FR 79198 through 79200), and as described in section III.G.7.c.(1).(b) of the CY 2025 PFS proposed rule. We noted that reopenings at any time for fraud or similar fault could extend to any prior performance year of the Shared Savings Program. Since Shared Savings Program policies have changed over time, in performing the recalculation we would apply the relevant financial model and benchmarking policy for the ACO for that performance year, in accordance with the applicable provisions of subpart G.

Third, we specified that we are considering limiting the instances in which we reopen an initial determination to account for improper payments, pursuant to § 425.315(a), to strike a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations. We explained that in rulemaking for the Shared Savings Program during 2016, we considered factors for balancing the need to reopen and correct Shared Savings Program payment determinations with the need for administrative finality, which has implications for both ACOs and CMS (81 FR 5853 through 5858, and 81 FR 37997 through 38002). Some of these factors were discussed more generally, in the February 2016 proposed rule, with respect to our consideration of options for further developing our reopening policy (see, for example, 81 FR 5854 and 5855). We explained that an approach of correcting even very minor errors might result in significant operational burdens for ACOs and CMS, including multiple financial reconciliation re-runs and off-cycle payment/recoupment activities that could have the potential for significant and unintended operational consequences, and could jeopardize the certainty of performance results for both ACOs and CMS. We explained our concern that a relatively broad scope and extended timeframe for reopening could introduce financial uncertainty that could limit an ACO's ability to invest in additional improvements to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors and/or to obtain funds from lenders or investors.

We noted our concern about the potential for financial uncertainty resulting from a broad scope and extended timeframe for reopening for ACOs and CMS, particularly if correcting minor errors resulting from improper payments. We stated our concern that reopening payment determinations for minor issues impacting calculations for one or several performance years of an ACO's earlier agreement period could in turn disrupt the administrative finality of calculations for multiple performances years, in one or more subsequent agreement period, if the impacted year(s) become benchmark year(s) used in resetting the ACO's historical benchmark. We also noted that since an ACO's performance can vary from year to year (in terms of whether the ACO generates savings or losses and is eligible for shared savings or owes shared losses), it is possible for there to be a mixed effect across reopening payment determinations for multiple performance years. If the recalculation of financial performance identifies relatively small changes in the amount of shared savings or shared losses, it could be possible for these changes to balance out over a span of multiple performance years. This raises further questions about the utility of reopening payment determinations versus maintaining administrative finality of initial determinations.

We noted that a relatively straightforward case would be to reopen a single performance year that we identify as having been impacted by improper payments. When a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's subsequent agreement period, whether we reopen an ACO's payment determination to account for the impact of improper payments in Shared Savings Program calculations would differ depending on whether or not we have issued an initial determination for a performance year of the ACO's subsequent agreement period. If the subsequent agreement period is the ACO's current agreement period, and CMS has not yet issued an initial determination for a performance year within the current agreement period, we would account for the impact of improper payments on future financial calculations pursuant to the proposed benchmark adjustment specified in modifications to §§ 425.601(a)(9) and 425.652(a)(9).[595] In section III.G.7.c.(2).(d) of the CY 2025 PFS proposed rule we discussed our proposals related to modifying these provisions.

We specified that CMS' decision to reopen an initial determination for a performance year is independent of a determination by CMS to reopen an initial determination for any other performance year, including in cases where multiple performance years are impacted by the same improper payments, whether within the ACO's current agreement period, or a past agreement period. In these circumstances, we would need to potentially consider reopening initial determinations for multiple performance years, which may span multiple agreement periods, in cases where an ACO has continued its participation in the Shared Savings Program over time. Therefore, we may use a combination of the following factors in determining whether to reopen an initial determination: (1) consideration of the timing of reopening and recalculating the payment determination for a performance year, and the timing of financial reconciliation for one or more performance year of a subsequent agreement period that includes the affected period as a benchmark year, and (2) consideration of whether the improper payments result from conduct of individuals or entities performing functions or services related to the ACO's activities.

Regarding the timing for reopening, we stated that we may consider whether a performance year that is being reopened corresponds to a benchmark year of an ACO's subsequent agreement period. We may consider whether we have completed financial reconciliation for a subsequent performance year, using a benchmark that is impacted by the same improper payments that were accounted for in reopening a payment determination for a performance year corresponding to a benchmark year.

We explained our expectation that ACOs continuing their participation over multiple agreement periods in the Shared Savings Program have a heightened interest in administrative finality of payment determinations, which would provide greater financial certainty to the continued operation of ACOs and progress towards meeting the program's goals. In such cases, our belief is that (1) reopening payment determinations for a performance year to account for the impact of improper

applied to certain ACOs in an earlier agreement period (87 FR 69898 through 69915).

[595] We note that the description in the CY 2025 PFS proposed rule is an illustration of the applicability of the benchmark adjustment, among other possible scenarios in which it could be applied. We refer readers to section III.G.7.c.(2).(d) of this final rule, in which we clarify the applicability of the benchmark adjustment.

payments remains important to improving the accuracy of the Shared Savings Program's calculations, and (2) maintaining the administrative finality of subsequent payment determinations, if the same improper payments impact a benchmark year of an ACO's subsequent agreement period, could provide ACOs greater financial certainty with respect to their participation which may outweigh the benefits of reopening the calculations. Maintaining administrative finality of the payment determinations for these subsequent performance years may be warranted in cases where the improper payments are not a result of the conduct of individuals or entities within the ACO. On the other hand, in cases where improper payments impacting Shared Savings Program calculations results from conduct by individuals or entities within the ACO, CMS' interest in addressing program integrity concerns would warrant reopening all affected payment determinations. In these cases, if left unaddressed, ACOs, ACO participants and ACO providers/suppliers, among others, may have incentives to continue to engage in conduct, which could include fraud or similar fault, in a way that could improve the ACO's performance under the Shared Savings Program.

We noted in the CY 2025 PFS proposed rule, although not expressly stated in § 425.315, improper payments that are the basis of a reopening may result from the conduct of individuals or entities including but not limited to: (1) conduct of an ACO, ACO participant, ACO provider/supplier, ACO professional, or other individuals or entities performing functions or services related to the ACO's activities; or (2) conduct of a provider or supplier, or other individuals or entities outside the ACO. For purposes of the discussion within section III.G.7.c of the CY 2025 PFS proposed rule, we referred to the former as improper payments originating ''inside the ACO,'' and the latter as improper payments originating ''outside the ACO.''

We provided a brief summary of an approach we may use for differentiating between cases where improper payments originate inside the ACO versus outside the ACO. If we identify a single performance year for which we have issued an initial determination that has been impacted by improper payments, we would seek to reopen the payment determination if the improper payments originated either inside the ACO or outside the ACO.

When a performance year for which we issue a revised initial determination becomes a benchmark year of an ACO's subsequent agreement period, we would consider whether to reopen each initial determination for a subsequent performance year that is impacted. We explained that we may take the following approach as one means to operate reopenings in an equitable and manageable manner:

- *In cases where improper payments originated outside the ACO:* Generally, we would not seek to reopen payment determinations for any performance year of the ACO's subsequent agreement period in order to mitigate the extent to which we disrupt the administrative finality of payment determinations for ACOs when the improper payments impacting Shared Savings Program calculations originate outside the ACO. However, we may consider reopening the initial determination for the performance year upon the ACO's request for a reopening if the improper payments are anticipated to result in significant adjustment to the ACO's initial determination upon recalculation.
- *In cases where improper payments originated inside the ACO:* As a means to address our program integrity concerns, we would reopen the payment determination for any performance year of the ACO's subsequent agreement period issued prior to the revised initial determination for the performance year corresponding to the benchmark year impacted by improper payments originating inside the ACO, if the improper payments are anticipated to result in significant adjustment to the ACO's initial determination upon recalculation. We believe this approach would guard against circumstances where an ACO may benefit from improper payments remaining in its benchmark calculations that result from conduct by individuals or entities performing functions or services related to the ACO's activities.

We solicited comment on the factors we described in section III.G.7.c.(2).(b) of the CY 2025 PFS proposed rule (89 FR 61895 through 61898), that may inform our decision of whether to reopen an initial determination of an ACO's financial performance to account for the impact of improper payments. In particular, we solicited comment on the approach we outlined for conducting initial analysis of whether the improper payments would warrant reopening the ACO's payment determination. We also solicited comment on approaches to, and considerations in connection with, balancing the need for accuracy in payment calculations with the need for administrative finality in payment determinations.

We received public comments on the considerations we described and sought comment on, for reopening payment determinations to account for the impact of improper payments. The following is a summary of the comments we received and our responses.

Comment: One commenter urged that CMS provide additional clarity around CMS' considerations for determining if an improper payment is of sufficient magnitude to reopen a determination. Another commenter, an ACO, explained that it was difficult to model the impact of improper payments outside the ACO on its ACO and on regional and national trends, and on providers and ACOs more generally. As a result, the commenter stated that they were unable to ascertain the meaningfulness of the approach, including consideration of whether there is resulting ''significant'' change to ACO financials.

Response: In response to commenters indicating it was unclear from the discussion in the proposed rule our considerations for determining if an improper payment is of sufficient magnitude to reopen a payment determination, for one, we note that in the CY 2025 PFS proposed rule (89 FR 61896) we specified that we would be highly unlikely to exercise our discretion to reopen a payment determination to address particular instances of low-value improper payments which, in an individual case may be to the benefit of either the ACO or CMS and in the aggregate are likely to have a de minimis net effect on program expenditures in the long run. In the case of a reopening to account for the impact of improper payments, we wish to clarify that this consideration about our concerns with reopening payment determinations to address low-value improper payments is also relevant at the level of individual ACO expenditures, in addition to more broadly with respect to program expenditures. We also explained that we may reopen an ACO's payment determination if accounting for the impact of improper payments would result in a significant change in the amount of shared savings paid to or shared losses owed by the ACO, including if we estimate that the improper payments have impacted the dollar amount of earned shared savings, or the amount of shared losses that the ACO owes or has paid to CMS. There could be a wide range of potential financial impacts as a result of reopening payment determinations that could be considered ''significant''.

As described in the CY 2025 PFS proposed rule (89 FR 61896), and reiterated in this section of this final

rule, we may consider a combination of factors to evaluate the significance of the improper payments to an ACO's financial calculations. This includes considerations for whether accounting for the improper payments would cause a change in the ACO's eligibility for shared savings or liability for shared losses, or the extent to which an ACO would share in either a higher or lower amount of savings or losses, compared to its performance under its initial determination. We decline at this time to further specify how we may determine whether improper payments have significant impact on an ACO's financial calculations, and what may constitute a significant impact, or sufficient magnitude of an impact, to warrant reopening an ACO's payment determination. As we gain experience with the application of the methodology for recalculating expenditures to account for the impact of improper payments on Shared Savings Program financial calculations being finalized with this final rule, we may address these factors and related considerations further in future notice and comment rulemaking.

We agree with the commenter that explained it is potentially difficult for an ACO to model the impact of improper payments outside the ACO on its ACO and on regional and national trends, as well as on providers and ACOs more generally, because they may lack insight into these larger impacts. The hypothetical example calculations described in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule (89 FR 61901 through 61906) provide a basis for ACOs and other interested parties to understand how the recalculation methodology to account for improper payments would be applied, and considerations in connection with the potential impact of the recalculation on factors based on national and regional expenditures for the assignable population (under the scenarios illustrated in the examples). An ACO, for example, could follow the approach illustrated in the hypothetical examples using a range of assumptions on the impact to national and regional expenditures to estimate the potential range of impacts to the ACO's own savings/losses calculations. In section III.G.7.c.(2).(e) of this final rule, we described in another response to comments, additional considerations regarding ACOs' ability to estimate the financial impact of improper payments on their shared savings or shared losses calculations in reference to the types of information ACOs may submit to CMS with a reopening request, and refer the commenter and other interested parties to the cross-referenced discussion for additional considerations. In particular, we wish to underscore that with respect to the evidence or analysis of financial impact of improper payments that an ACO may provide with its reopening request, although an ACO may undertake this analysis and submit related information to CMS, this does not necessarily need to involve a complex analysis or include an analysis of the impact on national expenditures, regional expenditures, or both.

Comment: A few commenters expressed general support for the approach discussed in the CY 2025 PFS proposed rule under which CMS would limit the instances in which it reopens an initial determination, and thereby maintain administrative finality of initial determinations. One commenter explained that it is important to minimize the reopening of previous years to avoid a perception of instability for the program, and recommended CMS avoid reopening previous years' financial determinations without ''significant reasons.''

Response: We appreciate commenters' support for the approach we specified in the CY 2025 PFS proposed rule under which we would consider limiting the instances in which we reopen an initial determination to account for improper payments, pursuant to § 425.315(a), to strike a balance between improving the accuracy of the calculations and ACOs' and CMS' interest in administrative finality of payment determinations. ACOs continuing their participation over multiple agreement periods in the Shared Savings Program have a heightened interest in administrative finality of payment determinations, which would provide greater financial certainty to the continued operation of ACOs and progress towards meeting the program's goals.

In response to the commenter that underscored the importance of minimizing the reopening of previous years' initial determinations to avoid a perception of instability for the program, we agree that preserving administrative finality of ACO payment determinations, when possible, would provide greater certainty to ACOs currently participating in the Shared Savings Program, and also may impact participation decisions by ACOs considering entering the program or renewing to continue their participation in the program. An approach to reopening in which we differentiate between cases where improper payments originate inside the ACO versus outside the ACO when considering whether to reopen a payment determination or to maintain administrative finality strikes an important balance. The approach outlined elsewhere in this section of this final rule, balances mitigating disruption to the administrative finality of payment determinations for ACOs when the improper payments impacting Shared Savings Program calculations originate outside the ACO and guarding against circumstances where an ACO may benefit from improper payments remaining in its benchmark calculations that result from conduct by individuals or entities performing functions or services related to the ACO's activities.

Comment: One commenter, addressing the circumstance in which adjustment to ACO financial performance under the proposed approach results in a recoupment from ACOs, suggested that CMS delay recoupment until ''the next shared savings settlement,'' to enable ACOs to financially plan with confidence since many ACOs operate without significant cash reserves.

Response: We appreciate that ACOs operate under financial constraints, and we will take the commenter's suggestion under consideration as we adjudicate reopening requests. We will continue to consider ways to minimize program disruptions for ACOs that could result from one or more reopenings, to the extent feasible, and to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments, as reflected in the discussion in the CY 2025 PFS proposed rule (89 FR 61896 through 61897), and earlier rulemaking (see for example, 81 FR 38001 through 38002; see also, 87 FR 69868 through 69872).

Comment: One commenter expressed support for an approach under which revised initial determinations should be subject to reconsideration review to allow for an ACO to ''appeal recalculations.''

Response: As we have explained in earlier rulemaking (see, for example, 81 FR 37998), the financial reconciliation calculation/methodology and the amount of shared savings an ACO might earn, including all underlying financial calculations, are not appealable. That is, the determination of whether an ACO is eligible for shared savings under section 1899(d) of the Act, and the amount of such shared savings, as well as the underlying financial calculations are precluded from administrative and judicial review under section 1899(g)(4) of the Act and § 425.800(a)(4). Section 425.800(a)(4) specifies there is no reconsideration, appeal, or other administrative or judicial review of the initial determination or revised initial

determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the initial determination or revised initial determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries assigned to the ACO and the average benchmark for the ACO in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, 425.610, and 425.652. For more information on reconsideration review under the Shared Savings Program, we would refer readers to Subpart I of our regulations, and the Shared Savings Program's guidance on Requesting Technical Assistance and Reconsideration Review, which is located on the Shared Savings Program website, For ACOs web page, at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/application-information.*

Comment: One commenter suggested an alternative approach under which CMS should be able to recalculate shared savings or shared losses for instances other than fraud or similar fault, or good cause as currently specified in the regulations under § 425.315. In particular, the commenter requested that CMS reopen and adjust benchmark periods, trends, and performance year expenditures in situations when ACOs are without recourse from improper agency actions significantly impacting ACO reconciliation and for which there is no opportunity to otherwise mitigate reconciliation impact. Further, the commenter gave as an example that several ACOs experienced significant benchmark discrepancies as a result of the payment remedy for 340B-acquired drugs, referring to earlier rulemaking for the Hospital Outpatient Prospective Payment System,[596] among other details.

Response: We decline, at this time, the commenter's suggestion to expand the reopening authority to potentially address circumstances other than fraud or similar fault, or good cause as currently specified in the regulations under § 425.315. Changes to the basis for which CMS reopens a payment determination under the Shared Savings Program were not contemplated in the proposals and other policy considerations we specified in the CY 2025 PFS proposed rule. Further, the existing standard strikes a good balance between allowing for the correction of significant issues impacting payment determinations and providing finality to ACOs. We also refer to our response to comments in earlier rulemaking (see 88 FR 77184 through 77185) in which we explained that the Shared Savings Program's benchmarking methodology has the potential to mitigate the differences between the 340B-acquired drug payments included in historical benchmark year and performance year expenditure calculations, among other considerations with respect to how the payments amounts would be considered in Shared Savings Program calculations.

(c) Methodology for Recalculating Expenditures To Account for Improper Payments

In section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule (89 FR 61898 through 61907), we proposed to establish a financial calculation methodology that may be used to account for the impact of improper payments on Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a). We proposed to add to subpart G a new section of the Shared Savings Program regulation at § 425.674 specifying provisions on accounting for the impact of improper payments on Shared Savings Program financial calculations.

As a general rule, we proposed to specify in paragraph (a) of § 425.674, that upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology set forth in § 425.674 to account for the impact of improper payments when: (1) determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination, and (2) adjusting the benchmark by recalculating benchmark year expenditures in the event that we recalculate a payment determination and issue a revised initial determination for the corresponding performance year in a prior agreement period (discussed in section III.G.7.c.(2).(d) of the CY 2025 PFS proposed rule, 89 FR 61907).

We proposed to specify in paragraph (b) of § 425.674 that for the purpose of the Shared Savings Program, ''improper payment'' includes: (1) an amount associated with a demanded overpayment determination, and (2) an amount identified in a settlement agreement or judgment, pursuant to conduct of individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages.

We proposed to establish a methodology under § 425.674 under which we would adjust Medicare Parts A and B FFS expenditure values used in certain Shared Savings Program financial calculations to account for a per capita amount of improper payments for an identified population used in calculating performance year or benchmark year expenditures, and in calculating county-level FFS expenditures used in factors based on regional expenditures.

We proposed to specify under § 425.674 a generalized approach to calculating the per capita amounts of improper payments that accounts for the fact that improper payments may be associated with specific claims or line items, or may be aggregate amounts. A number of factors informed our consideration of this approach. For one, we considered the need to establish a calculation methodology to account for demanded overpayment determinations that result in adjustments to payment amounts associated with claims and line items used in Shared Savings Program calculations, such as the denial of claims or line items that occur after the 3-month claims run out period, or in an aggregate amount, such as based on extrapolated overpayment demands that do not result in adjustments to claim or line item payment amounts. Medicare Parts A and B FFS claim adjustments for overpayments would be reflected in current Shared Savings Program expenditure calculations if processed before the end of the 3-month claims run out period but are not included in calculations if processed after the 3-month claims run out period. Regarding the latter, the amounts of the claims adjusted overpayments can be identified for Medicare FFS beneficiaries, and can be aggregated across a population of Medicare FFS beneficiaries that is the basis for certain Shared Savings Program calculations. Additionally, aggregate amounts of demanded overpayment determinations, such as extrapolated overpayment demands, may be used to identify the amount of improper payments for a large set of claims for a particular provider or supplier and a certain time period, since error rates are extrapolated and applied to a universe of claims rather than individual claims. In these cases, an aggregate amount of a demanded overpayment determination is attributable to a provider or supplier and would have to be further prorated to determine its relevance to a particular population of Medicare FFS

[596] Referring to a comment letter submitted in response to the proposed rule entitled ''Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022'' (file code CMS–1793–P) which appeared in the July 14, 2023 **Federal Register** (88 FR 44078).

beneficiaries that is the basis for certain Shared Savings Program calculations.

Second, we considered the need for the calculation methodology to account for improper payments resulting from conduct by an ACO, ACO participant, ACO provider/supplier, ACO professional, or other individuals or entities performing functions or services related to the ACO's activities identified in certain settlements, or judgments. With respect to the Shared Savings Program calculations, we noted that we anticipate that a key focus would be on improper payments pursuant to conduct of individuals or entities performing functions or services related to an ACO's activities as identified in certain False Claims Act (31 U.S.C. 3729 *et seq.*) settlement agreements, or judgments. In considering the amount of improper payments that are relevant to Shared Savings Program calculations, we would exclude the amount of any penalties or damages included in the settlement or judgment. In addition, we may seek to attribute an aggregate improper payment amount to a provider or supplier that is specified within a settlement agreement, or judgment, across a population of Medicare FFS beneficiaries that is the basis for the applicable Shared Savings Program calculation.

Further, we explained there may be circumstances that warrant adjustment to payment amounts used in Shared Savings Program calculations, at the claims level, instead of or in addition to accounting for the amount of demanded overpayment determinations or an aggregate amount in a settlement agreement or judgment. For instance, in analyzing improper payments impacting Shared Savings Program calculations, we may conclude that a provider's or supplier's billings for a particular HCPCS or CPT code for a population of Medicare FFS beneficiaries resulted in inaccuracies in payment amounts used in Shared Savings Program calculations. We proposed that we may address these circumstances by decreasing or entirely removing the value of HCPCS or CPT code payment amounts for certain claims or line items used in Shared Savings Program calculations, in reopening and recalculating the ACO's payment determination. We specified that we anticipated using all information available to us from an investigation, settlement agreement, or judgment to determine the correct payment amount or level of billing. This could include considering the nature of the remedy in the case and how any related amount would be applied in the proposed methodology to account for improper payments impacting Shared Savings Program financial calculations. In particular, we would consider if it would be a more precise adjustment to Shared Savings Program financial calculations to adjust the claim or line item payment amounts, instead of or in addition to accounting for the amount of demanded overpayment determinations or an aggregate amount in a settlement agreement or judgment (if applicable). For instance, in cases where an investigation, settlement agreement, or judgment has determined inaccurate use of a higher paying code [597] that is reflected in payment amounts used in Shared Savings Program calculations, we may identify use of a code with lower reimbursement within a HCPCS or CPT code category that would result in a more precise adjustment to the ACO's payment determination.

We proposed to specify in paragraphs (c) and (d) of § 425.674 the general approach for adjusting Medicare Parts A and B FFS expenditures for improper payments, according to the following steps:

- *Step 1*—Identify *calculation for adjustment:* Identify each Shared Savings Program expenditure calculation for a performance year or benchmark year, as calculated according to the standard methodology described in subpart G and expressed as a per capita dollar amount, that would be adjusted for the impact of improper payments (as proposed in § 425.674(c)(1)).
- *Step 2—Determine the relevant population for adjustment:* Determine each specific population of Medicare FFS beneficiaries used to calculate the expenditure amount identified in Step 1, expressed as person years (as proposed in § 425.674(c)(2)). The populations relevant for a specific expenditure calculation may include:

++ The population of beneficiaries assigned to the ACO for calculating the ACO's performance year or benchmark year expenditures.

++ The population of assignable beneficiaries in each county in the ACO's regional service area for calculating county-level expenditures.

++ The national population of assignable beneficiaries for calculating national assignable expenditures.

++ The national population of Medicare FFS beneficiaries for calculating national expenditures.

- *Step 3—Determine per capita amount of improper payments attributable to the relevant population:* Determine the per capita amount of improper payments for the performance year or benchmark year included in the per capita Medicare Parts A and B FFS expenditure amount for a population identified in Step 2 (as proposed in § 425.674(c)(3)). We may use one or more of the following approaches to determine the per capita amount of improper payments, for all providers or suppliers with improper payments, that would be used to adjust the expenditure calculations identified in Step 1 (as proposed in § 425.674(d)):

++ *Step 3(i):* Calculate aggregate improper payments attributable to a population identified in Step 2 for each provider or supplier that had improper payments.

—For improper payments associated with specific claims, we would do the following:

(A) For improper payments to a provider or supplier that correspond to payment amounts on claims or line items that were used in a Shared Savings Program calculation identified in Step 1, and subsequently adjusted after the 3-month claims run out period, we would sum the improper payment amounts across all such claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures, for a population identified in Step 2.

To allow for this approach, we proposed to adjust Shared Savings Program expenditure calculations to reflect adjustments occurring after the original 3-month claims run out period for claim or line item payment amounts associated with improper payments. We would not capture payments or payment adjustments occurring outside the original 3-month claims run out period for claims or line items unrelated to improper payments.

(B) In the event that CMS determines it is necessary to account for the impact of improper payments on Shared Savings Program financial calculations by adjusting the payment amounts for a specific HCPCS or CPT code billed by the provider or supplier for the population identified in Step 2, we would do the following: identify the applicable claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures processed before the end of the applicable 3-month claims run out period, and sum the

[597] See, for example, CMS, Medicare Claims Processing Manual Chapter 23—Fee Schedule Administration and Coding Requirements, section 20.9.5 ''Adjustments'', available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c23.pdf* (explaining that if the wrong, higher paying code is paid on the first of multiple claims submitted, A/B MACs processing Medicare Part B claims pay the subsequent claim(s) and initiate recovery action on the previously paid claim(s)).

claim or line item payment amounts on the claims or line items identified; and if applicable, multiply the resulting sum by a scaling factor to compute the payment differential between the HCPCS or CPT code that was improperly billed and a CMS-identified alternate code. We would apply a scaling factor in cases where it is determined that the provider or supplier did not bill the correct code for a particular service. In cases where we determine it is appropriate to remove payments for the billed HCPCS or CPT code in their entirety, we would not apply a scaling factor.

—For aggregate improper payment amounts that are not linked to specific claims or line items, we would calculate the amount attributable to the population identified in Step 2 by applying a proration factor to the aggregate improper payment amount identified for that provider or supplier. We would calculate the proration factor as follows:

(A) The denominator of the proration factor would be total Medicare Parts A and B claim or line item payment amounts to the provider or supplier for all FFS beneficiaries on claims of specified claim types for the time period associated with the aggregate improper payment amount identified for the provider or supplier that were made before the end of the applicable 3-month claims run out period.

(B) The numerator of the proration factor would be the portion of the total from the denominator that CMS determines is attributable to the population identified in Step 2 with dates of service during the period used to calculate expenditures for the applicable performance year or benchmark year.

Under the proposed approach, if an aggregate amount of improper payment is associated with claims activity that spans multiple calendar years, we would account for this in the proration factor by expanding the time period used to compute payments for the denominator to include the relevant years. For example, if the aggregate amount of improper payments was associated with claims activity in 2021 and 2022, we would include in the denominator payments on claims or line items with dates of service in 2021 (made before the end of March 2022) and on claims or line items with dates of service in 2022 (made before the end of March 2023). If we were adjusting PY 2022 expenditures for an ACO's assigned population, the numerator of the proration factor would be the portion of the denominator that is attributable to the ACO's assigned population during CY 2022.

++ *Step 3(ii):* Sum the amounts calculated under Step 3(i) attributable to the population identified in Step 2 across providers or suppliers that had identified improper payments.

++ *Step 3(iii):* Take the lesser of the following two values:

—The sum from Step 3(ii); or

—Total Medicare Parts A and B claim or line item payment amounts to all providers or suppliers that had improper payments for the population identified in Step 2 on claims of specified claim types with dates of service within the performance year or benchmark year made before the end of the applicable 3-month claims run out period.

The purpose of taking the lesser of two values in this step is to ensure that the improper payment amount that we attribute to a given population cannot be greater than the total amount of payments for the providers or suppliers at issue that was included in the original expenditure calculation for that population.

++ *Step 3(iv):* Express the lesser-of-amount from Step 3(iii) as a per capita value by dividing by the total beneficiary person years in the population identified in Step 2 for the applicable performance year or the benchmark year.

• *Step 4—Subtract per capita improper payment amount from original expenditures:* From the expenditure calculation identified in Step 1 for the population identified in Step 2, subtract the per capita amount calculated in Step 3(iv) for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries (as proposed in § 425.674(c)(4)).

• *Step 5—Determine adjusted regional expenditures:* If applicable, we would do the following to adjust regional expenditures for improper payments (as proposed in § 425.674(c)(5)):

++ *Step 5(i):* Adjust county-level FFS expenditures determined in Step 4, for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. This calculation would be for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We note that under this approach CMS would not adjust the risk scores used to calculate risk adjusted county-level FFS expenditures.

++ *Step 5(ii):* Weight the risk-adjusted county-level FFS expenditures determined in Step 5(i) according to the ACO's proportion of assigned beneficiaries in the county, determined in accordance with § 425.601(d)(1), § 425.603(f)(1), or § 425.654(b)(1), as applicable, for each of the populations of beneficiaries by Medicare enrollment type.

++ *Step 5(iii):* Aggregate the values determined in Step 5(ii) for each of the populations of beneficiaries (by Medicare enrollment type) across all counties within the ACO's regional service area.

We illustrated how the proposed calculation methodology would be applied, considering the following hypothetical example in which CMS confirmed that two suppliers, NPI 1 and NPI 2, received improper payments from Medicare during calendar year 2022. Specifically, CMS identified $8 million in demanded overpayment determinations for NPI 1 which resulted in CMS adjusting payment amounts after the 3-month claims run out period for PY 2022 on claims or line items with dates of service during the performance year, and CMS identified an aggregate extrapolated overpayment demand amount of $30 million for NPI 2. This example assumes that CMS determines that reopening the ACO's PY 2022 initial determination is warranted, and CMS recalculates that ACO's financial performance using the proposed methodology to account for improper payments. To recalculate the ACO's financial performance for PY 2022, we would identify three separate expenditure calculations that need to be recalculated to determine the impact on an ACO's earned performance payment or owed shared losses: (1) PY 2022 expenditures for the ACO's assigned beneficiaries; (2) PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area; and (3) PY 2022 expenditures for national assignable beneficiaries. For this example, in Table 47 we outlined the steps and calculations for recalculating expenditures for beneficiaries assigned to the ACO for PY 2022. In Table 48, we outlined how PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area and PY 2022 expenditures for national assignable beneficiaries, recalculated to account for improper payments, would be incorporated into the blended national-regional benchmark update factor. In Table 49, we outlined how an ACO's

financial performance may be recalculated after accounting for improper payments in PY 2022 expenditures for the ACO's assigned beneficiaries, and using the recalculated blended national-regional benchmark update factor.

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TABLE 47: Hypothetical Example of Steps for Recalculating ACO Assigned Beneficiary Expenditures Using Proposed Methodology to Account for Improper Payments

	Amount
Steps 1 and 2: Identify calculation and relevant population for adjustment	
ACO PY assigned beneficiary expenditures by enrollment type (per capita) [A]	
ESRD	$80,000
Disabled	$11,000
Aged/dual	$15,000
Aged/non-dual	$12,000
ACO PY total assigned beneficiary person years [B]	20,000
Step 3: Determine per capita amount of improper payments attributable to the relevant population	
Aggregate improper payments attributable to the ACO's assigned beneficiaries for NPI 1 (identified at the claim or line item level)	
Total aggregate improper payments for NPI 1 [C]	$8,000,000
Aggregate improper payments for NPI 1 attributable to the ACO's assigned beneficiaries [D]	$200,000
Aggregate improper payments attributable to the ACO's assigned beneficiaries for NPI 2 (identified at the NPI level)	
Total aggregate improper payments for NPI 2 [E]	$30,000,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 2 for the ACO's assigned beneficiaries for PY (a portion of row [G]) [F]	$4,800,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 2 for all Medicare FFS beneficiaries, on claims of specified claim types for the time period associated with improper payment amount, made before the end of the 3-month claims run out period for PY [G]	$80,000,000
Proration factor [H] = [F] / [G]	0.06
Aggregate improper payments attributable to the ACO's assigned beneficiaries [I] = [E] x [H]	$1,800,000
Sum of improper payments attributable to the ACO's assigned beneficiaries for NPI 1 and NP1 2 [J] = [D] + [I]	$2,000,000
Total Medicare Parts A and B claim or line item payment amounts to NPI 1 and NPI 2 for the ACO's assigned beneficiaries made before the end of the 3-month claims run out period for PY [K]	$5,200,000
Total aggregate improper payments attributable to the ACO's assigned beneficiaries [L] = Lesser of [J] and [K]	$2,000,000
Per capita improper payments attributable to the ACO's assigned beneficiaries [M] = [L] / [B]	$100
Step 4: Subtract per capita improper payment amount from original expenditures	
Adjusted ACO PY assigned beneficiary expenditures by enrollment type (per capita) [N] = [A] – [M]	
ESRD	$79,900
Disabled	$10,900
Aged/dual	$14,900
Aged/non-dual	$11,900

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In Step 1, we identify expenditures for the ACO's assigned beneficiaries in PY 2022 as the calculation to be recalculated. In Step 2, we identify the ACO's assigned beneficiaries in PY 2022 as the population relevant for this expenditure calculation. In Step 3, we determine the per capita amount of improper payments that is attributable to the ACO's assigned beneficiaries. For NPI 1, we identify that $200,000 of the NPI's total aggregate improper payments were on claims for the ACO's assigned beneficiaries (row [D]). Because improper payments for NPI 2 were identified at the NPI level and thus are not tied to individual claims, we need

to apply a proration factor to calculate the share of the total aggregate improper payments, $30 million (row [E]), that is attributable to the ACO's assigned beneficiaries. We calculate this proration factor as the total Medicare Parts A and B claim or line item payment amounts made to NPI 2 for the ACO's assigned beneficiaries for PY 2022 ($4.8 million, row [F]), divided by the total Medicare Parts A and B claim or line item payment amounts made to NPI 2 for all Medicare FFS beneficiaries ($80 million, row [G]); this results in a proration factor of 0.06 (row [H]), which when applied to NPI 2's total aggregate improper payments results in $1.8 million in aggregate improper payments attributable to the ACO's assigned beneficiaries (row [I]). Summing across NPI 1 and NPI 2, we calculate $2 million in total aggregate improper payments attributable to the ACO's assigned beneficiaries for PY 2022 (row [J]). We then compare this sum (row [J]) with total Medicare Parts A and B claim or line item payment amounts to the two suppliers for the ACO's assigned beneficiaries for PY 2022 (row [K]) and take the lesser of the two values (row [L]). We then express this lesser-of value in per capita terms by dividing by the ACO's total assigned beneficiary person years for PY 2022, 20,000, arriving at a $100 per capita improper payment amount attributable to the ACO's assigned beneficiaries (row [M]). Finally, in Step 4, we subtract the $100 per capita improper payment amount from the original PY 2022 per capita expenditure amount for the ACO's assigned beneficiaries used to make the initial payment determination, conducting this adjustment by enrollment type (row [N]).

We noted that subtracting the same per capita improper payment amount ($100 in this example) from the expenditure calculation for each enrollment type population implicitly assumes that improper payments attributable to the overall population are distributed in proportion to the four enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). For example, if the aged/non-dual eligible population represents 82 percent of an ACO's overall assigned population for the performance year, we are assuming that 82 percent of improper payments attributable to the ACO's entire assigned population are associated with aged/non-dual eligible beneficiaries. We explained our belief that this is a reasonable assumption as we expect that, in most cases, improper payments are unlikely to be associated with a particular enrollment type as defined by the Shared Savings Program and used in program financial calculations.[598] This also allows for a standard approach across the potential variety of reopening scenarios, lending greater transparency and simplicity to the proposed methodology.

We would follow the same overall methodology to account for the impact of improper payments in recalculating PY 2022 expenditures for assignable beneficiaries in the ACO's regional service area and for national assignable beneficiaries. These amounts are calculated for the following populations of beneficiaries, by Medicare enrollment type: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We would then use these adjusted expenditure calculations as new inputs along with other original calculations that were not adjusted for the impact of improper payments (such as the ACO's historical benchmark for PY 2022) to recalculate the ACO's financial performance for PY 2022, following the standard financial methodology described in § 425.605 (for ACOs participating in the BASIC track) or § 425.610 (for ACOs participating in the ENHANCED track), as applicable.

[598] For criteria used to identify the four Medicare enrollment types, refer to the Medicare Shared Savings Program, Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications (version #11, January 2023), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2* (Appendix E: Identifying Medicare Enrollment Type).

In Table 48, we expanded upon the hypothetical example described in Table 47 and summarized how we would calculate national and regional update factors following the methodology specified in § 425.652(b)(2) but using the adjusted regional and national expenditures for the performance year for each enrollment type in place of the original values. Because benchmark update factors are calculated by enrollment type under the standard financial methodology, they would also be recalculated by enrollment type when using the adjusted national and regional expenditures. However, for brevity, we described only the recalculation of the update factors for the aged/non-dual eligible population in Table 48.

In this continued hypothetical example, we used the proposed methodology to account for the impact of improper payments in recalculating national and regional per capita expenditures in the performance year, resulting in adjusted expenditures of $11,609 (row [A]) and $11,210 (row [C]), respectively. Dividing these PY values by the original BY3 national and regional per capita expenditures ($10,977, row [A], and $10,900, row [C], respectively), we recalculate the national update factor (1.058, row [B]) and regional update factor (1.028, row [D]). In this example, there is a $1 difference between the original and recalculated national per capita expenditure amount. The resulting value for the recalculated national update factor, shown rounded to the third decimal place, remains the same as the original value, but there would be a difference in the values if additional precision was shown. We then blend these adjusted update factors using the original national and regional weights (0.250, row [E], and 0.750, row [F], respectively). As shown in row [G], accounting for improper payments in PY 2022 causes the blended benchmark update factor to decrease from 1.042 to 1.036.

TABLE 48: Hypothetical Example of How the Blended National-Regional Benchmark Update Factor for the Aged/Non-Dual Eligible Enrollment Type May Be Recalculated After Accounting for Improper Payments

	BY3	PY (Original)	PY (Adjusted)
National per capita expenditures [A]	$10,977	$11,610	$11,609
National update factor [B] = $[A]_{PY}$ / $[A]_{BY3}$		1.058	1.058
Regional per capita expenditures [C]	$10,900	$11,300	$11,210
Regional update factor [D] = $[C]_{PY}$ / $[C]_{BY3}$		1.037	1.028
National weight [E]		0.250	0.250
Regional weight [F]		0.750	0.750
National-regional blended update factor [G] = [B] x [E] + [D] x [F]		1.042	1.036

Table 49 summarized how the recalculated blended update factor to account for improper payments, based on adjusted national and regional expenditures for PY 2022, would be used with other original calculations and adjusted PY expenditures for ACO assigned beneficiaries to recalculate the ACO's financial performance for PY 2022. Applying the blended update factor (row [B]) to the original historical benchmark values by enrollment type (row [A]), we recalculate the updated benchmark values by enrollment type (row [C]) that account for improper payments occurring in PY 2022. The adjusted updated benchmark values (row [C]) and adjusted PY expenditures for ACO assigned beneficiaries by enrollment type (row [D]), also described in Table 47, are multiplied by original PY assigned beneficiary proportions by enrollment type (row [E]), and summed across enrollment types to recalculate the per capita updated benchmark (row [F]) and per capita ACO PY assigned beneficiary expenditures (row [G]). We then express these per capita quantities as the total updated benchmark amount (row [I]) and the total ACO PY assigned beneficiary expenditures amount (row [J]) by multiplying the per capita dollar amount by the ACO's total assigned beneficiary person years for PY 2022 (row [H]). The recalculated total updated benchmark (row [I]) can then be used to recalculate the MSR/MLR dollar threshold (row [L]). We subtract the recalculated total ACO PY assigned beneficiary expenditures (row [J]) from the recalculated total updated benchmark (row [I]) to determine if the ACO has gross savings or gross losses. Under this example, the recalculation indicates the ACO has total gross savings (row [K]). Finally, because the recalculated total gross savings (row [K]) is greater than the recalculated MSR dollar threshold, we recalculate the ACO's shared savings (row [N]) by multiplying the total gross savings (row [K]) by the original sharing rate (row [M]).

The result of these calculations is an adjusted shared savings amount of $17,355,000 (before accounting for sequestration), compared to an original amount of $16,950,000. Thus, while adjustments for improper payments reduced the ACO's PY assigned beneficiary expenditures by $2 million, the impact on the ACO's recalculated shared savings is only $405,000 due to the impact of improper payments on the expenditures for assignable beneficiaries that factor into the ACO's recalculated updated benchmark for PY 2022.

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TABLE 49: Hypothetical Example of How an ACO's Financial Performance May Be Recalculated After Accounting for Improper Payments

	Original	Adjusted	Adjusted Minus Original
Historical benchmark by enrollment type (risk adjusted, per capita) [A]			
ESRD	$89,200		
Disabled	$12,700		
Aged/dual	$17,700		
Aged/non-dual	$12,200		
National-regional blended update factor by enrollment type [B]			
ESRD	1.007	1.006	-0.001
Disabled	1.028	1.022	-0.006
Aged/dual	1.043	1.039	-0.004
Aged/non-dual	1.042	1.036	-0.006
Updated benchmark by enrollment type (per capita) [C] = [A] x [B]			
ESRD	$89,824	$89,735	-$89
Disabled	$13,056	$12,979	-$77
Aged/dual	$18,461	$18,390	-$71
Aged/non-dual	$12,712	$12,639	-$73
ACO PY assigned beneficiary expenditures by enrollment type (per capita) [D]			
ESRD	$80,000	$79,900	-$100
Disabled	$11,000	$10,900	-$100
Aged/dual	$15,000	$14,900	-$100
Aged/non-dual	$12,000	$11,900	-$100
ACO PY assigned beneficiary proportions by enrollment type [E]			
ESRD	0.010		
Disabled	0.100		
Aged/dual	0.070		
Aged/non-dual	0.820		
Updated benchmark (per capita) [F] = Sum of [C] x [E]	$13,920	$13,847	-$73
ACO PY assigned beneficiary expenditures (per capita) [G] = Sum of [D] x [E]	$12,790	$12,690	-$100
ACO PY total assigned beneficiary person years [H]	20,000		
Total updated benchmark [I] = [F] x [H]	$278,400,000	$276,940,000	-$1,460,000
Total ACO PY assigned beneficiary expenditures [J] = [G] x [H]	$255,800,000	$253,800,000	-$2,000,000
Total updated benchmark expenditures minus Total ACO PY assigned beneficiary expenditures [K] = [I] – [J] (example showing gross savings)	$22,600,000	$23,140,000	$540,000
Minimum savings rate / Minimum loss rate in dollars [L] = 0.02 x [I]	$5,568,000	$5,538,800	-$29,200
Sharing rate [M]	75%		
Shared savings [N] = [K] x [M]	$16,950,000	$17,355,000	$405,000

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Under the proposed financial methodology, accounting for the impact of improper payments on expenditures could increase or decrease an ACO's amount of shared savings or shared losses. As demonstrated in the hypothetical example, the direction of changes to an ACO's shared savings or shared losses would depend on the differential impact of improper payments on the ACO's assigned beneficiary expenditures compared to

the impact on expenditures for assignable beneficiaries used to determine the national and regional updates to the ACO's benchmark. In this example, the reduction in ACO PY assigned beneficiary expenditures due to the adjustment for improper payments was larger than the reduction to the updated benchmark stemming from adjustments to PY national and regional expenditures, ultimately causing the ACO to see an increase in both gross savings and shared savings. Other ACOs for which the reduction in ACO PY assigned beneficiary expenditures is greater than the reduction to the updated benchmark, may switch from earning no shared savings to earning shared savings or may see a reduction in shared losses owed. However, if accounting for improper payments results in relatively larger reductions to the expenditures for assignable beneficiaries in the ACO's regional service area or in the national assignable population, and relatively smaller reductions to the ACO's PY assigned beneficiary expenditures, the ACO might observe a reduction in shared savings or increase in shared losses, or potentially cause the ACO to switch from earning shared savings to not earning any shared savings or to owing shared losses.

As we proposed in section III.G.7.c.(2).(d) of the CY 2025 PFS proposed rule (89 FR 61907), if the reopened PY becomes a BY for a subsequent agreement period, CMS would adjust the historical benchmark to be used for any PY in that subsequent agreement period that has not yet been reconciled. We explained that accounting for improper payments as it affects the ACO's benchmark could then result in changes to the ACO's shared savings or shared losses for a future performance year that differ in direction compared to the change in shared savings or shared losses observed with the initial reopening that affected PY expenditures. That is, following the example from Table 49, accounting for improper payments occurring in calendar year 2022 might result in the ACO earning greater shared savings (or smaller shared losses) for PY 2022 (because the reduction in ACO PY assigned beneficiary expenditures outweighs the reduction in national and regional expenditures used to update the benchmark), but may result in smaller shared savings (or greater shared losses) for future performance years for which CY 2022 becomes a benchmark year (because the adjustment for improper payments in BY 2022 causes a reduction in the overall benchmark with no corresponding reduction to ACO PY expenditures).

We explained that administrative action and judicial action leading to the identification of improper payments may be subject to appeal, and ultimately the amount of the improper payments may be redetermined or otherwise amended. We acknowledged the potential inaccuracy in using amounts of improper payments that may be reversed, in whole or in part, in recalculating an ACO's financial performance. However, waiting for each possible appeal to be raised and resolved with respect to improper payments could delay our ability to reach a determination of whether to reopen an ACO's payment determination, identify the amounts of improper payments to be used in the recalculation, or both. We explained that we considered whether to account for the possibility that the improper payment amounts would be appealed, and the amount redetermined, as part the proposed methodology, but did not propose a related approach. For instance, we considered whether to apply an adjustment factor as part of the methodology, that would reduce the amount of improper payments by a percentage, to account for the rate at which the amounts could change, and to base this rate on statistics gathered on the outcomes of Medicare Parts A and B administrative appeals processes. Given that the proposed approach, if finalized, would be the initial use of improper payment amounts in Shared Savings Program calculation, we noted our intent to monitor for the impact of appeals on the amounts of improper payments that may be used in reopenings under the Shared Savings Program. We stated that we may revisit our approach in future notice and comment rulemaking, after we gain additional experience with using improper payment amounts in Shared Savings Program calculations.

We proposed to use our authority under section 1899(d)(1)(B)(ii) of the Act to calculate benchmark year expenditures using the proposed methodology to account for the impact of improper payments. This provision authorizes the Secretary to adjust the benchmark for beneficiary characteristics and ''such other factors as the Secretary determines appropriate''. When reopening an initial determination for a performance year pursuant to § 425.315, we considered it appropriate to account for the impact of improper payments on expenditures used to establish the ACO's historical benchmark, consistent with our proposal.

We proposed to use our authority under section 1899(i)(3) of the Act to use the proposed methodology to account for the impact of improper payments in calculating performance year expenditures and calculating the historical benchmark update factors. CMS may only adopt an alternative payment methodology pursuant to section 1899(i)(3) of the Act if we determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures.

We explained that the proposed adjustments would remove improper payments from the performance year expenditures and factors used to calculate updated historical benchmarks, among other financial calculations, that resulted in inaccuracies in an ACO's payment determination, including the amount of shared savings CMS paid an ACO or the amount of shared losses owed to CMS by an ACO participating under a two-sided model. We stated that these policies improve the accuracy of financial calculations by which ACOs are held accountable for the cost and quality of care for their assigned beneficiary populations.

Further, addressing the impact of improper payments on ACO payment determinations could serve as a mechanism to bolster program integrity. ACO accountability for the total cost of care can deter fraud, waste, and abuse that is otherwise under the control of ACO participants. Additionally, ACOs have unique insight into Medicare Part A, B, and D claims data for their assigned beneficiary populations from monthly claim and claim line level data ACOs receive from CMS for care coordination and quality improvement. This vantage point makes ACOs uniquely situated to observe trends in expenditures and utilization patterns, including by providers and suppliers that are not participating in the ACO. Further establishing policies to specify the approach to excluding improper payments from Shared Savings Program calculations could encourage ACOs to report to CMS and the HHS–OIG potential fraud and abuse within the Medicare program. Addressing improper payments in the Medicare program would protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations, and lead to greater beneficiary protections and protection of the Trust Funds.

Accounting for the impact of improper payments in financial calculations promotes continued

integrity and fairness of Shared Savings Program payment determinations and may in turn bolster ACO participation in the Shared Savings Program. Policies that improve the accuracy of the payment calculations could provide greater certainty to organizations considering entering or continuing their participation in the Shared Savings Program and thereby lead to more robust and sustained participation by ACOs in the Shared Savings Program. This, in turn, means that these organizations would continue working towards meeting the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

As described in the Regulatory Impact Analysis of the CY 2025 PFS proposed rule (89 FR 62183), accounting for the impact of improper payments on performance year expenditures and factors used to calculate updated historical benchmarks would not result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. As we also discuss in the CY 2025 PFS proposed rule, across an ACO's reconciliations where improper payments impact performance year or BY expenditures, the overall net impact of using the proposed methodology on the ACO's aggregate shared savings or shared losses across those reconciliations could be positive or negative and would depend on the circumstances of a given reopening scenario.

We stated that we will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed general support for CMS' proposal to recalculate expenditures and payment amounts to account for improper payments upon reopening a payment determination, and a few commenters specifically stated support for the proposed calculation methodology, in general. A few commenters specifically supported the approach to accounting for improper payments identified beyond the Shared Savings Program's 3-month claims run-out period.

Response: We appreciate commenters' support for our proposed calculation methodology, and we are finalizing the methodology as proposed.

After consideration of the public comments, we are finalizing our proposal to add to subpart G a new section of the Shared Savings Program regulation at § 425.674 specifying provisions on accounting for the impact of improper payments on Shared Savings Program financial calculations, as described in this section of this final rule. Specifically, as finalized, paragraph (a) of § 425.674 specifies that upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology set forth in § 425.674 to account for the impact of improper payments when: (1) determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination, and (2) adjusting the benchmark by recalculating benchmark year expenditures in the event that we recalculate a payment determination and issue a revised initial determination for the corresponding performance year in a prior agreement period. Paragraph (b) of § 425.674 specifies that for the purpose of the Shared Savings Program, ''improper payment'' includes: (1) an amount associated with a demanded overpayment determination, and (2) an amount identified in a settlement agreement or judgment, pursuant to conduct of individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages. Paragraphs (c) and (d) of § 425.674 specify the general approach for adjusting Medicare Parts A and B FFS expenditures values used in certain Shared Savings Program financial calculations to account for a per capita amount of improper payments for an identified population used in calculating performance year or benchmark year expenditures, and in calculating county-level FFS expenditures used in factors based on regional expenditures.

(d) Adjusting Historical Benchmarks To Account for the Impact of Improper Payments

In the CY 2025 PFS proposed rule (89 FR 61907), we explained that CMS adjusts an ACO's historical benchmark annually, during the term of the ACO's agreement period, to account for certain changes, as specified in the Shared Savings Program regulations. The related adjustment is specified under § 425.601(a)(9), for the benchmarking methodology applicable to agreement periods beginning on or after July 1, 2019, and before January 1, 2024, and under § 425.652(a)(9), for the benchmarking methodology applicable to agreement periods beginning on January 1, 2024, and in subsequent years. As finalized with the CY 2024 PFS final rule (88 FR 79195 through 79200), § 425.652(a)(9) introductory text was amended to specify, among other changes, that for each performance year during the term of the agreement period, the ACO's benchmark is adjusted for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315 (among other factors). Similar language is not currently included in § 425.601(a)(9) introductory text.

We proposed to use our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark to account for the impact of improper payments, in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's current agreement period. We proposed to adjust an ACO's historical benchmark for use in reaching an initial determination of financial performance for a performance year, in cases where an ACO has a benchmark year that corresponds to a performance year for which we issued a revised initial determination. In such a case, we would apply the same methodology to recalculate the ACO's BY expenditures as used in recalculating the expenditures for the corresponding performance year, as part of a reopening. Under the proposed approach, we would be able to improve the accuracy of the benchmark year calculations used in reaching an initial determination for a performance year, by addressing the impact of previously identified improper payments on the expenditure calculations. Such an adjustment to the benchmark expenditures would appropriately calculate the ACO's historical benchmark that might otherwise be under- or over-stated due to improper payments.

We expanded upon the example illustrated in Table 49, to explain that if we have issued a revised initial determination for PY 2022 in December 2025, for an ACO that renewed to continue its participation under a new agreement period beginning on January

1, 2025, our proposed policy would enable us to use the same methodology for calculating BY 2022 expenditures for PY 2025, in reaching the initial determination for PY 2025.

We proposed to amend §§ 425.601(a)(9) and 425.652(a)(9) to specify the proposed adjustment to the historical benchmark. We proposed to revise § 425.601(a)(9) introductory text to further specify that for the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark would be adjusted for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315. We also proposed to add a new paragraph (a)(9)(iii) to § 425.601 and to add a new paragraph (a)(9)(viii) to § 425.652, each specifying that we would recalculate benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS would apply the same calculation methodology applied in recalculating expenditures for the corresponding performance year, in accordance with the proposed new section of the regulation at § 425.674.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for accounting for improper payments in ACO historical benchmarks, and a few commenters stated generalized support for the proposal to adjust the historical benchmark to account for the impact of improper payments. More specifically, one commenter stated support for CMS' proposal to adjust the historical benchmark to account for the impact of improper payments if CMS recalculates a payment determination in a prior agreement period that corresponds to a benchmark year of the ACO's current agreement period. One commenter stated that accounting for improper payments in benchmarks is a ''welcome change and significant improvement.''

Response: We appreciate commenters' support for our proposal to establish an adjustment to Shared Savings Program benchmark calculations to account for the impact of identified improper payments for use in reaching an initial determination of financial performance for a performance year, in certain cases. We have further considered the phrasing of our proposal, as specified in the preamble of the CY 2025 PFS proposed rule (89 FR 61907), and reflected in one commenter's statement, that the adjustment would be applied ''in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's *current agreement period*'' (emphasis added).

In the CY 2025 PFS proposed rule, although we provided one example of a potential scenario in which this adjustment would apply (89 FR 61907), we did not discuss the potential for there to be various scenarios around the timing of when the revised initial determination is issued for a performance year relative to when the ACO enters a subsequent agreement period for which the performance year for which we issue a revised initial determination corresponds to a benchmark year (BY). These scenarios could include the following, with hypothetical examples included to further illustrate:

- *CMS issues a revised initial determination for a PY that corresponds to a BY of an ACO's agreement period while the current agreement period is underway, and before completing financial reconciliation for one or more performance years of the current agreement period.* This could have been one interpretation of the scenario we provided in the CY 2025 PFS proposed rule. To restate and expand upon this example: An ACO participates under and completes an agreement period beginning on January 1, 2020, and renews to continue its participation in a new agreement period beginning on January 1, 2025. We issue a revised initial determination for PY 2022 in Fall 2025. We would use the same methodology for calculating BY 2022 expenditures as we used to reach the revised initial determination for PY 2022, in calculating the benchmark used to reach the initial determination for all performance years of the ACO's agreement period beginning on January 1, 2025 (PYs 2025–2029).
- *CMS issues a revised initial determination for a PY that corresponds to a BY of an ACO's agreement period prior to the start of a future agreement period, while the ACO was participating in an earlier agreement period.* For example: An ACO participates under and completes an agreement period beginning on January 1, 2022, and renews to continue its participation in a new agreement period beginning on January 1, 2027. We issue a revised initial determination for PY 2024 in Fall 2026. We would use the same methodology for calculating BY 2024 expenditures as we used to reach the revised initial determination for PY 2024, in calculating the benchmark used to reach the initial determination for all performance years of the ACO's agreement period beginning on January 1, 2027 (PYs 2027–2031).
- *CMS issues a revised initial determination for a PY that corresponds to a BY of more than one agreement period, which could occur in cases where an ACO's participation agreement is terminated and the ACO quickly enters a new agreement period, such as under the option for an ACO to early renew.*[599] For example: An ACO participates under an agreement period beginning on January 1, 2020, and early renews to continue its participation in a new agreement period beginning on January 1, 2024. The ACO early renews again to enter a new agreement period beginning on January 1, 2025. We issue a revised initial determination for PY 2023 in Spring 2025. We would use the same methodology for calculating BY 2023 expenditures as we used to reach the revised initial determination for PY 2023, in calculating the benchmark for the agreement period beginning on January 1, 2024 used to reach the initial determination for PY 2024, and in calculating the benchmark used to reach the initial determination for all performance years of the ACO's new agreement period beginning on January 1, 2025 (PYs 2025–2029).

In light of the number and complexity of the scenarios in which a PY corresponds to a BY that is used in calculating the benchmark that is in turn used to determine financial performance for a performance year that has not yet been reconciled, we are concerned that the phrasing ''current agreement period'' in reference to the benchmark being adjusted could make unclear the applicability of the adjustment, and prove unduly limiting depending on how it could be interpreted. We clarify that we would apply the adjustment in calculating benchmark expenditures used in reaching an initial determination of financial performance for a performance year within an ACO's agreement period that has concluded, or its current agreement period which is underway, as well as a future agreement period, to account for improper payments in expenditures for a benchmark year that corresponds to a performance year for which we issued a revised initial determination.

[599] ACOs have the option to ''early renew'', meaning to terminate their current participation agreement under § 425.220 and immediately enter a new agreement period to continue participation in the Shared Savings Program.

Therefore, we are finalizing our proposal with the aforementioned clarification to generalize the description of benchmark adjustment to allow for the continued applicability of the adjustment over time. Under the finalized approach we will adjust the benchmark to account for the impact of improper payments, in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's *agreement period* (emphasis added to reflect revised text) instead of referencing the ACO's *current agreement period* (emphasis added). This clarification only impacts our discussion of the proposal in preamble of the CY 2025 PFS proposed rule. The potentially problematic language was not included in the text of proposed regulations to establish the benchmark adjustment.

After consideration of the public comments, we are finalizing, with a clarification, our proposal to use our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark to account for the impact of improper payments, in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's *agreement period* (emphasis added). We are also finalizing without modification our proposed amendments to the regulations at §§ 425.601(a)(9) and 425.652(a)(9) to specify the adjustment to the historical benchmark. In recalculating expenditures for the benchmark year, CMS will apply the same calculation methodology applied in recalculating expenditures for the corresponding performance year, in accordance with the new section of the regulation at § 425.674.

(e) ACO Reopening Requests

In section III.G.7.c.(2).(e) of the CY 2025 PFS proposed rule (89 FR 61907 through 61908), we described our proposal to establish a process by which ACOs may request a reopening review, and related considerations. We stated that the discussion of requesting and conducting a reopening pertained to reopening a payment determination for good cause or for fraud or similar fault, unless specified otherwise.

We proposed to establish a process at § 425.315(b) by which an ACO may request a reopening of an initial determination, or a final agency determination under subpart I, of shared savings or shared losses. Although an ACO's submission of a reopening request is optional, we proposed to require that the ACO's request be in a form and manner specified by CMS. Further, we proposed that the timing of the ACO's reopening request must be consistent with the timeframes specified in § 425.315(a)(1)(i) and (ii), respectively, either (i) at any time in the case of fraud or similar fault, or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause. We noted that we anticipate providing additional information on the reopening request process for ACOs through guidance, including the form and manner in which CMS must receive a reopening request.

We stated that CMS will need to receive sufficient, detailed information from ACOs to evaluate an ACO's reopening request. For instance, in the case of a reopening request in connection with improper payments, or fraud or similar fault potentially impacting the ACO's financial calculations, receiving detailed information about the issue, including the following information, would aid in our analysis of the ACO's request:

- ACO identifier(s) (also referred to as ''ACO ID'') and Legal Business Name(s).
- Identity of the provider or supplier for which there may be improper payment(s), or that may be suspected of fraud or similar fault, including name, NPI or Provider Transaction Access Number (PTAN), TIN, or other identifier.
- Time period during which potentially impacted claims were submitted or improper conduct occurred.
- Short description of the improper payment, alleged fraud or similar fault, and how it was identified, including information such as any specific claim type codes and HCPCS or CPT codes.
- Evidence of financial impact on the ACO's shared savings or shared losses calculation, such as any analysis supporting the calculation of financial impact to the ACO and a list of beneficiaries assigned to the ACO for whom claims were submitted by the provider or supplier suspected of fraud or similar fault, or for which expenditures may be impacted by improper payments.

We reiterated that a recalculation of shared savings and shared losses to account for improper payments could result in a variety of outcomes. We stated that an ACO should weigh these potential outcomes when considering whether to submit a reopening request.

We acknowledged that the proposed process for requesting a reopening, whether for good cause or for fraud or similar fault, would represent a new process. Therefore, we solicited comments and suggestions on the form and manner in which CMS should receive these requests. We also solicited comment on approaches to ensuring that ACOs submit reopening requests with sufficient information to allow CMS to identify and evaluate the impact of improper payments, or fraud or similar fault, on Shared Savings Program financial calculations.

We described the following steps to illustrate how the Shared Savings Program may conduct review of an ACO's request to reopen a payment determination to account for the impact of improper payments (restated with a minor correction for clarity):

- Upon receiving an ACO's reopening request, CMS would evaluate this request, and ask the requesting ACO to provide supplemental information if needed.
- We would work with program integrity staff and law enforcement agencies to identify, validate and quantify improper payments potentially impacting expenditures used in Shared Savings Program calculations. We noted that identification of improper payments may be contingent on the conclusion of an investigation that is underway.
- We may conduct initial analysis to consider the basis for reopening the ACO's payment determination under § 425.315(a), and the significance of the improper payments to an ACO's financial calculations under the Shared Savings Program (described in section III.G.7.c.(2).(b) of the CY 2025 PFS proposed rule, see 89 FR 61896):

++ If we find that the potential improper payment does not meet CMS' standards for reopening the payment determination, we noted we would notify the ACO of our decision.

++ If we reach a determination to reopen the ACO's payment determination for a performance year:

—We would recalculate expenditures to account for improper payments using the methodology proposed in section III.G.7.c.(2).(c) of the CY 2025 PFS proposed rule (89 FR 61898 through 61907), recalculate the ACO's shared savings or shared losses, issue a revised initial determination, and engage in payment activities and recoupment activities, as needed.

—During the recalculation period CMS would also identify whether the relevant performance year is also serving as a benchmark year for the

ACO's current agreement period and prepare to adjust the ACO's benchmark year expenditures to account for the revised initial determination (once issued), as discussed in section III.G.7.c.(2).(d) of the CY 2025 PFS proposed rule (89 FR 61907).

We noted that in the event that improper payments identified in analyzing an ACO's reopening request have the potential to impact the payment determinations of one or more other ACOs, we may only determine whether to reopen the payment determination for an ACO that submitted the reopening request. More generally, we may initiate analysis of the impact of improper payments on Shared Savings Program financial calculations, and potentially reopen the payment determination for one or more ACOs absent an ACO's request for reopening. For instance, in learning of improper payments that may potentially impact Shared Savings Program calculations for multiple ACOs, including through the reopening request process, we may seek to reopen payment determinations where improper payments are anticipated to result in significant adjustments to ACOs' initial determinations upon recalculation. We also noted that we anticipate initiating analysis of the impact of improper payments on an ACO's payment determination upon learning of improper payments originating inside the ACO that may potentially impact Shared Savings Program calculations, and may reopen the ACO's payment determination, as needed, to address program integrity concerns.

We stated that we anticipate that our review and analysis of reopening requests could occur over a protracted period of time during which we may be able to provide little additional information to the ACO until we have reached our decision. We would aim to conduct a reopening such that the timing of any issuance of a revised initial determination aligns with the timeframe for when CMS typically completes annual performance year financial reconciliation and payment and recoupment. However, because investigations into improper payments, including considering whether there is reliable evidence of fraud or similar fault, may involve varying degrees of complexity and scale, and because the application of our proposed methodology for calculating expenditures relies on information that may result from such investigations, among other sources of information, CMS may not always be able to conduct a reopening within a specific timeframe after an ACO submits a reopening request. We specified that the process for analyzing an ACO's reopening request, reaching a decision on whether to reopen the initial determination, recalculating the ACO's payment determination, and issuing a revised initial determination, may occur over a period of months or potentially years, and may have impacts on future agreement periods. In cases where CMS and law enforcement officials may have investigations underway, CMS must refrain from providing details to ACOs, and other individuals or entities, of pending actions to protect the integrity of those investigations. Therefore, we explained that we may be limited in the information we can communicate to an ACO about our consideration of the ACO's reopening request.

We solicited comment on the aforementioned considerations for how we could conduct review of an ACO's request to reopen a payment determination to account for the impact of improper payments. We specified that as we gain additional experience with ACOs' submission of reopening requests, including the volume of the requests, and nature of the requests, we may revisit the reopening request process, as needed, in future notice and comment rulemaking.

We received public comments on these proposals and related considerations. The following is a summary of the comments we received and our responses.

Comment: The commenters addressing the proposal to create a process by which ACOs can request CMS reopen a payment determination, expressed support for the concept. One commenter explained that codifying a process for reopening a payment determination provides clarity on the steps an ACO needs to take and will, subsequently, encourage institutions to pursue the process. This commenter further explained a formal reopening process is necessary for any and all value-based care models that involve two-sided risk, as it clarifies how the agency will address any issues regarding miscalculations or fraud.

Response: We appreciate commenters' support for our proposal to establish a process by which ACOs may request a reopening review by CMS of a Shared Savings Program payment determination. In response to the commenter's assertion that a formal reopening process is necessary for value-based care models that involve two-sided risk, we note that the Shared Savings Program's long-standing reopening policy, and the changes to our policies being finalized in this final rule, apply program-wide, to ACOs participating in the program's one-sided models and two-sided models. Further, we note that the proposals being finalized in this section of this final rule are specific to the Shared Savings Program.

Comment: Some commenters addressing the proposed reopening request process provided a variety of suggestions in connection with an ACO's initiation of a reopening request. A few commenters requested greater transparency around the reopening request process including on the type of information CMS will request, potential timelines, and steps ACOs should take to request reopening, and several of these commenters urged CMS to publish related information in subregulatory guidance.

Some commenters urged CMS to employ a reopening process that minimizes the burden to ACOs with respect to the types of information it must receive from ACOs. In particular, a few commenters explained that ACOs can perform in depth analysis of their data, but lack detailed information on national or regional billing to make comparisons and urged that CMS not request ACOs provide such information as part of the reopening request process.

Response: As we specified in the CY 2025 PFS proposed rule (89 FR 61907), we anticipate providing additional information on the reopening request process for ACOs through guidance, including the form and manner in which CMS must receive a reopening request. As we develop the guidance, we will carefully consider the commenters' suggestions for the types of information to include, such as the information from ACOs that will aid our analysis, timing considerations, and steps involved for an ACO to submit a reopening request.

We agree with commenters on the importance of developing the requirements for a reopening request process in a way that would minimize additional burden on ACOs, including with respect to ACOs' submissions of reopening requests, and compiling related information, among other possible actions. We anticipate considering approaches to minimizing the burden on ACOs in connection with the reopening request process, as we develop related requirements and operational procedures.

In the CY 2025 PFS proposed rule (89 FR 61907 through 61908), as restated elsewhere in this section of this final rule, we explained that CMS will need to receive sufficient, detailed

information from ACOs to evaluate an ACO's reopening request. We listed certain information that would aid in our analysis of the ACO's request in the case of a reopening request in connection with improper payments, or fraud or similar fault potentially impacting the ACO's financial calculations. In the initial discussion of these factors we did not specify a priority for the information listed. We believe clarifying this information addresses, in part, commenters' requests for CMS to provide transparency around the type of information CMS will request from ACOs as part of the reopening request process, and to address concerns over whether the information CMS may request would be readily available to ACOs.

To clarify, we would need to receive certain, basic details within the ACO's reopening request to allow us to effectively identify, validate and quantify the improper payments, or evaluate the alleged fraud or similar fault, potentially impacting expenditures used in Shared Savings Program calculations, in particular: (1) the identity of the provider or supplier for which there may be improper payment(s), or suspected of fraud or similar fault; (2) the time period during which potentially impacted claims were submitted or improper conduct occurred; (3) a description of the improper payment, alleged fraud or similar fault, and how it was identified, including any specific claim type codes and HCPCS or CPT codes; and (4) a list of beneficiaries assigned to the ACO for whom claims were submitted by the provider or supplier suspected of fraud or similar fault, or for which expenditures may be impacted by improper payments. While it may aid our review of the ACO's reopening request to receive evidence of financial impact on the ACO's shared savings or shared losses calculation, this could include a brief description with any available evidence, and does not necessarily need to involve a complex analysis. We recognize there may be limitations to the analyses ACOs can perform, particularly with respect to potential impacts on national or regional billing, as commenters point out. We note that in the CY 2025 PFS proposed rule, while we discussed the types of information we would find helpful to receive from ACOs (89 FR 61907 through 61908) and in a separate discussion provided detailed hypothetical examples illustrating how the proposed calculation methodology would be applied (89 FR 61901 through 61906), we did not specifically state that we were contemplating requesting or requiring ACOs to submit to CMS as part of their reopening request evidence or analysis of the financial impact of improper payments on national expenditures, regional expenditures, or both. If an ACO were to have available information or analysis of the estimated financial impact of improper payments on the ACO's shared savings or shared losses calculation, the ACO may submit these details with their reopening request. More generally, we will carefully consider the information provided by the ACO, and we will undertake our own internal analysis to inform our decision of whether to reopen an ACO's payment determination, and (if warranted) we will perform recalculations needed to issue a revised initial determination based on validated and quantified information.

Additionally, in response to the comment requesting that CMS provide greater transparency into the steps ACOs should take to submit a reopening request, we recognize that ACOs may be seeking specific additional information on how to prepare and submit a reopening request prior to the issuance of the guidance material on the reopening request process. In brief, as we specified elsewhere in this section of this final rule, ACOs seeking to submit a reopening request prior to the issuance of guidance material on the reopening request process, are encouraged to submit detailed information in writing to CMS by email to *SharedSavingsProgram@cms.hhs.gov*. For ACOs contemplating submitting a reopening request in connection with improper payments, or fraud or similar fault potentially impacting the ACO's financial calculations, we urge that they consider providing the types of information we specified would aid in our analysis of the ACO's request in preparing their submission, as outlined in the CY 2025 PFS proposed rule (89 FR 61907 through 61908), and about which we have provided additional explanations within this response.

Comment: Some commenters urged CMS to complete actions quickly or timely, and to provide detailed responses to ACO reopening requests outlining why an ACO's reopening request is granted or not granted, citing considerations about the need for ACOs to notify participants of the outcome and adjust any ''downstream'' payment or incentives. One of these commenters went on to explain transparency and timely action on CMS' behalf will enhance agency credibility, promote sustainable ACO financial planning and budgeting, and impact participants' willingness to participate in ACO models in the future, concepts echoed in other similar comments.

Response: We acknowledge the importance of completing reopening requests in a timely manner and communicating the findings as soon as possible to the ACO, including for the reasons outlined by commenters. We anticipate acknowledging receipt of each reopening request and providing a response as to the final outcome of the request.

Further, in response to commenters' suggestions that we complete actions quickly or timely and provide detailed responses to ACOs, we note that there are interactions between our investigation into the issues potentially impacting ACO financial calculations that may warrant reopening, and the extent to which we can provide additional information to ACOs to explain the status of our investigation and findings, and relatedly the timeline for communicating our decision or related information to the ACO that submitted the request. Until we reach a decision on whether or not to reopen the ACO's payment determination, we may be limited in the information that we can communicate to an ACO about the status of its reopening request. As explained in the CY 2025 PFS proposed rule (89 FR 61908), in cases where CMS, law enforcement officials, or both, may have investigations underway, CMS must refrain from providing details to ACOs and other entities, of pending actions to protect the integrity of those investigations. In addition, for a reopening request to account for improper payments, we must identify and quantify the improper payments, including certain demanded overpayment determinations, and improper payments resulting from conduct by individuals or entities performing functions or services related to an ACO's activities as identified in certain settlement agreements or judgments (as discussed in section III.G.7.c.(2).(b) of this final rule). We reiterate that it may take months or years to determine the actual amount of any improper payments impacting an ACO's payment determination, particularly if we are awaiting the conclusion of program integrity and law enforcement investigations, among other possible determinations about the related conduct of providers or suppliers.

With respect to commenters urging the need for CMS to provide ACOs with detailed responses to ACO reopening requests, including for the purposes of notifying its participants of the outcome, and for the ACO to adjust

payment or incentives participants may receive, we note that in the event we decide to reopen an ACO's payment determination and issue a revised initial determination, we anticipate specifying related information in a financial reconciliation report delivered to the ACO. As we explained in the CY 2025 PFS proposed rule (see 89 FR 61896 through 61897; and 61908), a number of steps would follow after we decide to reopen the initial determination and perform the recalculations needed to reach a revised initial determination, including issuing the revised initial determination to the ACO, and engaging in payment and recoupment activities, as needed. As we previously explained in rulemaking (81 FR 38001 through 38002, see also 87 FR 69872), and continue to believe, we would provide ACOs with sufficient details regarding any necessary adjustments in their shared savings or shared losses resulting from reopened financial calculations for each performance year affected such that they will be able to attribute the additional payment or recoupment arising from the reopening internally with their ACO participants.

Comment: One commenter urged transparency on how ACO reopening requests will be ''prioritized'' but did not provide details on what this meant.

Response: In response to the commenter's suggestion that CMS provide transparency into how ACO reopening requests are ''prioritized,'' we note that it is unclear what form of ''prioritization'' the commenter is referring to given the lack of details in the comment. As a general matter, we agree with the importance of transparency in our processes for implementing the Shared Savings Program. However, we decline at this time to specify a particular approach we may use to create a prioritization among multiple reopening requests from different ACOs. There are various factors that may affect the timing for our consideration of an ACO's reopening request, including with respect to the timeframe for conducting our initial analysis, and reaching a decision on whether to reopen the calculations as we have described elsewhere in section III.G.7.c of this final rule. Further, the timing of the reopening must be consistent with the timeframes specified in § 425.315(a)(1)(i) and (ii), respectively, either (i) at any time in the case of fraud or similar fault, or (ii) not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause. Depending on the timing of when the issue potentially impacting ACO financial calculations comes to our attention, we may need to more urgently decide whether to reopen the payment determination, for good cause, in order to be able to exercise our authority under § 425.315(a)(1)(ii). Once a decision is reached on whether to reopen the payment determination, additional time would be needed to complete recalculation of a payment determination (if warranted), and issue the revised initial determination to an ACO, or otherwise notify the ACO of our decision with respect to their reopening request. Additionally, we may also consider that the timing of issuing a revised initial determination could impact other program calculations, such as benchmark calculations used in determining financial performance for a performance year that has not yet been reconciled, specifically in connection with calculating or recalculating the prior savings adjustment for the ACO (if applicable), or the application of the benchmark adjustment described in section III.G.7.c.(2).(d) of this final rule. In light of the complexity of these circumstances, and our limited experience with ACO reopening requests as of the time of this final rule, we believe it would be prudent to gain additional experience with the application of these policies, and related processes, to inform any potential consideration for development of a policy for prioritizing ACO reopening requests.

After consideration of public comments, we are finalizing our proposal, without modification, to establish a process at § 425.315(b) by which an ACO may request a reopening of an initial determination, or a final agency determination under subpart I, of shared savings or shared losses. We anticipate providing additional information on the reopening request process for ACOs through guidance, including the form and manner in which CMS must receive a reopening request, among other possible information.

(f) Preventing and Reporting Medicare Fraud

As we explained in the CY 2025 PFS proposed rule (89 FR 61908 through 61909), ACOs can help prevent fraud and abuse within the Medicare program or in other Federal healthcare programs. Program integrity requirements for the Shared Savings Program include the requirement under § 425.300 that the ACO must have a compliance plan. Among other required elements, an ACO's compliance plan must include a method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer (§ 425.300(a)(3)). ACOs' compliance plans must also include a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency (§ 425.300(a)(5)). (Refer to the November 2011 final rule, 76 FR 67951 and 67952.)

We reiterate that ACOs are encouraged to report potential fraud or abuse to the CMS Center for Program Integrity (CPI) and the HHS–OIG. ACOs may submit a complaint to the CMS CPI, Fraud Investigations Group (FIG), Division of Provider Investigations (DPI) at *dpi.intake@cms.hhs.gov.* ACOs can also report potential fraud or abuse by submitting a complaint to the HHS–OIG website, *https://oig.hhs.gov/fraud/report-fraud/*, HHS–OIG hotline at 1–800–HHS–TIPS (1–800–447–8477), TTY at 1–800–377–4950, by fax at 1–800–223–8164, or by mailing to: Office of Inspector General ATTN: OIG HOTLINE OPERATIONS, P.O. Box 23489, Washington, DC 20026. ACOs suspecting healthcare fraud, waste, or abuse are encouraged to visit the CMS CPI's website on Reporting Fraud at *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud* for more information. More generally, anyone suspecting healthcare fraud, waste or abuse is encouraged to report it to CMS or the HHS–OIG.

As we explained in the CY 2025 PFS proposed rule (89 FR 61909), in the absence of a reopening request submitted by an ACO in the form and manner specified by CMS (discussed in section III.G.7.c.(2).(e) of the proposed rule), the reporting of potential fraud or abuse to CMS CPI or the HHS–OIG does not itself constitute a reopening request under the Shared Savings Program.

We also solicited comments on considerations in connection with ACOs' potential role in preventing and reporting Medicare fraud, among other proposals and considerations described in section III.G.7.c of the CY 2025 PFS proposed rule.

We received public comments on considerations about ACOs' role in preventing and reporting Medicare fraud, in connection with the SAHS billing activity proposals. Therefore, we summarize and respond these public comments in section III.G.7.d of this final rule.

In summary, as described in section III.G.7.c of this final rule, we are

finalizing our proposals to modify the Shared Savings Program regulations to provide greater specificity on reopening ACO payment determinations. We are finalizing our proposal to revise § 425.315(a)(4) to make clear CMS' discretion to determine whether to reopen a payment determination applies in the case of fraud or similar fault, as well as to determining whether good cause exists to reopen a payment determination. We are finalizing our proposal to add to subpart G a new section of the Shared Savings Program regulation at § 425.674 specifying provisions on accounting for the impact of improper payments on Shared Savings Program financial calculations. We are finalizing with clarification our proposal to adjust the benchmark to account for the impact of improper payments, in the event CMS recalculates a payment determination and issues a revised initial determination for a performance year in a prior agreement period that corresponds to a benchmark year of the ACO's *agreement period* (emphasis added to reflect clarified text). Relatedly, we are finalizing without modification our proposed amendments to the regulations at §§ 425.601(a)(9) and 425.652(a)(9) to specify the adjustment to the historical benchmark. Lastly, we are finalizing our proposal to establish a process at § 425.315(b) by which an ACO may request a reopening of an initial determination, or a final agency determination under subpart I, of shared savings or shared losses.

d. Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Shared Savings Program Financial Calculations in Calendar Year 2024 or Subsequent Calendar Years

(1) Background

(a) Statutory Background on Shared Savings Program Financial Calculations

Section 1899 of the Act (42 U.S.C. 1395jjj), as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), establishes the general requirements for payments to participating ACOs in the Shared Savings Program. Specifically, section 1899(d)(1)(A) of the Act provides that providers of services and suppliers participating in an ACO will continue to receive payment under the original Medicare fee-for-service program under Medicare Parts A and B in the same manner as they would otherwise be made. However, section 1899(d)(1)(A) of the Act also provides for an ACO to receive payment for shared savings provided that the ACO meets both the quality performance standards established by the Secretary and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models in place of the one-sided model described in section 1899(d) of the Act. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. We have used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment model (see for example, 80 FR 32771 and 32772, and 83 FR 67834 through 67841) and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years (82 FR 60916 and 60917, 83 FR 59974 through 59977), among other uses of this authority described elsewhere in this final rule.

Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary.

In past rulemaking, we have used our authority under sections 1899(d)(1)(B)(ii) and 1899(i)(3) of the Act to establish adjustments to the benchmark and program expenditure calculations, respectively, to exclude certain Medicare Parts A and B payments. In the November 2011 final rule (76 FR 67920 through 67922), we adopted an alternate payment methodology that excluded Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH) payments from ACO benchmark and performance year expenditures due to concerns that the inclusion of these amounts would incentivize ACOs to avoid referring patients to the types of providers that receive these payments. In the CY 2023 PFS final rule (87 FR 69954 through 69956), we excluded new supplemental payments to Indian Health Service/Tribal hospitals and hospitals located in Puerto Rico consistent with our longstanding policy to exclude IME, DSH and uncompensated care payments from ACOs' assigned and assignable beneficiary expenditure calculations. In the May 8, 2020 COVID–19 IFC (85 FR 27577 through 27582), we established a methodology to adjust Shared Savings Program financial calculations to account for the PHE for COVID–19. Specifically, we established a methodology that would exclude all Medicare Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 to prevent distortion to, among other calculations, an ACO's benchmark and program expenditure calculations.

(b) Background on Significant, Anomalous, and Highly Suspect Billing Activity

Recently, ACOs and other interested parties have raised concerns about an increase in billing to Medicare for selected intermittent urinary catheter supplies on Durable Medical Equipment, Prosthetics, Orthotics & Supplies (DMEPOS) claims in CY 2023, alleging that the increase in payments represents fraudulent activity (the ''alleged conduct''). The observed DMEPOS billing volume for intermittent urinary catheters in CY 2023 represents significant, anomalous, and highly suspect (SAHS) billing activity.[600]

Generally, a level of billing for a given HCPCS or CPT code is considered SAHS billing activity when a given HCPCS or

[600] SAHS billing activity may appear in claims for items and services rendered to beneficiaries assigned to an ACO as well as for beneficiaries who are not assigned to an ACO. Such activity may be caused by providers and suppliers who participate in an ACO and who do not participate in an ACO. This discussion is primarily focused on SAHS billing activity performed by providers and suppliers that do not participate in ACOs billing items and services for beneficiaries who are assigned to ACOs or who are in the assignable population used in national and regional factors used in Shared Savings Program calculations.

CPT code exhibits a level of billing that represents a significant claims increase either in the volume or dollars (for example, dollar volume significantly above prior year, or claims volume beyond expectations) with national or regional impact (for example, not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level is significant and represents billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed.

In a separate proposed rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023'' (89 FR 55168, July 3, 2024) (referred to herein as the ''SAHS billing activity proposed rule''), we proposed an approach to address the SAHS billing activity identified by CMS for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations. Specifically, we proposed to exclude payment amounts for two HCPCS codes (A4352 (*Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.),* each) and A4353 (*Intermittent urinary catheter, with insertion supplies*)) on DMEPOS claims submitted by any supplier from expenditure and revenue calculations used for: assessing performance year (PY) 2023 financial performance of Shared Savings Program ACOs, establishing benchmarks for ACOs starting agreement periods in 2024, 2025, and 2026, and calculating factors used to determine revenue status and repayment mechanism amounts in the application and change request cycle for ACOs applying to enter a new agreement period beginning on January 1, 2025, or continue their participation in the program in PY 2025, respectively. After the comment period closed for the CY 2025 PFS proposed rule, we finalized the proposals without modification in the SAHS billing activity final rule (89 FR 79152, September 27, 2024).

Current Shared Savings Program regulations, codified at 42 CFR part 425, do not provide a basis for CMS to adjust program expenditure or revenue calculations to remove the impact of SAHS billing activity occurring in CY 2024 or in subsequent calendar years in advance of issuing an initial determination. As discussed in section III.G.7.c of this final rule, CMS may reopen an initial determination or a final agency determination and issue a revised initial determination at any time in the case of fraud or similar fault, and not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year for good cause (§ 425.315). This does not allow for CMS to address SAHS billing activity occurring in CY 2024 or in subsequent calendar years, which must be addressed prior to conducting financial reconciliation, which is an initial determination, to prevent significant inequity and inaccurate payment determinations.

In the CY 2025 PFS proposed rule (89 FR 61909 through 61916), we proposed a policy that would proactively make adjustments to Shared Savings Program calculations should new SAHS billing activity be identified in CY 2024 or in subsequent calendar years. We explained that we are concerned that such SAHS billing activity, should it occur in CY 2024 or later, would inflate Medicare Parts A and B payment amounts and affect Shared Savings Program calculations, including:

- Performance year reconciliation calculations, including expenditures for each ACO's assigned beneficiaries for the calendar year that has SAHS billing activity, the national-regional blended update factor used to update the benchmark for ACOs beginning an agreement period before January 1, 2024 (refer to § 425.601(b)), the three-way blended update factor used to update the benchmark for ACOs beginning an agreement period on January 1, 2024 and in subsequent years (refer to § 425.652(b)), and factors based on ACO participant revenue to determine the loss recoupment limits for ACOs participating under two-sided models of the BASIC track (Levels C, D, E) (refer to § 425.605(d)).
- Historical benchmark calculations for establishing the benchmark for ACOs beginning new agreement periods on January 1, 2025, or in subsequent years with a benchmark year that has SAHS billing activity (refer to § 425.652(a)).
- Factors used in the application cycle for ACOs applying to enter a new agreement period beginning 2 years after the SAHS billing activity occurred, and the change request cycle for ACOs continuing their participation in the program, including data used to determine an ACO's eligibility for Advance Investment Payments under § 425.630(b) or for the CMS Innovation Center's new ACO Primary Care Flex Model (ACO PC Flex Model) based on ACO revenue status (high revenue or low revenue), and to determine repayment mechanism amounts for ACOs entering, or continuing in, two-sided models (refer to § 425.204(f)).

The accuracy of the Shared Savings Program's determination of an ACO's financial performance (through a process referred to as financial reconciliation) in terms of the ACO's eligibility for and amount of a shared savings payment or liability for shared losses, depends on the accuracy of claims data. Absent CMS action, SAHS billing activity would affect performance year financial reconciliation program-wide rather than being limited to ACOs that have assigned beneficiaries directly impacted by the issue. For instance:

- An ACO with assigned beneficiaries impacted by the SAHS billing activity will see an increase in performance year expenditures, reducing the ACO's shared savings or increasing the amount of shared losses owed by the ACO. The impact on the ACO's performance may be partially mitigated if the SAHS billing activity also increases the ACO's regional service area expenditures and the national expenditures used to calculate the two-way national-regional blended benchmark update factor.
- An ACO with assigned beneficiary expenditures and regional service area expenditures with little or no impact from the SAHS billing activity will receive a relatively higher benchmark update under the national-regional blended update factors used in performance year reconciliation, and therefore, may appear to perform better as a result of the national impact of the SAHS billing activity, resulting in higher earned performance payments or lower or no losses for the ACO.

Unaddressed, SAHS billing activity in a given calendar year can distort the historical benchmarks for an ACO in an agreement period that have the calendar year as a benchmark year and the accuracy of any future financial reconciliation performed against those benchmarks. Similarly, inaccurate revenue and expenditure calculations based on data from a calendar year affected by SAHS billing activity may affect an ACO's revenue status and the amount of funds an ACO in a two-sided model must secure as a repayment mechanism, one of the program's important safeguards for protecting the Medicare Trust Funds. Absent CMS action, SAHS billing activity likely would significantly impact shared savings and losses calculations for the performance year affected by SAHS billing activity, and for future

performance years that have benchmark years affected by SAHS billing activity. Under these circumstances, some ACOs would likely experience adverse impacts (for example, lower or no shared savings or higher shared losses) while other ACOs would experience windfall gains (for example, higher shared savings or lower or no shared losses).

Failing to address SAHS billing activity will jeopardize the integrity of the Shared Savings Program. There are 480 ACOs in the Shared Savings Program with over 608,000 healthcare providers who care for 10.8 million assigned FFS beneficiaries.[601] In PY 2022, the most recent year for which data is available, savings achieved by ACOs relative to benchmarks amounted to $4.3 billion, of which ACOs received shared savings payments totaling $2.5 billion, and Medicare retained $1.8 billion in savings.[602] ACOs are held accountable for 100 percent of total Medicare Parts A and B expenditures for their assigned beneficiary populations (with limited exceptions). This incentivizes ACOs to generate savings for the Medicare program as they have the opportunity to share in those savings if certain requirements are met. It also discourages the ACO from generating unnecessary expenditures for Medicare as they may be required to repay those amounts to CMS. Accountable care arrangements such as this cannot function if the ACO may be held responsible for all SAHS billing activity that is outside of their control. Holding an ACO accountable for substantial losses due to SAHS billing activity is not only inequitable but will dramatically increase the level of risk associated with participation, making the Shared Savings Program unattractive.

The following is a summary of general comments we received on our discussion and proposals regarding mitigating the impact of SAHS billing activity on Shared Savings Program calculations should new SAHS billing activity be identified in CY 2024 or in subsequent calendar years.

Comment: Most commenters expressed broad support—or general support with additional recommendations—for the proposal to establish a policy that would allow CMS to proactively make adjustments to Shared Savings Program calculations should new SAHS billing activity be identified in CY 2024 or in subsequent calendar years. Many commenters characterized the combination of the SAHS billing activity proposed rule and the proposal for CY 2024 and subsequent years as an approach that holds ACOs ''harmless'' for fraudulent billing activity, as ''fair'' because the approach protects ACOs against SAHS billing activity outside of their control, or as a ''comprehensive approach''. One commenter agreed that it is appropriate and necessary for CMS to have the authority to mitigate the impact of SAHS billing activity on Shared Savings Program calculations. Many commenters commended CMS for taking action through the SAHS billing activity proposed rule and through this proposal to address concerns raised by ACOs and other interested parties about the impact of SAHS billing activity, and a few also characterized CMS's attention to the matter as prompt, responsive to concerns, or aligned with stakeholder recommendations. One commenter characterized the proposal as setting a standard policy for addressing SAHS billing activity.

Supportive commenters offered a variety of reasons why they supported the proposal. Many commenters agreed that the proposal will strengthen program or financial integrity, accuracy of calculations, sustainability of ACO business models, or effectiveness of the Shared Savings Program. Several commenters agreed that unaddressed, SAHS billing activity can impact ACOs' shared savings and losses and other financial calculations. A few commenters stated that the proposal would benefit ACOs, with a couple also stating that it will benefit beneficiaries or providers and suppliers. A couple commenters stated that their ACOs have been highly affected by SAHS billing activity in PY 2023 and PY 2024 and that keeping the codes in shared savings and losses calculations for those performance years would erase all the work they have done to generate savings.

Response: We thank commenters for their support for CMS's actions to undertake notice and comment rulemaking to establish a policy that would allow CMS to proactively make adjustments to Shared Savings Program calculations should SAHS billing activity be identified in CY 2024 or in subsequent calendar years. We agree with the commenters who stated that mitigating the impact of SAHS billing activity is important for promoting continued integrity and improving the accuracy of Shared Savings Program financial calculations.

Comment: Commenters addressed the role that ACOs play in the identification of SAHS billing activity or fraud, waste, and abuse in Medicare and the process by which ACOs report suspected fraud. A few commenters stated their belief that ACOs are well positioned to detect anomalous billing or uncover potential fraud, waste and abuse given their ongoing and in-depth analysis of claims and utilization data, with one noting that the HHS–OIG recommended that CMS prioritize referrals from ACOs. Some commenters urged CMS to work with ACOs to improve the process for reporting suspected fraud. A few commenters suggested that ACO referrals be given priority by CMS or be handled through an expedited process.

Several commenters requested that CMS and the HHS–OIG provide more transparency to ACOs into investigations of potential fraud and abuse. Several commenters requested CMS better educate ACOs on the processes that CMS and the HHS–OIG undertake to investigate fraud. Multiple commenters requested a ''feedback loop'' after the ACO notifies CMS and the HHS–OIG of suspected fraud, with several stating that ACOs need information to inform their patient communications and make decisions about future participation given fraud investigations can take years to resolve. These commenters requested that CMS explore additional ways to notify ACOs of actions being taken; for example, commenters suggested CMS could provide information in claim and claim line feeds to indicate when CMS is ''placing some claims into escrow''.

Response: We agree that ACOs are well positioned to support monitoring efforts that will improve the integrity of the Medicare program including value-based payment systems. ACOs have tools that may be used to detect unusual or suspect billing areas or activity among their assigned beneficiary population through data and reports provided by CMS and through their own data systems and care coordination and quality improvement activities. ACOs are encouraged to report potential fraud or abuse by submitting a complaint to the CMS Center for Program Integrity (CPI), Fraud Investigations Group (FIG), Division of Provider Investigations (DPI) at *dpi.intake@cms.hhs.gov.* ACOs can also report potential fraud or abuse by submitting a complaint to the HHS–OIG website, *https://oig.hhs.gov/fraud/report-fraud/*, HHS–OIG hotline at 1–800–HHS–TIPS (1–800–447–8477), TTY at 1–800–377–4950, by fax at 1–800–223–8164, or by mailing to: Office of

[601] Refer to CMS, Shared Savings Program Fast Facts—As of January 1, 2024, available at *https://www.cms.gov/files/document/2024-shared-savings-program-fast-facts.pdf.*

[602] Refer to CMS, Shared Savings Program Performance Year Financial and Quality Results, 2022, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results/data.*

Inspector General ATTN: OIG HOTLINE OPERATIONS, P.O. Box 23489, Washington, DC 20026. ACOs suspecting healthcare fraud, waste, or abuse are encouraged to visit the CMS CPI website on Reporting Fraud at *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud* for more information. We will continue to work with our program integrity colleagues on ways to improve ACO reporting of potential fraud or abuse.

Further, in response to commenters suggesting that ACO referrals be given priority by CMS or be handled through an expedited process we note that, in investigating leads that are vetted and approved by CMS to be opened as an investigation, the Unified Program Integrity Contractors (UPICs) focus investigations in an effort to establish the facts and the magnitude of the alleged fraud, waste, or abuse and take any appropriate action to protect Medicare Trust Fund dollars, unless otherwise specified by CMS. The UPICs ensure that all investigations originating from an ACO referral or involving ACOs, ACO participants or ACO providers/suppliers are provided a heightened level of priority and are promptly reviewed and investigated to ensure the appropriate administrative or other action(s) are taken in an expeditious manner.[603]

Comment: Some commenters addressed fraud prevention and mitigation actions in the Medicare program more broadly. One commenter urged CMS to develop clear, objective standards for identifying and refunding suspect claims, opining that current rules allow for subjectivity and inconsistent application and create operational challenges for ACOs and undermines ACOs' ability to provide comprehensive care. Another commenter recommended that, rather than removing specific HCPCS codes, CMS should ''focus on removing the bad actors'' who, if not restricted from billing Medicare, could simply target a new code.

Response: CMS continues to adapt its monitoring, investigative targeting, and data analytics programs to prevent future fraud, waste, and abuse. CMS also continues to work closely with the HHS–OIG and Department of Justice, as well as our UPICs, to investigate healthcare fraud activities that exploit the Medicare program.

[603] For additional information on how CMS conducts investigations of potential fraud, waste, or abuse, see, for example, Medicare Program Integrity Manual, Chapter 4—Program Integrity, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c04.pdf.*

This provision establishes a policy to mitigate the impact of SAHS billing activity in CY 2024 or in subsequent calendar years on Shared Savings Program calculations. We clarify that neither this provision nor the reopening policy provision described in section III.G.7.c. of this final rule, changes rules or processes for CMS or the HHS–OIG to investigate and resolve potential fraud, waste and abuse within the broader Medicare program.

(2) Revisions

In the CY 2025 PFS proposed rule (89 FR 61911), we explained that it is important to establish a policy that would allow CMS to proactively make similar adjustments for future calendar years, should new SAHS billing activity be identified. In general, we anticipated that billing activity that meets the high bar to be considered significant, anomalous, and highly suspect billing activity will be a rare occurrence. This is evidenced by the program's history. The SAHS billing activity surrounding selected catheter codes in 2023 is the first occasion we have had in the program's 12-year history to consider this issue. We proposed that we would notify ACOs and ACO applicants of our determinations to remove any codes and the aggregate per capita dollar amount of the codes removed as part of the annual financial reconciliation process. While we anticipate future occurrences of the scope and magnitude observed for urinary catheters in CY 2023 to be rare, having a permanent policy in place would:

- Allow CMS to move quickly to make adjustments to financial calculations without having to engage in additional rulemaking, ensuring timely issuance of initial determinations of savings and losses and disbursement of earned performance payments;
- Provide ACOs with greater certainty that they will not be held accountable for SAHS billing activity that is out of their control, promote integrity and fairness and ensure accuracy of program calculations;
- Limit requests to reopen initial determinations, thus reducing burden for ACOs and CMS.

In this final rule, we are finalizing an approach by which we will adjust Shared Savings Program calculations to mitigate the impacts of SAHS billing activity occurring in CY 2024 or subsequent calendar years.

(a) Identifying Significant, Anomalous, and Highly Suspect Billing *Activity*

In section III.G.7.d.(2).(a) of the CY 2025 PFS proposed rule (89 FR 61911 through 61912) we proposed that CMS would have the sole discretion to identify cases of SAHS billing activity for a particular calendar year that would warrant the adjustment of Shared Savings Program financial calculations. We explained that we anticipate routinely examining billing trends identified by CMS and other relevant information that had been raised through complaints by ACOs or other interested parties to the HHS–OIG or to CMS. We would seek to identify and monitor any codes that would potentially trigger the adjustment policy by meeting the high bar for removal under the criteria used to determine SAHS billing activity. Shortly after the start of a calendar year CMS would make a final determination as to which codes, if any, warrant adjustments for the previous calendar year. For example, in early CY 2026 CMS would make a final determination of whether any codes met the high bar for removal under the criteria used to determine SAHS billing activity in CY 2025, allowing time for the adjustments to be incorporated in forthcoming calculations.

We explained that CMS must retain sole discretion to identify cases of SAHS billing activity because we cannot anticipate what SAHS billing activity we may encounter in the future that may warrant adjustments to the program's financial calculations. We also stated our concern about balancing adjustments for billing activity that rises to the level of SAHS versus removing payment amounts associated with billing activity due to inefficiencies that are within the ACO's control. We explained that depending on the frequency of the use of this authority and the occurrence of SAHS billing activity, and thus the experience we develop in this area, we would consider proposing to codify criteria to identify SAHS billing activity in the future through additional rulemaking. We stated that nonetheless, CMS should retain sole discretion to determine whether SAHS billing activity occurred on a case-by-case basis at this time.

We explained that we anticipate considering multiple criteria in determining whether SAHS billing activity warrants removal of the corresponding billing codes from Shared Savings Program financial calculations. These criteria include:

- The observed increase in claims for a HCPCS or CPT code year-to-year meets the definition of SAHS billing activity, as defined elsewhere in this section of this final rule;
- The observed billing activity has national or regional impact or significance, such as:

++ Involves a Medicare provider or supplier, a beneficiary population and/or States with claims activity that that significantly impacts national or regional expenditure values or trends;

++ Warrants adjustment (all or partial) to national Medicare expenditure trend calculations used in payment (for example, United States Per Capita Cost) and/or Federal budget forecast calculations;

++ Warrants removal from national and regional growth rates used to update ACO historical benchmarks;

• If no action is taken there would be an imbalance between ACO performance year and historical benchmark year expenditures;

• Use of payment amounts associated with the SAHS billing activity could result in payment inaccuracies that produce significantly inaccurate and inequitable payment determinations in the Shared Savings Program (including the amount of shared savings or shared losses), due to factors beyond the control of ACOs; and

• The claims in question may be disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked.

Further, we explained that we anticipate utilizing this authority only in rare and extreme cases where a number of the criteria are satisfied. We specified that we would consider the extent to which the billing activity meets each criterion when developing a holistic assessment of the billing activity's impact on the Shared Savings Program.

The extent of the geographic impact of the SAHS billing activity in question is relevant given that the proposed policy would entail adjustments program-wide. One consideration for determining whether the billing activity has national or regional significance would be if the pattern warrants an adjustment to or special assumption for calculating official Medicare expenditure trends (such as the United States Per Capita Cost (USPCC) or Federal budget forecasts) due to the activity's significant, anomalous, and highly suspect nature. For example, the 2024 Medicare Trustees Report noted a significant increase in suspected fraudulent spending on certain intermittent catheters in 2023.[604] The DME projections in the report include the assumption that this suspected fraud will be addressed during 2024.[605] Billing activity in the Medicare FFS program at a scale warranting a special assumption for calculating the USPCC or Federal budget forecasts has *per se* national or regional significance, and thus would likely rise to the high bar of warranting adjustment to Shared Savings Program expenditure and revenue calculations.

We would seek to assess whether the billing activity creates an imbalance between ACO performance year and historical benchmark year expenditures. This assessment could involve considering whether the increase in billing activity was at such scale that it causes the difference between performance year and benchmark year expenditures for an ACO's assigned beneficiary population for the claim type affected by the billing activity (for example, DMEPOS) to be substantially larger than differences for other claim types.

We stated that we would also consider whether the billing activity, and any inaccurate or inequitable payment determinations that could result from using the related payment amounts, was outside of Shared Savings Program ACOs' ability to reasonably control. Most commonly, this would entail examining whether the Medicare providers or suppliers billing the codes in question are ACO providers or suppliers. Generally, we explained that we would be more likely to apply the proposed policy if the SAHS billing activity were outside of the ACO's control as the program may otherwise lack a means to control the growth of such amounts.

Finally, we stated that we would consider whether billing activity was disproportionately represented by Medicare providers or suppliers whose Medicare enrollment status has been revoked. Such a circumstance would provide further evidence that the billing activity surrounding these codes was highly suspect. We solicited comment on the processes and criteria described.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters addressed the proposed approach for identifying cases of SAHS billing activity for a particular calendar year. One commenter supported the proposal to identify cases in time to make adjustments to forthcoming calculations prior to issuance of initial determinations of shared savings and losses. A couple commenters requested that CMS determine whether certain billing activity meets the definition of SAHS billing activity on an ad hoc basis. Similarly, other commenters urged CMS to maintain flexibility to notify ACOs more frequently than on the proposed annual basis after the end of a performance year if billing activity on any codes is determined to be SAHS billing activity. A few of these commenters stated that SAHS billing activity for intermittent urinary catheters persisted into the first quarter of 2024, and therefore, reasoned that if CMS is already planning to make adjustments for this billing during CY 2024 that CMS should notify ACOs sooner than spring 2025. Another commenter generally supported the concept of mitigating the impact of SAHS billing activity on Shared Savings Program calculations, but suggested that CMS remove payment amounts for suspect billing activity as soon as a provider submitting claims related to the billing activity is under indictment or investigation by the HHS–OIG. This commenter reasoned that while the reopening policy is a mechanism for removing fraud and abuse from shared savings and losses calculations, the extended periods of time ACOs must wait for resolution negatively impacts ACOs that rely on shared savings payments to operate.

Response: We decline to adopt an approach that would require CMS to make a SAHS billing activity determination and notify ACOs of the determination prior to the end of a performance year or to take action to remove payment amounts earlier than this timeframe. To meet the definition of SAHS billing activity we are establishing in this final rule, a given HCPCS or CPT code must exhibit a level of billing that represents a significant claims increase either in the volume or dollars (for example, dollar volume significantly above prior year, or claims volume beyond expectations) with national or regional impact (for example, not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level is significant and represents billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed. In making the determination that billing activity on a certain code during the calendar year

[604] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, ''2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'', p. 136, available at *https://www.cms.gov/oact/tr/2024.*

[605] Ibid.

represents SAHS billing activity that warrants adjustment, we anticipate that it will be necessary to consider the total level of billing in a calendar year compared to the total level of billing from prior years and therefore and that we would make this determination once we know all of the spending that has occurred for that code during the calendar year.

The policy to make adjustments to Shared Savings Program calculations to mitigate the impact of SAHS billing activity in CY 2024 and in subsequent calendar years is intended as a policy to be invoked in rare and extreme cases when CMS identifies a code that meets the high bar to be defined as SAHS billing activity as finalized in this final rule. We narrowly crafted the definition of SAHS billing activity in fairness to ACOs and to balance the goals of the Shared Savings Program to better coordinate care and improve quality, while not holding ACOs accountable for activity that is beyond their control. These high standards are appropriate because the remedy we are using to correct for SAHS billing activity is the broad exclusion of the relevant CPT or HCPCS code from certain important financial calculations, and this could have mixed impact on Shared Savings Program ACOs. Both under this rule and in the SAHS billing activity standalone rule, we are mindful of equitable concerns that may arise from CMS making adjustments to calculations of the ACO's historical benchmark or to performance year expenditures after the conclusion of a performance year.

We agree with the commenter that noted that the reopening policy is an appropriate channel for removing improper payments from an ACO's shared savings and losses calculations; see section III.G.7.c. of this final rule for more details on this policy.

Comment: Some commenters recommended codes for consideration as SAHS billing activity in CY 2023. Specifically, commenters suggested that CMS consider whether codes for skin substitutes, collagen dressings, laboratory services, telemedicine, ventilators, and diabetic supplies warrant adjustment to Shared Savings Program calculations, echoing some related suggestions made in response to the SAHS billing activity proposed rule.

Response: With respect to billing activity on other codes in CY 2023, we note that this is outside the scope of this final rule. We refer readers to the SAHS billing activity final rule (89 FR 79157 through 79158) for our responses to public comments related to these other codes for CY 2023. We remain committed to evaluating cases when improper payments may have been made and assessing the impact on Shared Savings Program calculations. The reopening policy we are finalizing in this final rule can potentially provide relief to ACOs that are affected by specific instances of fraud or other improper payments that may not be SAHS billing activity or for which there is not enough information available at the close of the affected calendar year to make a determination of whether SAHS billing activity occurred. Under this policy, CMS may consider in its discretion whether to reopen the completed financial reconciliation results for fraud or similar fault or good cause, as specified under § 425.315(a). As discussed in section III.G.7.c of this final rule, we may conduct a reopening to account for the impact of improper payments, at the request of an ACO, after an initial determination has been issued.

Comment: A couple commenters recommended codes for consideration as SAHS billing activity in CY 2024. Specifically, commenters identified skin substitutes and the intermittent catheter codes as displaying SAHS billing activity in CY 2024.

Response: We appreciate commenters notifying us of their concerns over billing activity in CY 2024 for certain services. We will take this information into consideration when making a final determination of which codes, if any, displayed SAHS billing activity in CY 2024. We will make this determination shortly after the start of 2025.

Comment: Many commenters requested transparency into the process of CMS's determination whether codes meet the definition of SAHS billing activity, with most also requesting that ACOs receive written feedback on their requests that certain codes be considered SAHS billing activity including an explanation from CMS as to why the situation does or does not meet the SAHS criteria.

Response: As we explained elsewhere in this section, we will routinely examine billing trends identified by CMS and other relevant information that had been raised through complaints by ACOs or other interested parties to the HHS–OIG or to CMS. For instance, ACOs may alert the HHS–OIG or CMS when they suspect a code is displaying SAHS billing activity. Shortly after the start of a calendar year CMS will make a final determination as to which codes, if any, warrant adjustments for the previous calendar year. With respect to commenters urging the need for CMS to provide ACOs with written responses to ACO requests for certain codes to be considered SAHS billing activity, we note that in the rare case when CMS will determine that SAHS billing activity occurred in the previous calendar year, CMS will notify all program participants of this finding including the codes removed and the per capita expenditure amount for their assigned beneficiary population.

Comment: Commenters also addressed the criteria, described elsewhere in this final rule, to determine whether SAHS billing activity warrants removal of the corresponding billing codes from Shared Savings Program financial calculations. One commenter, while urging transparency into the determination process, stated that the requirements for initiating SAHS policies are reasonable and allow the agency to adjust to evolving and unpredictable requirements. A few commenters requested CMS provide more clarity on the criteria, with one requesting that CMS codify the criteria for identifying SAHS billing activity to ensure ACOs clearly understand when billing activity meets the ''threshold'' and another requesting CMS further define what is ''significant.'' Another commenter suggested CMS develop a threshold (such as two standard deviations from the mean) for individual billing codes such that any codes surpassing the threshold would automatically trigger adjustments.

A few commenters urged CMS to expand the criteria such that SAHS billing activity occurring on a more regional or local level can be considered SAHS billing activity that warrants adjustment. One of these commenters offered an expanded definition for SAHS billing activity specific to DMEPOS claims which would consider whether a DMEPOS code had a significant volume increase in billing for a particular ACO that was not supported by a referral from a treating provider or by a corresponding office visit. Additionally, the commenter requested that CMS remove from an ACO's own financial calculations any claims for which CMS payment is paid into escrow or a holding account while under investigation, any claims submitted by a provider under indictment or investigation by a Federal agency, and any claims for billing codes previously deemed SAHS in prior years. Another commenter suggested that CMS consider provider-level billing activity rather than code-level billing activity in identifying SAHS billing activity.

Response: We appreciate the support of the commenter who stated that the requirements for initiating SAHS policies are reasonable. We agree that the criteria allow the agency to adjust to

evolving and unpredictable requirements.

We decline to specify more specific and narrower criteria or a threshold that would automatically trigger the SAHS billing activity. The flexible definition of SAHS billing activity that we are adopting allows CMS to determine whether SAHS billing activity occurred on a case-by-case basis allowing us to develop experience in this area before further refining or codifying additional criteria. We also decline to codify a specific set of criteria for DMEPOS claims since the criteria we are establishing allow us to address SAHS billing activity related to DMEPOS.[606]

As we explain elsewhere in this section, we anticipate considering multiple criteria when making a determination of SAHS billing activity, including whether the observed billing activity has national or regional impact or significance. The extent of the geographic impact of the SAHS billing activity in question is relevant given that the policy we are finalizing in this final rule would entail program-wide adjustments. For this reason, we would not utilize this authority when billing activity did not have national or regional significance. The current set of criteria do not preclude CMS from determining a particular code for a particular year exhibits SAHS billing activity if the highly suspect billing activity is concentrated at one or a few providers. Indeed, the SAHS billing activity for intermittent urinary catheters was driven by a relatively small number of suppliers submitting a large majority of all claims for these devices.[607] [608]

After consideration of public comments, we are finalizing our proposal that CMS have the sole discretion to identify cases of SAHS billing activity for a particular calendar year that would warrant the adjustment of Shared Savings Program financial calculations. We anticipate that shortly after the start of a calendar year CMS would make a final determination as to which codes, if any, warrant adjustments for the previous calendar year. We will consider multiple criteria in determining whether SAHS billing activity warrants removal of the corresponding billing codes from Shared Savings Program financial calculations.

(b) Adjustments to Shared Savings Program Calculations

In section III.G.7.d.(2).(b) of the CY 2025 PFS proposed rule (89 FR 61912 through 61916), we indicated that in the event that CMS identifies one or more HCPCS or CPT codes with SAHS billing activity in CY 2024 or a subsequent calendar year that warrant adjustment, we proposed to exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified. For example, if CMS identifies one or more codes with SAHS billing activity in CY 2025 that warrant adjustment, we would exclude payments for those codes for both calculations where CY 2025 is the performance year and in calculations where CY 2025 is a benchmark year for ACOs in agreement periods beginning in 2026, 2027, and 2028.

We proposed that we would also adjust the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark that is used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified. In the example where CMS identified SAHS billing activity for 2025, we would adjust benchmark expenditures (ACO, national, and regional) for 2019, 2020, and 2021, for an ACO that began an agreement period in 2022 (for which PY 2025 is the fourth performance year in its agreement period) and would adjust benchmark expenditures (ACO, national, and regional) for 2022, 2023, and 2024 for an ACO that began its agreement period in 2025 (for which PY 2025 is the first performance year in its agreement period). We noted that in computing benchmark expenditures for 2023 for this second ACO, because 2023 is a benchmark year, we would also exclude payments for the catheter claims with SAHS billing activity in 2023, as proposed in the SAHS billing activity proposed rule, if finalized.

We explained that our proposal to adjust an ACO's historical benchmark to exclude Medicare Parts A and B FFS payment amounts associated with the HCPCS or CPT codes displaying SAHS billing activity during a performance year would achieve greater consistency between the benchmark period and the performance year, given that we are excluding all payments on specified claim types for the selected codes from performance year calculations, including payments that would have been made in the absence of any SAHS billing activity. This helps to ensure a balance between the benchmark and the performance year such that an ACO is not unfairly benefitting from a benchmark that includes certain expenditures that are excluded from the performance year. Under our proposal, we would identify any codes warranting adjustment at the start of the next calendar year and our operational schedule would accommodate the additional calculations required. Therefore, we stated that we anticipate being able to compute adjusted historical benchmarks for the affected reconciliation with minimal, if any, delays to the typical timeline for issuing initial determinations.

We proposed that we would provide the historical benchmark that has been adjusted to exclude payment amounts for HCPSC or CPT codes associated with SAHS billing activity occurring in the performance year being reconciled to ACOs as part of their financial reconciliation settlement package for the performance year, as opposed to providing a separate new historical benchmark report in advance of settlement. This approach is consistent with what we have done for rare past occasions where we computed revised benchmarks immediately prior to reconciliation to correct for late-breaking data issues. Consistent with existing operational practice, in calculating these adjusted benchmarks, we would recompute ACO expenditures using beneficiary assignment data that was generated during the performance year being reconciled for all ACOs. For example, if computing adjusted historical benchmarks for PY 2025 to exclude claim payments for codes with SAHS billing activity during the performance year, we would use beneficiary assignment data generated during CY 2025. Although the benchmark year assignment data generated during the performance year being reconciled would be based on the same ACO participant list, assignment methodology selection under § 425.226(a)(1), and assignment methodology under subpart E of Part 425 of the regulations as used in

[606] See, for example, the SAHS billing activity final rule, which removed payment amounts for HCPCS codes A4352 and A4353 on DMEPOS claims from Shared Savings Program financial calculations from CY 2023 with a determination made under substantially the same definition of SAHS billing activity we are now adopting.

[607] See the discussion in the SAHS billing activity final rule (89 FR 79156).

[608] As noted in the SAHS billing activity final rule (89 FR 79154), using our authority to suspend payments, CMS quickly stopped payment on almost all of these claims and began investigating the suppliers who were billing. Since then, the top 15 billers of suspicious catheter claims have had their Medicare enrollment revoked. We also described additional actions taken by CMS to prevent fraud, waste and abuse in the rule and in a case study, ''Urinary Catheter Case Study: CMS' Swift Action Saves Billions,'' available at *https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf.*

calculating the ACO's most recent prior benchmark, other factors, such as more recent Medicare beneficiary eligibility data along with the ACOs included in the claims-based assignment competition, could differ and impact an ACO's assigned population. We considered whether to provide ACOs with their adjusted benchmark at the time we announce our determination of SAHS billing activity for a given calendar year (anticipated to occur near the start of the next calendar year), however we concluded this would delay other important program milestones, such as the issuance of preliminary and adjusted historical benchmarks for the new performance year.

When the calendar year with SAHS billing activity becomes a benchmark year, we proposed adjustments to calculations for the calendar year itself, and not for other years in the benchmark period, or the performance years that will be reconciled against those benchmarks. Thus, in the example where we identified codes with SAHS billing activity in CY 2025, in establishing or resetting the benchmark for an ACO entering an agreement period in 2026, we would exclude payments for the relevant codes identified for CY 2025 from BY 2025 calculations and, if our proposed policy in the SAHS billing activity proposed rule is finalized, would remove payments for the specified catheter codes from BY 2023 calculations. We would not exclude the catheter codes identified as having SAHS billing activity in BY 2023 or the codes identified for CY 2025 from either BY 2024 calculations or calculations for PY 2026 or any subsequent performance years in the same agreement period.[609]

Specifically, we proposed to adjust the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B payment amounts associated with a HCPCS or CPT code on claims for the specified claim types displaying SAHS billing activity:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following:

-- Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4) and 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

-- Truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

-- Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita FFS expenditures for purposes of calculating the Accountable Care Prospective Trend (ACPT) according to § 425.660(b)(3).

++ Determining truncated national per capita expenditures FFS per capita expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

++ Determining national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.658(c)(1)(ii), capping the prepaid shared savings multiplier according to § 425.640(f)(2)(v), and calculating the proposed HEBA scaler according to § 425.662(b)(2).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified at § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined at § 425.20, determining an ACO's eligibility to receive advance investment payments according to § 425.630, and determining whether an a ACO qualifies for a shared savings payment at § 425.605(h).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

We explained that this approach would recognize that SAHS billing activity has the potential to impact an ACO's savings and loss determination for both the performance year when the SAHS billing activity occurred and future performance years for which the affected year is a benchmark year. Making adjustments when the affected period represents a performance year or benchmark year is consistent with our approach for the exclusion of payment amounts for episodes of care for treatment of COVID–19 that we established in the May 8, 2020 COVID–19 IFC (85 FR 27577 through 27581).

The listed calculations reflect the same set of calculations that CMS adjusts for a beneficiary's episode of care for treatment of COVID–19, specified at § 425.611(c), as amended by the CY 2021 PFS final rule (85 FR 85044), the CY 2023 PFS final rule (87 FR 70241), and the CY 2024 PFS final rule (88 FR 79548), with a few exceptions. First, § 425.611(c) includes certain provisions that are not relevant for the proposed policy.[610] Second, the proposed policy includes calculations related to truncated national per capita expenditures used in determining the ACPT as described at § 425.660(b)(3) that are not included at § 425.611(c),[611] as well as references to other new or

[609] This assumes these same codes were not identified as having SAHS billing activity in CY 2024 or CY 2026 or later years.

[610] This includes provisions under §§ 425.600, 425.602, 425.603, 425.604, and 425.606 which are not relevant for the proposed policy because they are not applicable to PY 2024 or later performance years or for agreement periods where CY 2024 or later years are benchmark years. These provisions are relevant for the COVID–19 episode exclusion policy under § 425.611 because they are applicable to performance or benchmark years that overlap with the PHE for COVID–19.

[611] When establishing the ACPT in the CY 2023 PFS final rule, we noted that the first ACPT release would be published in 2024 for agreement periods beginning on January 1, 2024, and would provide a projected annualized growth rate (or rates) relative to the 2023 benchmark year (BY3). We noted further that to the extent that Medicare projections made at that time (2024) anticipated lingering effects from the COVID–19 pandemic then they would be reflected in the ACPT (see 87 FR 69894) and we opted not to amend § 425.611 to include adjustments of ACPT-related calculations. In the CY 2025 PFS proposed rule, we explained our belief that it is appropriate to propose making adjustments to ACPT-related calculations.

proposed calculations that do not rely on expenditures from a period of time overlapping the PHE for COVID–19 for the United States which was in effect from January 27, 2020, through May 11, 2023 (capping the proposed prepaid shared savings multiplier (§ 425.640(f)(2)(v)), calculating the proposed HEBA scaler (§ 425.662(b)(2)), and determining whether an ACO that does not meet its minimum savings requirement qualifies for a shared savings payment (§ 425.605(h)). We proposed to adjust calculations used for the ACPT to mitigate the impact of any SAHS billing activity identified for CY 2024 or subsequent calendar years. Specifically, in projecting growth rates at the start of an agreement period according to § 425.660, we would make an adjustment to the growth rates to mitigate the impact that any known SAHS billing activity have on spending growth projections.

We explained our belief that it is unlikely that fixed growth rates projected at the start of agreement periods beginning in earlier years may also need mitigation from a code displaying SAHS billing activity. For example, if CMS identifies a HCPCS or CPT code displaying SAHS billing activity in CY 2025, the projected growth rate from 2023 to 2025—which will be used to update the historical benchmark for PY 2025 financial reconciliation for ACOs that began an agreement period on January 1, 2024—would likely have assumed typical billing patterns for the code in CY 2025. Additionally, the projected growth rate from BY 2024 to PY 2025—which will be used to update the historical benchmark for PY 2025 financial reconciliation for ACOs that began an agreement period on January 1, 2025—would likely also have assumed typical billing patterns for the code in CY 2025 given the projections were finalized early in CY 2025.

However, we explained that if we determine a bias exists due to differences between adjustments to the projected growth rates for the ACPT and other Shared Savings Program calculations, we could rely on our current policy under § 425.652(b)(4)(ii) to reduce the weight of the ACPT in the three-way blend. We proposed that we would use our discretion to reduce the weight of the ACPT rather than recalculate the growth rates that had been projected at the start of agreement periods starting in earlier years, as we believe it is important to maintain the policy that the projected growth rates remain fixed for the ACO's agreement period. In the CY 2023 PFS final rule (refer to 87 FR 69886 through 69898) we finalized our proposal to establish the ACPT at the outset of an agreement period, based on one or more annualized growth rates. We explained that we will not adjust the ACPT due to external factors such as geographic price changes, efficiency discounts, or other retrospective updates occurring during the performance years throughout the agreement period. In response to commenters concern that CMS might adjust the ACPT downward during the agreement period, we stated that we will not adjust the ACPT projections over the course of the agreement period (87 FR 69897). However, we acknowledged that a variety of circumstances could cause actual expenditure trends to significantly deviate from projections. If unforeseen circumstances occur during an ACO's agreement period, we retained flexibility to reduce the impact of the prospectively determined ACPT portion of the three-way blend when necessary to mitigate unforeseen circumstances. We explained that we will determine, on an ad hoc basis, whether an unforeseen circumstance warrants adjustment of the weight placed on the ACPT component of the three-way blend by considering whether it has a material impact across the entire Shared Savings Program. If we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered.

To summarize, we proposed that when projecting growth rates used for the ACPT at the beginning of an agreement period, we would make an adjustment to mitigate the impact of any known SAHS billing activity on spending growth projections. Additionally, in accordance with § 425.660(a), CMS would not adjust the ACPT projections over the course of the agreement period to account for SAHS billing activity later identified. Rather, CMS may use its discretion to reduce the weight of the ACPT in the three-way blend in accordance with § 425.652(b)(4)(ii) if CMS determines that the SAHS billing activity represents an unforeseen circumstance that warrants a reduction to the weight.

The direction and magnitude of the impact of the proposed adjustments may vary by ACO. However, by making these adjustments, we would be helping to ensure that no ACOs are held accountable, and financially penalized for SAHS billing activity that was outside their direct control while also protecting the Trust Funds from other ACOs potentially receiving windfall gains.

For this proposal, we relied on our authority under section 1899(d)(1)(B)(ii) of the Act. Section 1899(d)(1)(B)(ii) of the Act authorizes the Secretary to adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate. Here, we proposed to adjust the benchmark in order to remove payments for HCPCS or CPT codes identified as exhibiting SAHS billing activity in CY 2024 or subsequent calendar years from the determination of benchmark expenditures when the calendar year serves as a benchmark year or from the determination of benchmark expenditures that will be used to reconcile the calendar year when it serves as a performance year.

We proposed to use our authority under section 1899(i)(3) of the Act to remove payment amounts for HCPCS or CPT codes identified as exhibiting SAHS billing activity in CY 2024 or subsequent calendar years from the following calculations: (1) performance year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, including determinations of loss sharing limits in the two-sided models of the BASIC track,[612] determinations of eligibility for advance investment payments,[613] and expanded criteria for certain low revenue ACOs participating in the BASIC track to qualify for shared savings in the event the ACO does not meet the MSR.[614] Section 1899(i)(3) of the Act requires that we determine that the alternative payment methodology adopted under that provision would improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. The adjustments we proposed therein, which would remove payment amounts for codes with identified SAHS billing activity from the specified Shared Savings Program calculations as proposed at § 425.672(c) and (e), would capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, failing to remove these payments would likely create highly variable savings and loss results for

[612] Refer to § 425.605(d)(1)(iii)(D), (d)(1)(iv)(D), and (d)(1)(v)(D) for BASIC track Levels C, D and E, respectively.

[613] Refer to § 425.630(b).

[614] Refer to § 425.605(h).

individual ACOs that happen to have over-representation or under-representation of SAHS billing activity for the selected codes among their assigned beneficiary populations.

As described in the Regulatory Impact Analysis of the CY 2025 PFS proposed rule (89 FR 62183 through 62184), excluding payment amounts for the selected codes from the specified calculations are not expected to result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, these adjustments to our calculations to remove payment amounts for these codes would promote continued integrity and fairness and improve the accuracy of Shared Savings Program financial calculations. As a result, we expect these policies would support ACOs continued participation in the Shared Savings Program and the program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and as specified in the Regulatory Impact Analysis of the CY 2025 PFS proposed rule (89 FR 62183 through 62184), we determined that adjusting certain Shared Savings Program calculations to remove payment amounts for selected codes, in the event we determine SAHS billing activity occurs in CY 2024 or subsequent calendar years, from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used for multiple purposes across the Shared Savings Program, meets the requirements for use of our authority under section 1899(i)(3) of the Act when incorporated into the existing other payment model we have established pursuant to that section.

In the CY 2025 PFS proposed rule (89 FR 61915), we explained that the changes we proposed in section III.G.7.d of the proposed rule would apply to address the impact of SAHS billing activity identified in CY 2024 or subsequent calendar years, and thus would apply to ACOs currently participating in PY 2024. Therefore, these changes to policies applicable for PY 2024 constitute retroactive rulemaking. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest.

We found that failing to apply the proposed changes retroactively to PY 2024 would be contrary to the public interest because it would unfairly punish Shared Savings Program ACOs by forcing them to unexpectedly assume a substantial magnitude of financial risk for costs outside of their control and not previously contemplated in the Shared Savings Program, undermining both the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner, in the event we determine SAHS billing activity impacts CY 2024. We did not fully contemplate the potential for SAHS billing activity outside of an ACO's control when the Shared Savings Program was established.[615] For this reason, the Shared Savings Program financial methodology and the procedures we have utilized in the past did not provide a means to adequately account for instances of SAHS billing activity outside of an ACO's control, and thereby the related financial risk is assumed entirely by ACOs. We view this outcome as particularly inequitable to ACOs because they have no direct means of controlling such costs. Unlike Medicare Advantage organizations, ACOs are not responsible for processing claims for their assigned beneficiaries and otherwise have no means of causing the denial of such claims. CMS thus cannot reasonably have expected ACOs to have intended to assume responsibility for all instances of SAHS billing activity outside of an ACO's control when they joined the Shared Savings Program. For these reasons, it would be contrary to the public interest for CMS to fail to apply a policy mitigating this issue retroactively.

We explained that we did not foresee the acute need to address SAHS billing activity impacting CY 2023, and the need for the related policy proposal for addressing SAHS billing activity in CY 2024 or subsequent calendar years, with sufficient time in advance of the start of PY 2024 to undertake notice and comment rulemaking earlier, and to avoid retroactive rulemaking. More specifically, we were only able to determine that the increase in billing on HCPCS codes A4352 and A4353 in CY 2023 represented SAHS billing activity after the calendar year ended. To identify that the billing activity in CY 2023 was significant, anomalous, and highly suspect, CMS reviewed actual billing levels after the calendar year closed and services furnished in CY 2023 had occurred and the billing level could then be compared to billing levels observed in prior calendar years.

We solicited comment on our proposal to apply the policy retroactively to PY 2024, including whether failing to apply the policy retroactively would be contrary to the public interest and how it would affect ACOs and their ability to participate in the Shared Savings Program.

We proposed a new § 425.672 to describe adjustments CMS could make to Shared Savings Program calculations to mitigate the impact of SAHS billing activity for CY 2024 or subsequent calendar years. We proposed that § 425.672(b) specify that CMS, at its sole discretion, may determine that the billing of specified HCPCS or CPT codes represents SAHS billing activity in calendar year 2024 or subsequent calendar years that warrants adjustment to calculations made under this part. We proposed under § 425.672(c) to specify the Shared Savings Program calculations for which CMS would exclude all Medicare Parts A and B FFS payment amounts for the specified claim types associated with a HCPCS or CPT code identified at § 425.672(b) when an adjustment to the calculation is appropriate in light of the SAHS billing activity. The calculations specified at § 425.672(c) include all potentially relevant financial calculation provisions, including those covering the financial benchmarking methodologies (including the proposed HEBA scaler at § 425.662(b)(2)) and those covering calculation of shared savings and losses. We proposed at § 425.672(d) that for calendar year 2024 or subsequent calendar years,[616] we would adjust Shared Savings Program calculations for SAHS billing activity identified at § 425.672(b) for the calendar year when it is either a performance year or a benchmark year, as well as the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark, when such a benchmark is used to reconcile the ACO

[615] *See, for example,* 76 FR 67948 through 67950. Such approaches were more focused on policies to support monitoring of ACO performance and ensuring program integrity.

[616] We note that by anchoring this policy on the calendar year, this proposed provision differs from many other program regulations that are applicable for a given performance year or for agreement periods beginning on a given date or within a given range. However, we believe this approach is appropriate for this policy as (1) we would adjust expenditures for the affected calendar year both when it is a performance year and when it is a benchmark year and (2) it ties the policy to the period for which the SAHS billing activity was identified much in the way the policy for COVID–19 episodes of care specified in § 425.611 is tied to the related public health emergency.

for a performance year adjusted for SAHS billing activity. We proposed to specify at § 425.672(e) that we would also make adjustments for any calendar year corresponding to BY3 in projecting per capita growth in Medicare Parts A and B FFS expenditures according to § 425.660(b)(1) for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years. Additionally, we proposed conforming revisions to §§ 425.601(a)(9) and 425.652(a)(9), as well as paragraphs at §§ 425.601(a)(9)(iv) and 425.652(a)(9)(ix) to include adjustments for SAHS billing activity as one of the reasons that CMS would adjust an ACO's benchmark during the term of its agreement period. We explained our belief that while we expect that the identification of SAHS billing activity that triggers these proposed policies will be rare, if finalized, these policies will allow us to proactively ensure the accuracy of program calculations and provide greater certainty for ACOs and the Trust Funds.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters addressed the proposed adjustments to Shared Savings Program calculations. One commenter expressed support for CMS to adjust calculations prior to sending ACOs initial determinations of their shared savings and losses, stating that timely removal of SAHS billing activity is essential for ACOs that rely on shared savings revenue to operate or to make additional investments in patient care.

Response: We thank the commenter for their support of the proposal to adjust Shared Savings Program calculations for SAHS billing activity in advance of issuing initial determinations of shared savings and losses. We expect this policy will limit requests to reopen initial determinations, thus reducing burden for ACOs and CMS.

Comment: Some commenters addressed the proposal to exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified. A few commenters characterized the approach to exclude all payment amounts for the codes that displayed SAHS billing activity as comprehensive, and that it is the most straightforward approach and will help to minimize complications in the calculations for the impacted years. Another commenter recommended that CMS only remove payment amounts billed by certain providers or suppliers, as identified by NPIs, to avoid any unintended consequences for some ACOs.

Response: We thank commenters for their support of the proposal to exclude all Medicare Part A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier. We proposed to not limit the exclusion to payment amounts on claims submitted by certain suppliers that may have individually displayed SAHS billing activity so as to protect the integrity of any potential investigations which may be ongoing at the time CMS makes a determination of SAHS billing activity.

Comment: Some commenters addressed the proposal to exclude payment amounts associated with identified codes for the calendar year serving as a performance year as well as from the historical benchmark used to reconcile that performance year. A few commenters urged CMS to remove all payment amounts for a code from expenditure calculations for a performance year if payment amounts for that code are removed from expenditure calculations for an ACO's benchmark year.

A couple commenters appeared to address CMS's approach for intermittent urinary catheters. One commenter urged CMS to eliminate ''SAHS billing activity from future agreements,'' citing an example to remove ''2023 SAHS'' from both benchmark and performance years for agreements starting 2024, 2025 and 2026. Another commenter stated their support for an approach that would exclude SAHS billing activity from historical benchmarks for ACOs starting new agreement periods in 2024, 2025 and 2026, as well as from any calculation used to determine revenue status or the repayment mechanism.

Response: We proposed to exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified. We explained that we would also adjust the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark that is used to reconcile the ACO for a performance year corresponding to the calendar year for which the SAHS billing activity was identified. When the calendar year with SAHS billing activity is (or becomes) a benchmark year, we proposed adjustments to calculations for the calendar year itself, and not for other years in the benchmark period, or the performance years that will be reconciled against those benchmarks. This approach avoids adjusting calculations more than is necessary to reasonably mitigate the impact of SAHS billing activity on an ACO's financial performance. Given the potential for the adjustments to have mixed impact on ACOs' updated benchmarks, this approach is the most equitable. An ACO's historical benchmark is calculated using the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period. Thus, removing payment amounts for a HCPCS or CPT code from the benchmark year affected by SAHS billing activity from ACO expenditures and national and regional trend and update factors strikes a balance between mitigating the impact of SAHS billing activity and not introducing unnecessary bias into calculations.

As part of our final policy, we decline to remove payment amounts for the codes from future performance years that are reconciled using a historical benchmark that includes a benchmark year with codes excluded. For example, since we identified SAHS billing activity in CY 2023, then in the future when performing financial reconciliation for PY 2025 for an ACO with benchmark years 2022 through 2024, we will exclude payment amounts for the selected codes from BY 2023 expenditures and not from BY 2022, BY 2024, and PY 2025 expenditures.

Comment: One commenter supported the proposal but urged CMS to consider an approach that would ensure no ACOs are negatively impacted. Another commenter stated that CMS should calculate ACO shared savings and losses twice, both before and after adjusting calculations to remove the payment amounts.

Response: We interpret both comments as suggesting that CMS perform two versions of Shared Savings Program calculations—one that makes adjustments for SAHS billing activity and one that does not—and then issuing initial determinations based on the version of the calculations that would result in an ACO maximizing their shared savings or minimizing their shared losses for the performance year.

We decline to adopt such an approach. The inclusion of SAHS billing activity would cause significantly inaccurate and inequitable payments and potential repayment obligations if not addressed. It would be inequitable for ACOs to be held accountable for SAHS billing activity that occurred among their assigned population in the performance year. It would also be inequitable to allow other ACOs whose assigned populations were less affected by SAHS billing to benefit from the inclusion of these expenditures in benchmark update factors. Such ACOs would receive an inflated updated benchmark as a result of SAHS billing activity affecting national or regional expenditures. Allowing either source of inequity or imposing an artificial limit on the impacts of excluding the SAHS billing activity would undermine the integrity, fairness and accuracy of Shared Savings Program calculations.

Comment: One commenter urged CMS to provide ACOs with information about the impact of removing payment amounts for the codes displaying SAHS billing activity on ACO expenditures as well as regional and national expenditures. Additionally, the commenter suggested that CMS start providing ACOs with regional component-level data ''to help quantify these sorts of issues in the future.''

Response: Consistent with the SAHS billing activity final rule (89 FR 79164) in order to promote transparency in calculations and address commenter's concerns, within program reports provided with a given performance year's financial reconciliation results, we will identify the codes and provide ACOs with the per capita amount of any codes, determined to be SAHS billing activity, removed from their performance year assigned beneficiary expenditures consistent with other spending categories. Medicare claim payment amounts for any codes determined to be SAHS billing activity will continue to be included in the monthly Part A, B and D Medicare CCLF files sent to ACOs and ACOs may use that data and information to identify potentially impacted beneficiaries and healthcare providers.

Comment: Some commenters made recommendations for mitigating the impact of SAHS billing activity on Innovation Center models or the Quality Payment Program. Most of these commenters requested that the Center for Medicare and Medicaid Innovation (CMS Innovation Center) perform similar adjustments to mitigate SAHS billing activity for the catheter codes in the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model. One commenter requested that the CMS Innovation Center exclude payment amounts for the catheter codes from the Bundled Payments for Care Improvement Advanced Model and the Comprehensive Care for Joint Replacement Model. Some commenters urged CMS to perform similar adjustments to expenditure calculations on Merit-Based Incentive Payment System cost measures.

Response: The commenters' suggestions are beyond the scope of this rulemaking, which addresses adjustments to Shared Savings Program calculations to mitigate the impact of SAHS billing activity in CY 2024 or subsequent year, however, we will share these comments with our colleagues in the Innovation Center and Quality Payment Program.

We received no public comments on the retroactive application of the proposed policy in the event we determine SAHS billing activity impacts CY 2024, and we are finalizing our proposal to apply the policy with retroactive effect for PY 2024.

After consideration of public comments, we are finalizing without modification our proposal with retroactive effect for PY 2024, to exclude all Medicare Parts A and B payment amounts associated with the identified codes on specified claim types submitted by any provider or supplier from expenditure and revenue calculations for the relevant calendar year for which the SAHS billing activity is identified, in the event that CMS identifies one or more HCPCS or CPT codes with SAHS billing activity in CY 2024 or a subsequent calendar year that warrant adjustment. Specifically, we are finalizing our proposal to add a new section of the regulation at § 425.672 to describe adjustments CMS will make to Shared Savings Program calculations to mitigate the impact of SAHS billing activity involving CY 2024 or subsequent calendar years. Section 425.672(b) describes that CMS, at its sole discretion, may determine that that the billing of one or more specified HCPCS or CPT codes represents SAHS billing activity for a calendar year that warrants adjustment to calculations. Section 425.672(c) specifies the Shared Savings Program calculations for which CMS will exclude all Medicare Parts A and B FFS payment amounts for the specified claim types associated with a HCPCS or CPT code and includes references to all relevant sections of the regulations in these provisions. In § 425.672(d), on the period of adjustment, we specify that CMS will adjust Shared Savings Program calculations for SAHS billing activity identified for CY 2024 or subsequent calendar years when the affected calendar year is either a performance year or a benchmark year, and from the 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark when such a benchmark is used to reconcile the ACO for a performance year adjusted for SAHS billing activity. We specify under § 425.672(e) that we will make adjustments for payments associated with the identified HCPCS or CPT codes for BY3 in projecting per capita growth in Parts A and B FFS expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years. Additionally, we are finalizing as proposed conforming revisions to §§425.601(a)(9) and 425.652(a)(9), as well as paragraphs at §§425.601(a)(9)(iv) and 425.652(a)(9)(ix), to include adjustments for SAHS billing activity as one of the reasons that CMS would adjust an ACO's benchmark during the term of its agreement period.

e. Solicited Comment on Establishing Higher Risk and Potential Reward under the ENHANCED Track

(1) Background

As described in the CY 2024 PFS final rule (88 FR 79223), we have considered a higher risk Shared Savings Program track under which the shared savings/loss rate would be somewhere between 80 percent and 100 percent (that is, a rate higher than that currently offered under the ENHANCED track) and that builds on the experience of the Next Generation ACO (NGACO) and ACO REACH Models. A higher risk track would offer ACOs increased incentives to generate savings, which would help improve care delivery by promoting innovations in the delivery of high-quality care that is more patient-centered. In other words, by increasing sharing rates for ACOs, ACOs will be better incentivized to develop innovations in the delivery of high-quality care and, therefore, improve the care they offer to their beneficiaries. A revised ENHANCED track could be implemented in accordance with section 1899(i)(3) of the Act, provided the Secretary determines that such other payment model enhances the quality and efficiency of items and services furnished under the Medicare program and does not result in program expenditures greater than those that would result under the statutory payment model.

In the CY 2024 PFS final rule (88 FR 79223), we summarized public comments received in response to our Request for Information (RFI) regarding a potential track within the Shared Savings Program with higher risk than the current ENHANCED track. For a full summary of the comments submitted in response to our comment solicitation, we refer readers to the relevant discussion in the CY 2024 PFS final rule (88 FR 79225 through 79227). Commenters were broadly supportive of such an approach and referenced existing policies under the ACO REACH Model, and the NGACO Model. Some commenters suggested features of such a track that would serve to encourage more participation in the Shared Savings Program and help ACOs deliver more person-centered care to beneficiaries in Traditional Medicare. These features included prospective payments, full sharing rates (a sharing rate of 100 percent, similar to the Global Risk Sharing Option in the ACO REACH Model) as well as a benchmark discount rate (a reduction of the benchmark by a predetermined percentage) to protect the Medicare Trust Funds.

A higher risk sharing arrangement could incentivize participating ACOs to improve performance in the program as they would receive a greater share of any gross savings. That improved performance may, in turn, result in reduced healthcare costs for Medicare and more effective, efficient care for beneficiaries. In addition, higher risk sharing could incentivize ACOs to develop new care delivery strategies to improve their financial performance, such as a focus on specialty care integration and reduced care fragmentation. Offering a higher risk sharing track may also help CMS reach our goal of having all beneficiaries in the traditional Medicare program in a care relationship with a healthcare provider who is accountable for the costs and quality of their care by 2030 by encouraging currently participating ACOs to continue participation in the Shared Savings Program, as well as encourage ACOs not participating in the Shared Savings Program to join as a result of increased potential reward.

A recent CBO report [617] proposed that higher sharing rates might incentivize providers to decrease spending as they would stand to gain a larger portion of the savings generated. While in the short term this might diminish CMS savings, the report postulates that this would increase participation in the Shared Savings Program and provide a means for CMS to manage long-term healthcare spending growth. The report also highlights the necessity of striking a delicate balance: devising financial incentives enticing enough for ACOs to participate actively in the Shared Savings Program, while ensuring that such participation leads to savings for the Medicare program.

In the CY 2025 PFS proposed rule (89 FR 61916 through 61921), we solicited comment on a participation option that would allow for higher risk and reward than currently available under the ENHANCED track. A participation option of this type would replace the existing ENHANCED track in order to avoid the self-selection issues that would occur if a higher risk track were to be included alongside the ENHANCED track. If both participation options were made available to ACOs, we have concerns that only the highest-performing ACOs would self-select into the higher of the two risk tracks. While we included an RFI on the topic in CY 2024 PFS rulemaking, we are concerned that ACOs did not have enough detailed information to appropriately weigh the tradeoffs associated with a higher risk/reward option than the current ENHANCED track, and that the additional information we have generated since then will allow ACOs and other interested parties to provide more forthright and helpful feedback. We sought public comments on the design of a higher risk option within the Shared Savings Program that could be enacted under our authority granted by section 1899(i)(3) of the Act and that would encourage ACOs to participate actively in the Shared Savings Program while ensuring that such participation leads to savings for the Medicare program.

(a) Current ENHANCED Track

Currently, under the Shared Savings Program, ACOs may enter participation agreements under the ENHANCED track. The ENHANCED track is a two-sided model that represents the highest level of risk and potential reward currently offered under the Shared Savings Program. The rules governing the participation options available to ACOs and the progression from lower to higher risk for ACOs entering the program are described in § 425.600 of the regulations. To qualify for a shared savings payment, an ACO must meet a MSR requirement, meet the quality performance standard or alternative quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under 42 CFR part 425, subpart B (§§ 425.100 through 425.118). For ACOs meeting the applicable quality performance standard established under § 425.512(a)(2) or (a)(5)(i) (for PY 2024 and subsequent performance years), the final shared savings rate is equal to the maximum sharing rate of 75 percent, or savings at a rate of 75 percent multiplied by the ACO's health equity adjusted quality performance score if the ACO meets the alternative quality performance standard at § 425.512(a)(5)(ii). CMS computes an ACO's shared savings payment by applying the final sharing rate to the ACO's savings on a first dollar basis (meaning the final sharing rate is applied to the ACO's full total savings amount), with the payment subject to a cap that is equal to 20 percent of the updated benchmark (§ 425.610(e)(2)).

ACOs that operate under a two-sided model and have losses that meet or exceed a MLR must share losses with the Medicare program (§ 425.100(c)). Once this MLR is met or exceeded, the ACO will share in losses at a rate determined according to the ACO's track/level of participation, up to a loss recoupment limit (also referred to as the loss sharing limit) (§ 425.605(d); § 425.610(f), (g)). In determining shared losses, ACOs participating in the ENHANCED track are subject to losses at a rate determined using a sliding scale based on ACO's health equity adjusted quality performance score, if the applicable quality performance standard established in § 425.512(a)(2) or (a)(5)(i) or the alternative quality performance standard at § 425.512(a)(5)(ii) is met; with minimum shared loss rate of 40 percent and maximum of 75 percent. If the ACO fails to meet the applicable quality performance standard established in § 425.512 or the alternative quality performance standard, the ACO is subject to 1st dollar losses at a rate of 75 percent (§ 425.610(f)(4)(ii)). Shared losses are subject to a cap that is equal to 15 percent of updated benchmark (§ 425.610(g)).

CMS adjusts historical benchmark expenditures by Medicare enrollment type by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's historical benchmark amount (referred to herein as the ''regional adjustment'') (§ 425.652(a)(8)). The weights used in the regional adjustment calculation are determined in accordance with§ 425.656(e) and are dependent on whether the ACO has lower or higher

[617] For more details, please refer to Congressional Budget Office (CBO), ''Medicare Accountable Care Organizations: Past Performance and Future Directions'', April 2024, available at *https://www.cbo.gov/system/files/2024-04/59879-Medicare-ACOs.pdf.*

spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment. The *first time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using either 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(1)(i)); or 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(1)(ii)). The *second time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using either the 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(2)(i)); or 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(2)(ii)). The *third time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment using the 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area (§ 425.656(e)(3)(i)); or the 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area (§ 425.656(e)(3)(ii)). The *fourth or subsequent time* that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark (§ 425.656(e)(4)). Among the ACOs participating in PY 2024, 78 percent of BASIC track ACOs (176 of 227) received a positive regional adjustment, whereas 95 percent (155 of 163) of ACOs in the ENHANCED track received a positive regional adjustment. A positive regional adjustment indicates that their expenditures were less than that of their regional service area. For ACOs receiving a positive regional adjustment, the average regional adjustment amount was 2.21 percent ($237) of historical benchmark expenditures.

As of January 1, 2024, 43 percent (207 of 480) Shared Savings Program ACOs are participating under the ENHANCED track. Under Shared Savings Program policies, all ACOs participating in a two-sided model can select a symmetrical MSR and MLR which applies for the duration of its agreement period (§ 425.605(b)(2); § 425.610(b)(1)). Among ACOs participating in the ENHANCED track for PY 2024, 61 percent (126 of 207) have selected an MSR/MLR of 0.5 percent or greater while 39 percent (81 of 207) have selected an MSR/MLR of 0.0 percent. Among ACOs that participated in the ENHANCED track for PY 2022, 38 percent (55 of 146) generated gross savings between zero and 5 percent of their updated benchmark expenditures, and 12 percent (17 of 146) generated gross savings of 10 percent or more of their benchmark expenditures.

(b) Other CMS Innovation Center Models

In the NGACO Model, NGACOs were offered the choice between two risk arrangements, partial risk or full risk. Under both arrangements, the NGACO was responsible for 100 percent of performance year expenditures for services rendered to the NGACO's aligned beneficiaries. Under the partial risk arrangement, the NGACO could receive or owe up to 80 percent of savings/losses, whereas under the full risk arrangement, the NGACO could receive or owe up to 100 percent of savings/losses. To mitigate the ACO's risk of large shared losses, as well as to protect the Medicare Trust Funds against paying out excessive shared savings, NGACOs were required to choose a cap on gross savings/losses. The cap, expressed as a percentage of the benchmark, ranged from 5 percent to 15 percent. The risk arrangement chosen by the NGACO (80 or 100 percent) was applied to gross savings or losses after the application of the cap. In PYs 1–3, a discount was applied to the NGACO's benchmark that was set at a standard 3 percent, with various adjustments, that allowed the final discount to vary from 0.5 percent to 4.5 percent. In PYs 4–6, a discount of 0.5 percent was applied to the benchmark under the partial risk arrangement, and a discount of 1.25 was applied to the benchmark under the full risk arrangement. The purpose of the discount was to increase the likelihood that any savings achieved by the NGACOs participating in the model would also result in savings for the Medicare Program. The NGACO Model evaluation found that while NGACOs reduced gross Medicare Parts A and B expenditures relative to a comparison group of similar fee-for-service Medicare beneficiaries in their markets, they did not generate savings to the Medicare Trust Funds. ACOs that elected a risk cap greater than 5 percent and participated in model population-based payment mechanisms achieved greater declines in spending, suggesting that the combination of risk and payment flows is impactful. Spending reductions grew larger almost every year, reflecting a combination of NGACOs' improvements in infrastructure and clinical processes, exit by poorer-performing NGACOs, and the COVID–19 pandemic. While the NGACO Model reduced spending in Medicare Parts A and B, CMS paid back these reductions in the form of shared savings payments to ACOs. These results highlight the need to balance the tradeoff between incentivizing participation in higher levels of risk and reward, in alternative payment models such as the Shared Savings Program and ACO models tested by the Innovation Center, and reducing the risk of loss to the Medicare Trust Funds.

Under the ACO REACH Model, REACH ACOs are offered the choice of participating under the Global or the Professional Risk Sharing Options. As in the NGACO Model, under both risk sharing options, the REACH ACO is responsible for 100 percent of performance year expenditures for services rendered to aligned beneficiaries. Because ACOs electing the Global Risk Sharing Option retain up to 100 percent of the savings/losses on all savings up to 25 percent of their benchmark, with reduced sharing rates for savings exceeding 25 percent of their benchmark, a discount is applied to the benchmark to ensure savings are also generated for CMS. For ACOs in the Global Risk Sharing Option, the

benchmark is reduced by a fixed percentage based on the performance year.[618] The discount rate for PYs 2021 and 2022 was 2 percent, for PYs 2023 and 2024 is 3 percent, and for PYs 2025 and 2026 will be above 3.5 percent. The benchmark for ACOs participating in the Professional Risk Sharing Option does not include this discount, and these ACOs are only eligible to retain 50 percent of savings or owe 50 percent of any losses.

Preliminary evaluation results of the first 2 performance years of the Global and Professional Direct Contracting Model, before its transition to the ACO REACH Model, suggest that participating ACOs had mixed results in gross spending but consistent, significant increases in net spending relative to a comparison group of similar FFS Medicare beneficiaries in their markets, which included beneficiaries assigned to ACOs participating in the Shared Savings Program. Standard ACOs, comprised of organizations that generally have experience serving Medicare FFS beneficiaries, increased gross spending. Standard ACOs also reduced acute care spending and utilization but comparison providers had larger reductions in acute care spending and utilization. Increased spending among Standard ACOs was concentrated among the integrated delivery system/hospital system ACOs in the model. High Needs ACOs that serve Medicare FFS beneficiaries with complex needs, including dually eligible beneficiaries, decreased gross spending. High Needs ACOs comprised of organizations that have not traditionally provided services to Medicare FFS beneficiaries favorably reduced acute and post-acute care utilization and spending. New Entrant ACOs had declines in gross spending but these declines were similar to those of providers within their same markets. Standard and New Entrant ACOs showed statistically significant improvement on at least one quality measure. These interim evaluation results are mixed, and additional analyses and years of experience with the Model will inform which features of ACO REACH could drive continued growth and innovation in the Shared Savings Program and the focus of future Innovation Center ACO models.

[618] For more details, refer to CMS, ACO Realizing Equity, Access, and Community Health (REACH) Model, PY2023 Financial Settlement Overview, available at *https://innovation.cms.gov/media/document/aco-reach-py2023-fncl-settlement* (see Table 4: Schedule of Discounts by Risk Arrangement).

(2) Considerations for Incorporating Higher Risk and Potential Reward Under the ENHANCED Track

As we explained in the CY 2024 PFS final rule (88 FR 79223 through 79225), when considering a higher risk track, CMS would need to balance the incentives for ACOs to transition to higher levels of risk and potential reward and increase ACO participation in the Shared Savings Program and in two-sided risk tracks, all while ensuring sufficient financial safeguards to protect against inappropriately large shared losses for ACOs coordinating and improving quality of care for high-cost beneficiaries. Considerations must also be directed towards safeguarding the Medicare Trust Funds and ensuring that CMS satisfies any statutory requirements under section 1899(i)(3) of the Act.

In the CY 2025 PFS proposed rule (89 FR 61918 through 61919), we explained that a revised ENHANCED track could be implemented in accordance with section 1899(i)(3) of the Act, provided the Secretary determines that such other payment model enhances the quality and efficiency of items and services furnished under the Medicare program and does not result in program expenditures greater than those that would result under the statutory payment model. We also stated that increasing the sharing rate in the ENHANCED track may need to be accompanied by other modifications to prevent spending from increasing and possibly jeopardizing compliance with section 1899(i)(3) of the Act. One factor we stated we would consider is selective participation with regard to which ACOs would choose to participate in a higher risk track, if offered. For example, Shared Savings Program ACOs that have a history of high levels of earned shared savings or have received a favorable high regional adjustment to their benchmark may be more likely than other ACOs to switch to the higher risk track upon renewing or early renewing their participation in the program so they can receive additional benefit from the higher levels of potential reward offered in a higher risk track. This could result in increased spending on the part of CMS which may jeopardize compliance with section 1899(i)(3) of the Act. If a higher risk track were to be offered in the Shared Savings Program in the future, we stated CMS would consider replacing the existing ENHANCED track in order to prevent further selective participation and maintain the balance between increased participation and compliance with applicable statutory requirements.

In the CY 2025 PFS proposed rule (89 FR 61919), we solicited comment on the following potential features of a revised ENHANCED track:

(a) Benchmark Discount Rate

Both the NGACO Model and the Global Risk Sharing Option of the ACO REACH Model feature a discount rate that is applied to benchmarks. The discount rate serves to protect the Medicare Trust Funds by reducing benchmarks and thereby improves the likelihood of achieving savings for the Medicare program for risk tracks that can feature up to 100 percent shared savings rates, such as the Global Risk Sharing Option in the ACO REACH Model. A discount would be applied to an ACO's updated historical benchmark before gross savings/losses are calculated, which increases the likelihood of savings for CMS and the Medicare program. If an ACO were to participate in a potential higher risk track and potentially share in 100 percent of gross savings, this discount would serve as the primary means for CMS to capture savings from ACOs participating in this option, as in the absence of a discount any and all gross savings would go to ACOs in the form of a shared savings payment. For example, consider an ACO with an updated benchmark of $10,000 and mean per-capita performance year expenditures of $9,500. Applying a discount rate of 1 percent to the benchmark would reduce the ACO's benchmark to $9,900. Gross savings would then be calculated based on the discounted benchmark, and the ACO's shared saving rate would be applied to the savings, provided these savings met or exceeded the ACO's selected MSR.

A discount to the benchmark could also include a guardrail policy similar to the guardrail implemented in the three-way blended update factor that was finalized in the CY 2023 PFS final rule (87 FR 69881). Under such an approach, if an ACO were to be liable for shared losses after discounting the benchmark, then gross savings or losses would be recalculated using a benchmark without the discount. However, if the ACO were to generate gross savings in excess of their MSR under the benchmark without the discount, they would still not be considered eligible to share in savings. This approach would help ensure that CMS shares in any savings generated by ACOs participating in a potential revised ENHANCED track while also not increasing downside risk for ACOs that may be liable for shared losses.

In the CY 2025 PFS proposed rule (89 FR 61919), we solicited comment on what rate would be appropriate for a

discount to the benchmark that would protect the Medicare Trust Funds while providing an adequate incentive for ACOs to participate in a potential revised ENHANCED track. We also solicited comment on whether the model features described in following subsections might replace a discount to the benchmark while balancing financial incentives for ACOs and risk to CMS. Additionally, we also solicited comments from interested parties, including ACOs, on the discount to the benchmark and what level of discount would be acceptable to ACOs participating in the Shared Savings Program, as well as what would be considered too high of a discount.

(b) Tapered Sharing Arrangements

Currently in the ENHANCED track, ACOs can receive a shared savings payment of up to 20 percent of their updated benchmark (once the MSR is met or exceeded) (§ 425.610(e)(2)) or be liable for losses not to exceed 15 percent of their updated benchmark (once the MLR is met or exceeded) (§ 425.610(g)). Alternatively, CMS could set up marginal savings bands or risk corridors under which shared savings or losses rates would vary with the amount of gross savings or losses. As gross savings/losses increase, the ACO will retain a progressively smaller portion of the total savings or will be responsible for a progressively smaller portion of the total losses. For example, consider hypothetical marginal savings bands shown in Table 50. Under this arrangement, an ACO would share in all savings up to 10 percent of their updated benchmark at a rate of 100 percent. For savings between 10 to 15 percent, the ACO would share in 60 percent of savings and CMS would retain the remaining 40 percent. For savings between 15 to 20 percent, the ACO would share in 40 percent of savings and CMS would retain the remaining 60 percent. In case of losses, ACOs would be responsible for 50–100 percent of the losses, depending on the ACO's quality performance score.

TABLE 50: Hypothetical Marginal Shared Savings Bands

Gross savings as % of benchmark	*Shared Savings/Loss Rate*[1]
0-10%	100%
10-15%	60%
15-20%	40%
>20%	0%
Losses	50% - 100%[2]

[1] Percentage of savings or losses retained by the ACO.

[2] Shared Loss Rate would depend on an ACO's quality performance, similar to § 425.610(f)(4).

In the CY 2025 PFS proposed rule (89 FR 61919 and 61920), we solicited comment on whether the hypothetical marginal shared savings bands shown in Table 50 represent an appropriate tapering schedule that would provide sufficient incentive for an ACO to participate in a potential revised ENHANCED track, as well as whether the tapering schedule should begin with lower shared savings rates and feature increasing rates as an ACO generates greater amounts of savings. We also solicited comment on whether a potential tapering schedule should be symmetrical with respect to shared loss rates. Finally, we solicited comment on whether marginal shared savings bands provide the right incentives to ACOs relative to the fixed savings rate in the current ENHANCED track.

(c) MSR/MLR

As we explained in the CY 2025 PFS proposed rule (89 FR 61920), we are considering the option for all ACOs under a revised ENHANCED track to be subject to a symmetric MSR/MLR of 0 percent. This would increase many ACOs' exposure to both positive savings and negative risk. While this approach would guarantee that any ACO generating savings would share in those savings (provided they meet the quality performance standard established under § 425.512 and otherwise maintain their eligibility to participate in the Shared Savings Program), ACOs with performance year expenditures greater than their historical benchmark would be liable for those losses due to the 0 percent MLR. We solicited comment on whether a potential revised ENHANCED track should retain the existing symmetric MSR/MLR selection options that currently exist for ACOs in a two-sided risk model under § 425.610(b)(1).

(d) Cap On Regional Adjustment Weight

We solicited comment on adjusting the weights used to calculate the regional adjustment amounts under § 425.656(e) for ACOs in the revised ENHANCED track. This may take the form of applying a cap of 35 percent to all the weights used to calculate regional adjustment amounts. This would impact any ACOs in a second or subsequent agreement period subject to a regional adjustment if their historical benchmark spending is lower than their regional service area. If the cap were to apply to an ACO with lower spending than their regional service area, then this would result in a decreased regional adjustment to that ACO's historical benchmark. Overall, this feature would reduce the cost to CMS associated with high regional adjustments by reducing an ACO's historical benchmark in the event that an ACO in a second or subsequent agreement period receives a large positive regional adjustment, which may decrease the need for higher benchmark discount rates or lower tapered shared savings rates that are less favorable to ACOs and limit incentives for ACOs to transition from the BASIC track to the revised ENHANCED track. This feature may also increase the relative impact of the prior savings adjustment and the health equity benchmark adjustment proposed in section III.G.7.b. of the CY 2025 PFS proposed rule. We solicited comment on whether further reductions to or the removal of the regional adjustment to the historical benchmark would be appropriate as part of a potential revised ENHANCED track. We also solicited comment on whether maintaining the regional adjustment in its current State would warrant further changes to the revised ENHANCED track features described above, including, but not limited to, a discount to the benchmark or lower tapered shared savings rates.

(e) Payment Mechanisms

We solicited comments on alternative payment mechanisms the Innovation Center has tested and their ability to help transform care delivery and improve health outcomes for ACOs participating in the Shared Savings Program. These payment mechanisms test whether alternative payment flows (that is, those other than fee for service reimbursement) facilitate better investment in infrastructure and care coordination and encourage innovative downstream payment arrangements that can improve health outcomes for Medicare beneficiaries. The alternative payment mechanisms on which we solicited comments are described below:

- *Infrastructure Payments:* Under these arrangements, CMS makes a payment to the ACO, in addition to FFS reimbursement to the providers and suppliers participating in the ACO, that is unrelated to claims. Infrastructure payments have been distributed either as a lump sum or per beneficiary per month payments. Infrastructure payments are recouped during the payment reconciliation process.
- *Population-Based Payment, All-Inclusive Population-Based Payment, or Advance Payment Option:* In this arrangement, CMS provides a percentage of FFS reimbursement to the ACO in the form of a monthly payment to support ongoing ACO activities and provide the ACO flexibility in the types of arrangements it enters into with provider/suppliers. The ACO and providers with whom it has a written business arrangement determine percentage reductions to the base FFS payments to the providers interested in this payment arrangement. Providers participating in this option have their FFS payments reduced by the agreed upon percentage, which range from 1–100 percent. CMS pays the projected total annual amount taken out of the base FFS rates to the ACO in monthly payments. At the end of each performance year, the amount of payment paid to ACOs participating in this type of payment option is reconciled against the reductions actually made to claims payments to providers participating in these arrangements, linking the amount of these payments directly to utilization and FFS payment.
- *Capitation:* The ACO REACH Model [619] tests two capitation payment options—Primary Care Capitation and Total Care Capitation.

The Primary Care Capitation Payment is the payment for primary care services provided to aligned REACH beneficiaries by all Participant Providers and those Preferred Providers who have selected Primary Care Capitation Payment. In Primary Care Capitation, a per beneficiary, per month capitated payment is provided to an ACO for its aligned beneficiaries for the primary care services provided by the ACO's Participant Providers and its Preferred Providers who have opted to participate in Primary Care Capitation Payment. The Primary Care Capitation payment amount is generally equal to seven percent of the estimated total cost of care for the ACO's aligned population (that is, the risk adjusted, trended, and regionally blended benchmark).

The Primary Care Capitation payment includes two components, Base Primary Care Capitation and Enhanced Primary Care Capitation. The Base Primary Care Capitation amount is intended to cover primary care services furnished to aligned beneficiaries by Participant Providers and those Preferred Providers who have agreed to participate in Primary Care Capitation Payment that are thus subject to fee reductions under Primary Care Capitation Payment. The Enhanced Primary Care Capitation amount, which will be recouped by CMS in full during final financial settlement, is intended to enable ACOs to make upfront investments in infrastructure, technology, tools, and resources to support increased access to primary care, provision of care, and care coordination. The Primary Care Capitation Payment is expected to encourage greater flexibility in payment and innovative primary care service delivery as a means of improving the quality and cost effectiveness of care overall.

In Total Care Capitation, a per-beneficiary, per month capitated payment is provided to an ACO for all Medicare Part A and Part B services provided to aligned beneficiaries by the ACO's Participant Providers and its Preferred Providers who have opted to participate in Total Care Capitation payment. The Total Care Capitation payment amount reflects the estimated total cost of care for the ACO's aligned population (that is, the risk adjusted, trended, and regionally blended benchmark) and is only available to ACOs participating in the Global risk option. Participant Providers and those Preferred Providers that have elected to participate in the ACO's selected capitation payment mechanism continue to submit claims to CMS for services provided to aligned beneficiaries. The CMS FFS claims processing system reduces claims payment amounts according to the payment reduction arrangements with their providers. More details on ACO REACH Model's capitation payment mechanisms are available here: *https://www.cms.gov/files/document/aco-reach-py24-financial-ops-capitation-and-payment-mechanisms.pdf.*

Additionally, we solicited feedback on the following questions related to implementation of a revised ENHANCED track with higher risk and potential reward, as well as comments that could inform changes to the Shared Savings Program and future Innovation Center ACO models:

1. What would the option of a revised ENHANCED track allow an ACO to do that they are unable to do currently?
2. How would higher downside risk impact an ACO's care delivery strategies, including advanced primary care, behavioral health, specialty integration, and integration with community-based organizations to improve health outcomes or advance health equity?
3. How does higher downside risk impact an ACO's downstream provider arrangements to further advance incentives to reduce delivery of low value services and the total cost of care, and to increase savings performance?
4. What types of organizations, including but not limited to ACOs and providers, are interested in a higher risk and reward option in the Shared Savings Program?
5. What additional flexibilities or features (for example, benefit enhancements, advance payments, capitation payments, etc.) would ACOs in a revised ENHANCED track with higher risk and potential reward want CMS to offer to help them be successful in improving the quality of care and reducing costs?
6. How should a revised ENHANCED track with higher risk and potential reward also require additional accountability for quality? Should ACOs in this revised track be required to report all payer/all patient quality measures?
7. Should a revised ENHANCED track with higher risk and potential reward require ACOs with earned shared savings to share savings with beneficiaries or spend a flat dollar amount or a certain percentage on beneficiaries in the form of items or services not covered by original Medicare (for example, meals, dental,

[619] Refer to the ACO REACH Model Request for Applications, available at *https://www.cms.gov/priorities/innovation/media/document/aco-reach-rfa*, and the ACO REACH Model PY2024 Participant and Preferred Provider Management Guide (August 2023; v3), previously available at *https://www.cms.gov/files/document/aco-reach-py24-part-pref-provider-mgmt-guide.pdf*.

vision, hearing, or Part B cost-sharing reductions)?

8. How should CMS consider the discount, sharing rate, and risk corridors or marginal savings bands in the design of a higher risk option that can realize savings for Medicare? Are there special considerations that CMS should bear in mind when thinking through such features for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?

9. How might we improve beneficiary assignment and are there different considerations for different types of ACOs (for example, low revenue, high revenue, health system-based, safety net, etc.)?

10. What other features should CMS consider in designing financial benchmarks that balance prospectivity and accuracy, and that can lead to savings for both ACOs and Medicare? How might administratively set benchmarks achieve these goals and what considerations should we bear in mind if we test administrative benchmarking?

11. We are interested in ways to increase participation by healthcare providers and suppliers in the Shared Savings Program and future Innovation Center ACO models, including how an ACO model requiring provider participation or stronger participation incentives might be designed.

The following is a summary of the comments we received in response to the comment solicitation on establishing higher risk and potential reward under the ENHANCED track and our response.

Comment: The majority of commenters supported a higher risk track option in the Shared Savings Program. Commenters offered a variety of reasons for their support of a higher risk track, including that it would help encourage and sustain ACO participation in the Shared Savings Program and provide increased financial incentives that would allow ACOs to ''maintain or increase their level of investment in patient care and providers'' and ''increase staffing to support care management or establish initiatives for high-risk patients,'' and could serve as a track for ACO REACH Model participants to transition into after the ACO REACH Model expires at the end of 2026. Multiple commenters suggested that CMS use the experience and design features of the ACO REACH Model and the NGACO Model when introducing a higher risk track in the Shared Savings Program. Specifically, commenters pointed to the Part B cost sharing support, Nurse Practitioner Services Benefit Enhancement, and other benefit enhancements as features they would like to see in a potential higher risk track. Commenters also requested that a higher risk track be optional, not mandatory, for ACOs participating in the Shared Savings Program.

Nearly all commenters were opposed to a higher risk track replacing the existing ENHANCED track. Commenters supported a higher risk track being offered alongside the current ENHANCED track and other existing participation options. Commenters stated their belief that the current ENHANCED track is a stable and popular participation option and if CMS were to replace it with a revised higher risk track, then this may be counterproductive to ACOs taking on more risk. Specifically, commenters stated that some ACOs may be unwilling or unable to take on the higher risk associated with a higher risk track and would either participate in Level E of the BASIC track or voluntarily terminate their participation in the Shared Savings Program.

Many commenters provided feedback on the specific model design features that we described in the CY 2025 PFS proposed rule. Several commenters suggested that ACOs should have the option of choosing between a 100 percent sharing rate with a discount to the benchmark or a sharing rate between 85–90 percent and no discount to the benchmark. Several commenters said that a reasonable benchmark discount rate of 1.5 percent to 2 percent would be acceptable and that a discount rate of 3 percent would be prohibitively large. Several commenters were opposed to a benchmark discount rate entirely. Some commenters preferred tapered sharing rates over the adoption of a discount to the benchmark. Several commenters suggested that a higher risk track should allow ACOs to continue enjoying the flexibility they currently have when selecting their symmetrical MSR/MLR. One commenter argued that requiring ACOs participating in a higher risk track to spend a portion of their earned shared savings payments on beneficiaries would cause them to incur prohibitively large costs in connection with complying with Shared Savings Program monitoring and reporting requirements.

Several commenters requested that ACOs be offered the option of capitated payments, infrastructure payments, advance payments, or population-based payments. Commenters argued that these payments would mitigate the delay that ACOs face in receiving earned shared savings payments for a PY, and that access to such alternative payment mechanisms would provide ACOs the flexibility they need to ''ease provider burden and provide more consistent cash flow''.

One commenter suggested that CMS provide ACOs with a participation option similar to ACO REACH's High Needs Track. They argued that such a track would provide a bridge for current ACO REACH participants to join the Shared Savings Program after the ACO REACH Model expires at the end of 2026 and better support current Shared Savings Program ACOs that serve high needs or other underserved beneficiary populations.

Commenters expressed concerns about various Shared Savings Program policies that were not specific to a potential higher risk track. Several commenters expressed concern about the negative impact of the ratchet effect on long-term participation in the Shared Savings Program. Several commenters suggested that CMS allow beneficiaries to voluntarily align to ACOs under § 425.402(e) in writing (rather than only electronically), as is done in the ACO REACH Model. Several commenters also suggested that CMS allow Shared Savings Program participation at the NPI level rather than exclusively at the TIN level. One commenter expressed their opposition to the regional adjustment to an ACO's historical benchmark and argued that it ''maintains undesirable participation incentives and distorts the calculation of the prior-savings adjustment''.

Response: We appreciate the feedback we received in response to this comment solicitation. We will consider this information to inform future rulemaking.

f. Technical Change for Consistency in Financial Calculations

(1) Background

For the benchmarking methodology applicable to agreement periods beginning on January 1, 2024, and in subsequent years, we cap ACO prospective hierarchical condition category (HCC) risk score growth between BY3 and the performance year (as finalized in the CY 2023 PFS final rule, refer to 87 FR 69932 through 69946), as well as prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year (as finalized in the CY 2024 PFS final rule, refer to 88 FR 79174 through 79185).The policy to cap ACO prospective HCC risk score growth between BY3 and the performance year relied on our authority granted by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and such other factors as

the Secretary determines appropriate (see 87 FR 69934). The policy to cap prospective HCC risk score growth in an ACO's regional service area between BY3 and the performance year by applying an adjustment factor in calculating the regional component of the three-way blended benchmark update factor required use of our statutory authority under section 1899(i)(3) of the Act (see 88 FR 79182 and 79183).

The current regulations describe how we cap ACO prospective HCC risk score growth at §§ 425.605(a)(1) and 425.610(a)(2). As specified, positive adjustments in prospective HCC risk scores are subject to a cap equal to the ACO's aggregate growth in demographic risk scores between BY3 and the performance year (positive or negative) plus 3 percentage points. The cap applies to prospective HCC risk score growth for any Medicare enrollment type only if the ACO's aggregate growth in prospective HCC risk scores between BY3 and the performance year across all of the Medicare enrollment type exceeds this cap. Growth in an ACO's risk scores by enrollment type is expressed as the ratio of the ACO's performance year risk score for that enrollment type to the ACO's BY3 risk score for that enrollment type. The aggregate growth in demographic and prospective HCC risk scores risk scores is calculated by taking a weighted average of the risk ratio for demographic risk scores or prospective HCC risk scores, as applicable, for each Medicare enrollment type using specified weights.

The current regulations further describe how we cap prospective HCC risk score growth in the ACO's regional service area at § 425.655. As specified, CMS determines aggregate growth in regional prospective HCC and demographic risk scores by calculating growth in prospective HCC and demographic risk scores between BY3 and the performance year for each Medicare enrollment type, where growth in an ACO's regional risk score by enrollment type is expressed as the ratio of the performance year regional risk score for a Medicare enrollment type to the BY3 regional risk score for that enrollment type. We then calculate aggregate risk score growth by taking a weighted average of the regional prospective HCC or demographic risk ratios, as applicable, across the four Medicare enrollment types, using specified weights. We next determine the cap on regional risk score growth (refer to § 425.655(e)),[620] and then determine if the ACO's regional risk score growth is subject to a cap and apply a regional risk score growth cap adjustment factor for each Medicare enrollment type, as applicable (refer to § 425.655(f)).[621]

When describing how we will cap prospective HCC risk score growth in the ACO's regional service area in the CY 2024 PFS final rule, we included a footnote (see 88 FR 79178) that indicated that the weights to be used to compute aggregate risk score growth for this calculation are the same as the weights to be used when calculating weighted average ACO prospective HCC and demographic risk ratios under the risk adjustment methodology for capping ACO risk score growth adopted in the CY 2023 PFS final rule and codified in §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C). That is, it was our intention to use the same weights in both the regional risk score growth cap calculation and the ACO risk score growth cap calculation. However, in codifying the methodology for the regional risk score growth cap in the new section of the regulations, § 425.655, we inadvertently introduced a discrepancy.

In §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C), where we codified how we will calculate aggregate risk score growth used in determining the cap to apply to ACO prospective HCC risk score growth, we describe the weight applied to the growth in demographic or prospective HCC risk scores for each Medicare enrollment type as equal to the product of the *historical benchmark expenditures* for that enrollment type and the performance year person years for that enrollment type. In § 425.655(d)(2), where we codified how we will calculate aggregate risk score growth used in determining the cap to apply to regional prospective HCC risks score growth, we describe the weight applied to the growth in demographic or prospective HCC risk scores for each Medicare enrollment type as equal to product of the ACO's *regionally adjusted historical benchmark expenditures* (emphasis added) for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

The regulations at §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C) provide that we will use the ACO's historical benchmark expenditures in calculating the weights used to cap ACO risk score growth. By contrast, the regulations at § 425.655(d)(2) provide that we will use an ACO's regionally adjusted historical expenditures in calculating the weights used in the calculation of regional risk score growth cap. In the CY 2025 PFS proposed rule (89 FR 61922), we explained that, as written, the regulations at § 425.655(d)(2) is inconsistent with the language used at §§ 425.605(a)(1)(ii)(C) and 425.610(a)(2)(ii)(C) despite the fact that we indicated in the CY 2024 PFS final rule that we would use the same weights in both calculations. Additionally, it is unclear how we would apply the calculation described at § 425.655(d)(2) in practice. As we described in the CY 2025 PFS proposed rule, for agreement periods beginning on January 1, 2024, and in subsequent years, in computing an ACO's historical benchmark, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.400(a)(4)(ii). An ACO's historical benchmark may then be subject to a regional adjustment (refer to § 425.656), a prior savings adjustment (refer to § 425.658), or no adjustment (refer to § 425.652(a)(8) and (c)). This methodology, based on policies finalized in the CY 2023 and CY 2024 PFS final rules, under which an ACO may receive a prior savings adjustment, a regional adjustment, and or no adjustment at all, differs from the methodology that was in effect for ACOs in an agreement period beginning on or after July 1, 2019, but before January 1, 2024, under which all ACO historical benchmarks incorporated a regional adjustment (see § 425.601). Furthermore, in section III.G.7.b. of the CY 2025 PFS proposed rule (89 FR 61885 through 61892), we proposed to add a third type of adjustment that

[620] To determine the cap on regional risk score growth, we calculate the non-market share adjusted cap on the ACO's regional risk score growth as the sum of the aggregate growth in regional demographic risk scores and 3 percentage points, then adjust the cap to reflect the ACO's aggregate market share.

[621] If the aggregate regional prospective HCC risk score growth does not exceed the cap on regional risk score growth, the ACO's regional risk score growth is not subject to the cap. For these ACOs we set the risk score growth cap adjustment factor equal to 1 for each Medicare enrollment type. If the aggregate regional prospective HCC risk score growth exceeds the market share adjusted cap, the ACO's regional risk score growth is subject to the cap. For these ACOs we next determine whether the cap on regional risk score growth applies for each Medicare enrollment type.

could be applied to an ACO's historical benchmark, the health equity benchmark adjustment. We explained that if the health equity benchmark adjustment was to be finalized as proposed, an ACO may receive a regional adjustment, a prior savings adjustment, a health equity benchmark adjustment, or no adjustment to its historical benchmark.

(2) Revisions

As discussed in the CY 2025 PFS proposed ruled (89 FR 61923), it was our intention at the time of the CY 2024 PFS rulemaking (see 88 FR 79178) to use the same weights to calculate the cap for prospective HCC risk score growth in an ACO's regional service area as the weights used to calculate the cap on prospective HCC risk score growth for the ACO. We explained our belief that the same weights should apply to both calculations. However, the regulation text language is not currently aligned among the relevant provisions or with the preamble discussion and may also create confusion with respect to how CMS will compute the weights used in setting the caps on ACO and regional prospective HCC risk score growth, given that some ACOs will receive a regional adjustment to their benchmarks, some will receive a prior savings or, if finalized, a health equity benchmark adjustment, and some will receive no adjustment at all.

To address these issues, we proposed technical changes to the regulation text at §§ 425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2) to align the language describing the calculation of the weights that will be used to compute aggregate risk score growth across the three provisions and to clarify that the weight applied to the growth in ACO and regional risk scores for each Medicare enrollment type, respectively, would be equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type. That is, we would use the ACO's historical benchmark expenditures that would have already been adjusted to reflect a prior savings adjustment, a regional adjustment, a health equity benchmark adjustment, if finalized, or no adjustment. Aligning the description of the weight calculation across the three provisions would address the discrepancy that exists between the current regulation text and the preamble discussion in the CY 2024 PFS final rule. Additionally, providing additional detail in the description of the weight calculation, namely by indicating that we will use an ACO's historical benchmark expenditures adjusted in accordance with § 425.652(a)(8), clarifies how we will operationalize the calculation which we believe is important, especially given the proposed health equity benchmark adjustment, which, if finalized, would add greater complexity to this historical benchmark calculation.

The technical changes that we proposed in section III.G.7.f. of the CY 2025 PFS proposed rule relate to benchmark calculations for ACOs in agreement periods beginning on or after January 1, 2024. We explained that although we will not implement the proposed methodologies for the first time until summer 2025 when we reconcile PY 2024, these policies, if finalized, would constitute retroactive rulemaking because they are the standards under which we will score ACOs that are currently participating in agreement periods that began on January 1, 2024, for PY 2024. Section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Here, we proposed a technical change that would align the regulation text with our stated intention as described in previous rulemaking. The current regulation text, in combination with related discussion in the CY 2024 PFS final rule, fails to provide sufficient clarity with regard to how CMS will calculate the weights used to calculate aggregate ACO or regional risk score growth. While the discussion in the CY 2024 PFS final rule indicates that the same weights should be use in both calculations, the related regulation text does not make this clear and, furthermore, could raise questions for how CMS will perform calculations given that not all ACO historical benchmarks will include a regional adjustment. Failure to apply the proposed changes to our regulations at §§ 425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2) retroactively would be contrary to the public interest because it creates unintended ambiguity in the standard CMS will use when calculating risk score growth. Such ambiguity may make it difficult for ACOs and other interested parties to understand how CMS will perform these calculations or be interpreted to suggest that CMS would calculate risk score growth in a different manner, which was not the agency's intention.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters addressing the proposal were supportive of this change as it updates benchmarking calculations to reflect new policies, explaining their understanding that the proposal clarifies the use of an ACO's benchmark that has been adjusted for prior savings, the HEBA, and the regional adjustment to align the three percent cap on HCC risk score growth with that of the ACO's region. The commenters also noted that if finalized this change would be reflected in PY 2024 financial reconciliation calculations.

Response: We thank commenters for their support of the proposed technical change and the retroactive applicability of said change.

After consideration of public comments, we are finalizing as proposed technical changes to the regulation text at §§ 425.605(a)(1)(ii)(C), 425.610(a)(2)(ii)(C), and 425.655(d)(2) to align the language describing the calculation of the weights that will be used to compute aggregate risk score growth across the three provisions and to clarify that the weight applied to the growth in ACO and regional risk scores for each Medicare enrollment type, respectively, would be equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

8. Beneficiary Notification Requirements

a. Modifying the Requirements for When ACOs Must Provide the Beneficiary Information Follow-Up Communication

Under § 425.312(a), ACOs are required to notify beneficiaries about the ACO's participation in the Shared Savings Program, the beneficiary's ability to decline claims data sharing, and the beneficiary's ability to select a provider for the purposes of voluntary alignment. In the CY 2023 PFS final rule (87 FR 69961), we added the beneficiary information follow-up communication requirement under § 425.312(a)(2)(v), which requires an additional follow-up with a beneficiary who has received the beneficiary notification. In the CY 2023

PFS final rule (87 FR 69960 through 69963), CMS noted that the follow-up communication promotes transparency and empowers beneficiaries to make an informed decision in choosing a primary care physician and how they share their health data. The beneficiary information follow-up communication affords the opportunity for additional direct engagement between the beneficiary and the ACO, or ACO participant, and provides a chance for a meaningful dialog between the patient and provider about the coordination of their care, the benefits of receiving care from an ACO provider/supplier (as defined at § 425.20), the organizational operations of the ACO, and how data is used to improve care and report quality outcomes.

Currently, at § 425.312(a)(2)(v)(A), ''The follow-up communication must occur no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided.'' Regulations at § 425.312(a)(2)(v)(B) require ACOs to document the beneficiary information follow-up communication. and to make the information available to CMS upon request.

Since CMS implemented the beneficiary information follow-up communication requirement, we have received feedback from ACOs that requiring the follow-up communication no later than the earlier of the beneficiary's next primary care service visit or 180 days from the date the standardized written notice was provided is difficult for ACOs to operationalize as they do not always know when the beneficiary's next primary care service will be and in some cases it can be very soon after the beneficiary receives the original beneficiary notification.

To address this issue and the burden it creates, in the CY 2025 PFS proposed rule (89 FR 61923), we proposed to remove the requirement that ACOs must provide this follow-up at the beneficiary's next primary care visit. Specifically, we proposed to modify § 425.312(a)(2)(v)(A) to read ''The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.'' This will provide ACOs with more flexibility to implement their strategy for following up with beneficiaries after they receive the beneficiary notice, while still providing the opportunity for a meaningful dialog between a beneficiary and their provider. We solicited comment on this proposal. This proposal will be effective beginning January 1, 2025.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Most commentors expressed support for CMS' proposal to modify the follow-up communication requirement to require ACOs to follow-up on the beneficiary notification within 180 days of when the ACO furnished the initial beneficiary notification, and believed it would be less burdensome for ACOs to operationalize.

Response: We agree with commenters that modifying requirements for furnishing the follow-up communication may reduce burden for ACOs.

Comment: A few commenters disagreed with the removal of this requirement and believe ACOs should have a follow-up communication requirement tied to the timing of a beneficiary's primary care visit, as they believe that will improve beneficiary understanding of these notices.

Response: We appreciate these commenters' point of view that tying beneficiary notices to primary care visits may improve beneficiary understanding. The current requirement for the initial beneficiary notice, which must be distributed to beneficiaries before or at the first primary care visit of the agreement period, allows beneficiaries an opportunity to ask questions at a primary care visit. Additionally, under the proposed policy, the follow-up communication may still occur at the beneficiary's follow-up primary care visit as long as it is provided no later than 180 days from the date the standardized written notice was provided.

Comment: Some commenters encouraged CMS to do more to minimize administrative burden for ACOs. Specifically, commenters noted operational challenges, unnecessary administrative burden, and continued lack of understanding from beneficiaries about ACO objectives and the impact of their providers participation, caused by mandated, standardized beneficiary notifications.

Response: We understand that some commenters find the beneficiary notification burdensome, however, all current components of the beneficiary notification requirements are important for appropriately informing beneficiaries about their provider's participation in an ACO. In the CY 2023 PFS final rule (87 FR 69960 through 69963), CMS noted that the follow-up communication promotes transparency and empowers beneficiaries to make an informed decision in choosing a primary care physician and how they share their health data. The beneficiary information follow-up communication affords the opportunity for additional direct engagement between the beneficiary and the ACO, or ACO participant, and provides a chance for a meaningful dialog between the patient and provider about the coordination of their care, the benefits of receiving care from an ACO provider/supplier (as defined at § 425.20), the organizational operations of the ACO, and how data is used to improve care and report quality outcomes. At this time, additional modifications to the beneficiary notification are not appropriate, but we will continue to consider feedback from interested parties in order to improve beneficiary comprehension of these notifications. In 2023, CMS conducted focus groups with beneficiaries and interested parties to improve the beneficiary notification template and improve beneficiary comprehension of the communicated materials. Our efforts to revise the notification templates, based on feedback from the focus groups, empowers beneficiaries and engages them in managing their health care and clearly communicates the benefits of value-based care.

After consideration of public comments, we are finalizing our policy to modify when ACOs must provide the beneficiary information follow-up communication as proposed, as specified in revisions to § 425.312(a)(2)(v)(A).

b. Limiting the Distribution of the Beneficiary Notification to Beneficiaries Likely To Be Assigned for ACOs Under Preliminary Prospective Assignment With Retrospective Reconciliation

ACOs that select preliminary prospective assignment with retrospective reconciliation are assigned beneficiaries in a preliminary manner and before the start of the performance year. Beneficiary assignment for these ACOs is then updated quarterly based on the most recent 12 or 24 months of data, as applicable. This assignment methodology is codified at § 425.400(a)(2). In the CY 2025 PFS proposed rule (89 FR 61924), we proposed to limit the distribution of the beneficiary notification at § 425.312(a)(2)(iii) to beneficiaries who are more likely be assigned to ACOs that select preliminary prospective assignment with retrospective reconciliation, when compared to the population of beneficiaries who must receive the beneficiary notification under current § 425.312(a)(2)(iii). Please note that this was not a proposal to

modify the Shared Savings Program's assignment methodology.

Currently, ACOs that select preliminary prospective assignment with retrospective reconciliation are required to send a beneficiary notice to ''each fee-for-service beneficiary'' under § 425.312(a)(2)(iii). At § 425.312(a)(2)(iii), the standardized written notice must be furnished to ''all fee-for-service beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.'' This can result in ACOs sending notices each year to beneficiaries who may not ultimately be assigned to the ACO, as there are ''fee-for-service beneficiar[ies]'' to whom ACOs must send notices under § 425.312(a)(2)(iii) and who are not eligible to be assigned to those ACOs for a variety of reasons. This policy was intended to ensure that all beneficiaries who receive a primary care visit from a ACO provider/supplier receive the beneficiary notice. However, we have heard feedback from ACOs that this creates confusion for the beneficiary and unnecessary administrative work for the ACO.

To reduce burden on ACOs and confusion for beneficiaries, we proposed to update the beneficiary notice requirement for ACOs that select preliminary prospective assignment with retrospective reconciliation to focus on beneficiaries that are likely to be assigned to the ACO. These beneficiaries are those who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined at § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined at § 425.20 or who has one of the primary specialty designations included at § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care at § 425.402(e).

This proposed policy would reduce the burden of sending the beneficiary notice to all ''fee for service beneficiar[ies],'' including those who ultimately would not be eligible to be assigned to ACOs that select preliminary prospective assignment with retrospective reconciliation. Specifically, we proposed to modify § 425.312(a)(2)(iii) to state in the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, the beneficiary notice must be provided by the ACO or ACO participant to each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined at § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined at § 425.20 or who has one of the primary specialty designations included at § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO whom the beneficiary designated as responsible for coordinating their overall care at § 425.402(e). Each such beneficiary must receive a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

For ACOs that select prospective assignment, beneficiaries are prospectively assigned to the ACO at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 or 24 months, as applicable, for which data are available, using the assignment methodology described at §§ 425.402 and 425.404. *See* § 425.400(a)(3)(i). Beneficiaries that are prospectively assigned to an ACO at § 425.400(a)(3)(i) remain assigned to the ACO at the end of the benchmark or performance year unless they meet any of the exclusion criteria at § 425.401(b). *See* § 425.400(a)(3)(ii). We note that ACOs that select prospective assignment are subject to § 425.312(a)(2)(iv). Under this regulation, ACOs that select prospective assignment are required to furnish the beneficiary notice to all prospectively assigned beneficiaries once during an agreement period.

This proposed change will be effective beginning on January 1, 2025.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally appreciative of CMS' proposal for better targeting beneficiaries to receive the beneficiary notice for ACOs that have selected preliminary prospective assignment with retrospective reconciliation, and they supported the proposal.

Response: We appreciate the commenters' support and agree that this proposal will better target the beneficiary notice to appropriate beneficiaries.

Comment: A few commenters expressed concern that this proposal does not fully resolve their issues with identifying beneficiaries that require the beneficiary notice at or before their first primary care visit of the agreement period and note that it requires frontline primary care practices to manage the administrative burden of providing these notices to beneficiaries. These commenters suggested that CMS remove the beneficiary notification requirement entirely, provide ACOs with additional information on potential beneficiary assignment overlaps between ACOs, or provide additional flexibility for when and how these notices are provided.

Response: We appreciate commenters' feedback on the operational challenges of distributing the beneficiary notices. For ACOs that select preliminary prospective assignment with retrospective reconciliation, the proposed policy reduces the selection of beneficiaries who must receive the beneficiary information notice from any FFS beneficiary to only those beneficiaries who are likely to be assigned to the ACO.

We note that these ACOs will receive a report that identifies the initial population of assignable beneficiaries who must receive the beneficiary information notice in December, prior to the start of each performance year, to support the ACO's ability to distribute beneficiary notices as soon as a new performance year begins. ACOs will also receive an updated report on a quarterly basis through the performance year, to facilitate the distribution of the beneficiary notice to any beneficiaries newly identified on the report.

We acknowledge that it is possible a beneficiary may receive the beneficiary information notice from more than one ACO, and we are considering potential options to update the files received by ACOs to reduce this potential confusion.

Additionally, as noted earlier, we understand that some commenters find the beneficiary notification burdensome, however, all current components of the beneficiary notification requirement are important for appropriately informing beneficiaries about their provider's participation in an ACO, beneficiary data sharing, and freedom to choose where they receive their care. At this time, we do not think additional modifications are appropriate, but we will continue to consider feedback from stakeholders.

After consideration of public comments, we are finalizing our policy limiting the distribution of the

beneficiary notification to beneficiaries likely to be assigned for ACOs under preliminary prospective assignment with retrospective reconciliation as proposed, as specified in revisions to § 425.312(a)(2)(iii).

H. Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152)

1. Part B Preventive Vaccines and Their Administration

a. Statutory Background

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and vaccine administration for the specified preventive vaccines—pneumococcal, influenza, hepatitis B and COVID–19 vaccines. Section 1861(s)(10)(B) of the Act specifies that the hepatitis B vaccine and its administration is only covered for those who are at high or intermediate risk of contracting hepatitis B, as defined at § 410.63. Under section 1833(a)(1)(B) of the Act (pneumococcal, influenza and COVID–19 vaccines) and section 1833(a)(1)(Y) of the Act (hepatitis B vaccines), there is no applicable beneficiary coinsurance for these vaccines or the services to administer them. Under section 1833(b)(1) of the Act, the annual Part B deductible does not apply to Part B preventive vaccines. Please see 75 FR 73415 for more information on the applicability of Part B coinsurance and deductible to preventive vaccines.

Per section 1842(o)(1)(A)(iv) of the Act, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for the vaccine product, except when furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department (HOPD), rural health clinic (RHC), or federally qualified health center (FQHC). Some other preventive vaccines, such as the zoster vaccine for the prevention of shingles, are not specified for Medicare Part B coverage under section 1861(s)(10) of the Act and are instead covered under Medicare Part D.

b. Pneumococcal, Influenza and Hepatitis B Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65185), we finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit. We explained that since payment policies for the administration of the preventive vaccines described under section 1861(s)(10) of the Act are independent of the PFS, these payment rates will be updated as necessary, independent of the valuation of any specific codes under the PFS. (Please see COVID–19 vaccine administration payment information in the next section.) The CY 2022 PFS final rule (86 FR 65180 through 65182) provides a detailed discussion on the history of the valuation of the three Level II Healthcare Common Procedure Coding System (HCPCS) codes, G0008, G0009, and G0010, which describe the services to administer an influenza, pneumococcal, and hepatitis B vaccine, respectively.

In the CY 2023 PFS final rule (87 FR 69984), we finalized a policy to annually update the payment amount for the administration of Part B preventive vaccines based upon the percentage increase in the Medicare Economic Index (MEI). Additionally, we finalized the use of the PFS Geographical Adjustment Factor (GAF) to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the preventive vaccine is administered. These adjustments and updates apply to HCPCS codes G0008, G0009, G0010.

These adjustments and updates also apply to Current Procedural Terminology (CPT) code 90480 (Immunization administration by intramuscular injection of coronavirus disease [COVID–19] vaccine, single dose) that describe the service to administer COVID–19 vaccines and HCPCS code M0201 (Administration of pneumococcal, influenza, hepatitis b, and/or covid-19 vaccine inside a patient's home; reported only once per individual home per date of service when such vaccine administration(s) are performed at the patient's home), discussed below in section III.H.1.c and III.H.1.d, respectively, of this final rule.

The current payment rates for G0008, G0009, and G0010, as finalized in the CY 2024 PFS final rule, can be found on the CMS Vaccine Pricing website under the ''Seasonal Flu Vaccines'' tab, and then under the heading ''Locality-Adjusted Payment Rates.'' [622] As we stated in the proposed rule (89 FR 61925), the final rates for CY 2025 will be based on the final CY 2025 MEI increase factor. The final CY 2025 MEI increase factor, based on the 2017-based MEI, reflecting historical data through the 2nd quarter of 2024, is 3.5 percent. Tables 51 and 52 in section III.H.1.f. of this final rule provide the CY 2025 payment rates for G0008, G0009, and G0010, with the 3.5 percent annual update applied for CY 2025.

We solicited comments on these proposed rates. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our CY 2025 proposed payment rates for Part B vaccine administration of pneumococcal, influenza and hepatitis B vaccines. We received several comments thanking CMS for annually updating the Part B preventive vaccine administration payment rate with the MEI. Commenters stated that this helps ensure that Medicare beneficiaries continue to have access to essential vaccines, and it supports CMS' ongoing commitment to preventive care and public health.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to improve access to vaccines and preventive care for Medicare enrollees and all Americans.

After consideration of public comments, we are finalizing these rates as proposed. Tables 51 and 52 in section III.H.1.f. of this final rule provide the CY 2025 payment rates for G0008, G0009, and G0010, with the 3.5 percent annual update applied for CY 2025.

c. COVID–19 Vaccine Administration

In the CY 2022 PFS final rule (86 FR 65181 and 65182), we provided a detailed history regarding the determinations of initial payment rates for the administration of COVID–19 vaccines, and an explanation of how the payment policy evolved to a rate of $40 per dose. For CY 2022, we maintained the payment policy for the administration of COVID–19 vaccines and stated that while we believe it is appropriate to establish a single, consistent payment rate for the administration of all four Part B preventive vaccines in the long term, we will pay a higher, $40 payment rate for administration of COVID–19 vaccines in the short term, while pandemic conditions persisted (86 FR 65185).

In the CY 2023 PFS final rule (87 FR 69988 through 69993), we stated that due to timing distinctions between a PHE declared under section 319 of the Public Health Service (PHS) Act and an Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), we reconsidered the policies finalized in the CY 2022 PFS final rule in light of our goal to promote broad and timely access to COVID–19 vaccines. We explained that our goal would be better served if our policies

[622] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under the tab ''Seasonal Flu Vaccines'', and then under the header ''Locality-Adjusted Payment Rates.''

with respect to payment for administration of these products, as addressed in the November 6, 2020 COVID–19 IFC (85 FR 71142) and CY 2022 PFS final rule (85 FR 18250), continue until the EUA declaration for drugs and biological products with respect to COVID–19 is terminated. Therefore, we finalized that we would maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the March 27, 2020 EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products ends. Effective January 1 of the year following the year in which the EUA declaration ends, the COVID–19 vaccine administration payment would be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines, that is, approximately $30 per dose. As mentioned above, we also finalized that, beginning January 1, 2023, we would annually update the payment amount for the administration of all Part B preventive vaccines based upon the percentage increase in the MEI, and that we would use the PFS GAF to adjust the payment amount to reflect cost differences for the geographic locality based upon the fee schedule area where the vaccine is administered.

On September 11, 2023, the Food and Drug Administration (FDA) announced its recommendation to shift to a monovalent coronavirus disease 2019 [COVID–19] vaccine that targets the predominant XBB lineage virus strain for the 2023–2024 vaccine administration season.[623] In anticipation of this recommendation, in August 2023, the CPT Editorial Panel approved five new monovalent COVID–19 vaccine product codes for Pfizer and Moderna vaccines. In addition, they approved a new vaccine administration code (90480) for reporting the administration of any COVID–19 vaccine for any patient (pediatric or adult), replacing all previously approved specific vaccine administration codes. All previously approved COVID–19 vaccine product and vaccine administration codes were deleted from the CPT code set effective November 1, 2023, except for product code 91304, which represents the Novavax COVID–19 vaccine product and remains active.[624]

The current payment rate for CPT code 90480 is available on the CMS COVID–19 Vaccine Pricing website, under ''COVID–19 Vaccines & Monoclonal Antibodies''.[625] As we stated in the proposed rule (89 FR 61926), the final rates for CY 2025 will be based on the final CY 2025 MEI increase factor. As noted above, the final CY 2025 MEI increase factor, based on the 2017-based MEI, is based on historical data through the 2nd quarter of 2024 and is 3.5 percent. Tables 51 and 52 in section III.H.1.f. of this final rule provide the CY 2025 payment rates for 90480 with the 3.5 percent annual update applied for CY 2025. Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, Tables 51 and 52, at the end of section III.H.1.f. of this final rule, reflect the potential alternative payment amounts for Part B preventive vaccine administration for CY 2025. Table 51 displays the CY 2025 Part B payment rates for preventive vaccine administration if the EUA declaration continues into CY 2025, and Table 52 displays the CY 2025 Part B payment rates for preventive vaccine administration if the EUA declaration ends on or before December 31, 2024.

We solicited comments on these proposed rates. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our CY 2025 proposed payment rates for COVID–19 vaccine administration. We received several comments thanking CMS for annually updating the payment rate for the administration of preventive vaccines covered under Medicare Part B with the MEI. Commenters stated that this helps ensure that Medicare beneficiaries continue to have access to essential vaccines, and it supports CMS' ongoing commitment to preventive care and public health. Commenters also thanked CMS for providing a clear path forward on payment for both EUA declaration scenarios for 2025.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to improve access to vaccines and preventive care for Medicare enrollees and all Americans.

Comment: Some commenters had feedback regarding our existing policy to maintain the current payment rate of $40 per dose for the administration of COVID–19 vaccines through the end of the calendar year in which the EUA declaration ends.

Several commenters supported this existing policy and thanked CMS for maintaining the higher payment rate relative to other Part B vaccine administration payments. One commenter requested that, when the EUA declaration is terminated, CMS communicate any changes in payment and allow for a transition time to adjust claims systems. Another commenter asked that CMS continue the $40 payment rate for COVID–19 vaccine administration beyond the end of CY 2024 and extend it to all Medicare preventive vaccines. Other commenters requested that CMS maintain the higher payment rate through the end of the 2024–2025 respiratory disease season, even if the EUA declaration ends before the end of the season. One commenter suggested that CMS finalize one payment rate for administration of the COVID–19 vaccine for CY 2025, regardless of the date that the EUA declaration is terminated.

Response: We thank commenters for their feedback. In last year's CY 2024 PFS final rule (88 FR 79233–34), we explained that the CY 2022 PFS final rule (87 FR 65184–86) contains an extensive discussion on our rationale for initially setting the $40 COVID–19 vaccine administration rate, and for eventually aligning the COVID–19 vaccine administration rate with the rate for administration of the other Part B preventive vaccines, that is, $30 per vaccine administered. In the CY 2023 final rule (87 FR 69988–93), we set this transition to occur on January 1 of the year following the year in which the Secretary ends the March 27, 2020, EUA declaration under section 564 of the FD&C Act (EUA declaration) for drugs and biological products, and we also gave a detailed explanation of this decision. We also stated that when the transition to a calendar year post-EUA declaration does arrive, we plan to provide both vaccine providers and Medicare enrollees with sufficient notice and thorough guidance regarding the transition (88 FR 79233–34). As of the publication of this final rule, the EUA declaration has not yet ended.

Additionally, CMS is dedicated to the goal of promoting vaccine access for Medicare enrollees. We appreciate that these commenters share CMS' priorities in this area.

Comment: We received several comments that were outside of the scope of our proposals for Part B preventive vaccines for CY 2025. Several commenters requested that CMS evaluate coverage and payment policies

[623] *https://www.fda.gov/news-events/press-announcements/fda-takes-action-updated-mrna-covid-19-vaccines-better-protect-against-currently-circulating.*

[624] CPT® Assistant Special Edition: August Update/Volume 33/2023. *https://www.ama-assn.org/system/files/cpt-assistant-guide-coronavirus-august-2023-updated.pdf.*

[625] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing,* under ''COVID–19 Vaccines & Monoclonal Antibodies''.

for potential combination vaccines under Medicare Part B, and to determine those policies. Other commenters requested that all ACIP-recommended vaccines transition to coverage under Medicare Part B, including vaccines for mpox and RSV. Some commenters asked CMS to continue working with Congress to achieve Medicare Part B provider status for pharmacists. Another commenter suggested policy changes that would encourage emergency departments to administer vaccines.

Response: We thank commenters for their feedback. These comments are outside of the scope of our proposals in the CY 2025 PFS proposed rule. We note that, in accordance with statute, Part B payment can be made only for the preventive vaccines specified at section 1861(s)(10) of the Act, as well as their administration (please see section III.H.1 of this final rule for more information). Therefore, we did not make any proposals regarding expanding the Part B preventive vaccine benefit to additional vaccines. We did not address vaccine administration in other health care settings, and we did not make any proposals regarding the scope of practice for those who would administer the vaccines.

However, as noted above, CMS is dedicated to the goal of promoting vaccine access for Medicare enrollees. We appreciate that these commenters share CMS' priorities in this area. We are actively taking these comments into consideration for future policymaking, as appropriate under our statutory authority.

After consideration of public comments, we are finalizing these rates as proposed. Tables 51 and 52 in section III.H.1.f. of this final rule provide the CY 2025 payment rates for CPT code 90480, with the 3.5 percent annual update applied for CY 2025.

d. In-Home Additional Payment for Administration of Preventive Vaccines

In the CY 2022 PFS final rule (86 FR 65187 and 65190), we provide a detailed discussion on the payment policy for COVID–19 vaccine administration in the home. In summary, providers and suppliers that administer a COVID–19 vaccine in the home, under certain circumstances, could bill Medicare for one of the existing COVID–19 vaccine administration CPT codes along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). For CY 2022, we continued to make an additional payment when a COVID–19 vaccine was administered in a beneficiary's home under certain circumstances and stated that we would make this payment until the end of the year in which the PHE expires.

In the CY 2023 PFS final rule (87 FR 69984 through 69986), we discussed that we had received many comments and requests from interested parties that the in-home add-on payment be applied more broadly to all preventive vaccines. Commenters also expressed concerns that discontinuation of the in-home additional payment would negatively impact access to the COVID–19 vaccine for underserved homebound beneficiaries. Therefore, we continued the policy of making an additional payment when a COVID–19 vaccine is administered in a beneficiary's home, under certain circumstances for the duration of CY 2023. We explained that we were continuing the policy of additional payment for at-home COVID–19 vaccinations for another year to provide us time to track utilization and trends associated with its use, in order to inform the Part B preventive vaccine policy on payments for in-home vaccine administration for CY 2024. In addition, for CY 2023 we updated the payment amount by the CY 2023 MEI percentage increase and adjusted for geographic cost differences as we do the payment for the preventive vaccine administration service, that is, based upon the fee schedule area where the COVID–19 vaccine is administered, by using the PFS GAF (87 FR 69986).

In the CY 2024 PFS final rule (88 FR 79235 through 79237), we discussed the policy for the in-home additional payment for COVID–19 vaccine administration under the Part B preventive vaccine benefit for CY 2024 and subsequent years. We maintained the payment policy for COVID–19 vaccine administration and extended the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit—the pneumococcal, influenza, and hepatitis B vaccines. As described at § 410.152(h)(3), effective January 1, 2024, the payment amount for the in-home administration of all four vaccines is identical, that is, Medicare Part B pays the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID–19 vaccine in the home. This additional payment amount is annually updated using the percentage increase in the MEI and is adjusted to reflect geographic cost variations with the PFS GAF.

We stated that the in-home additional payment is limited to one payment per home visit, even if multiple vaccines are administered during the same home visit. We noted that every vaccine dose that is furnished during a home visit still receives its own unique vaccine administration payment. The additional payment for in-home Part B vaccine administration is only made if certain circumstances are met, as outlined at § 410.152(h)(3)(iii). Providers and suppliers that administer one of the Part B preventive vaccines in the home, under those circumstances, can bill Medicare for one of the existing Part B vaccine administration CPT codes along with HCPCS code M0201 (Administration of pneumococcal, influenza, hepatitis b, and/or covid-19 vaccine inside a patient's home; reported only once per individual home per date of service when such vaccine administration(s) are performed at the patient's home) (88 FR 79235 through 79237).

The current *payment* rate *for* M0201 can be found on the CMS Vaccine Pricing website under ''COVID–19 Vaccines & Monoclonal Antibodies''.[626] As we stated in the proposed rule (89 FR 61926), the final rates for CY 2025 will be based on the final CY 2025 MEI increase factor. The final CY 2025 MEI increase factor, based on the 2017-based MEI, is based on historical data through the 2nd quarter of 2024 and is 3.5 percent. Tables 51 and 522 in section III.H.1.f. of this final rule provide the CY 2025 projected payment rate for M0201 with the 3.5 percent annual update applied for CY 2025.

We solicited comments on this proposed rate. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposed rate for the in-home additional payment for Part B preventive vaccines. We received several comments thanking CMS for annually updating the payment rate for the in-home additional payment with the MEI. One commenter stated they believe that, despite the end of the COVID–19 public health emergency (PHE), there are still many Medicare enrollees who can benefit from in-home vaccinations who are challenged by mobility or geographic distance.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to promote access to vaccines and preventive care for Medicare enrollees.

[626] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies''.

Comment: Some commenters requested that we expand the in-home additional payment to all vaccines recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) (*https://www.cdc.gov/acip/index.html*).

Response: We thank commenters for their feedback. These comments are outside of the scope of our proposals in the CY 2025 PFS proposed rule. We note that, in accordance with statute, Part B payment can be made only for the preventive vaccines specified at section 1861(s)(10) of the Act, and their administration (please see section III.H.1 of this final rule for more information). Therefore, we did not make any proposals regarding expanding the Part B in-home additional payment to other vaccines.

After consideration of public comments, we are finalizing this rate as proposed. Tables 51 and 52 in section III.H.1.f. of this final rule provide the CY 2025 payment rate for M0201, with the 3.5 percent annual update applied for CY 2025.

e. COVID–19 Monoclonal Antibodies and Their Administration

In CY 2023 PFS final rule (87 FR 69987 through 69993), we discussed that all COVID–19 monoclonal antibody products and their administration are covered and paid for under the Part B preventive vaccine benefit through the end of year in which the Secretary terminates the EUA declaration for drugs and biological products with respect to COVID–19. In addition, we explained that, under the authority provided by section 3713 of the CARES Act, we have established specific coding and payment rates for the COVID–19 vaccine, as well COVID–19 monoclonal antibodies and their administration, through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on the CMS website (87 FR 69987).

In the CY 2023 PFS final rule, we also established a policy to continue coverage and payment for monoclonal antibodies that are used for pre-exposure prophylaxis (PrEP) of COVID–19 under the Part B preventive vaccine benefit if they meet applicable coverage requirements (87 FR 69992). We explained that we will continue to pay for these products and their administration even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization. Additionally, we established that payments for the administration of monoclonal antibodies that are used for PrEP of COVID–19 would be adjusted for geographic cost variations using the PFS GAF. In the CY 2024 PFS rule (88 FR 79239 through 79240), we codified these policies in regulations at §§ 410.10(l) and 410.57(c).

In CY 2024 PFS final rule (88 FR 79239 through 79240), we noted that we did not finalize any payment regulations regarding monoclonal antibodies for PrEP of COVID–19, since at the time of the publication of the CY 2024 PFS final rule, there were no COVID–19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID–19 in the United States. We stated that if a new monoclonal antibody for PrEP of COVID–19 became authorized for use, we would use the authority provided by section 3713 of the CARES Act, as discussed in the CY 2023 PFS final rule (87 FR 69987), to establish specific coding and payment rates for the administration of that product through technical direction to MACs and information posted publicly on the CMS website. We explained that we would subsequently propose coding and payment rates for the administration of that product via rulemaking.

We also noted that, for the purposes of the in-home additional payment discussed above in section III.H.1.d. of this final rule, that additional payment is not applicable to the administration of monoclonal antibodies for PrEP of COVID–19. For monoclonal antibodies for PrEP of COVID–19, we set the coding and payment rates for the administration of COVID–19 monoclonal antibodies in the home (when applicable) to be higher than those in other health care settings, and therefore such amounts already account for the higher costs of administering the product in the home.

On March 22, 2024, the FDA issued an EUA for Pemgarda (pemivibart) injection, for intravenous use.[627] Pemgarda is a monoclonal antibody product authorized for emergency use for pre-exposure prophylaxis to help prevent COVID–19 in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) who:

- Are not currently infected with SARS-CoV–2 and who have not been known to be exposed to someone who is infected with SARS-CoV–2 and
- Have moderate-to-severe immune compromise because of a medical condition or because they receive medicines or treatments that suppress the immune system and they are unlikely to have an adequate response to COVID–19 vaccination.

Therefore, under the authority provided by section 3713 of the CARES Act, we established specific coding and payment rates for the administration of Pemgarda through technical direction to MACs and information posted publicly on the CMS website. Since Pemgarda is authorized for use in pre-exposure prophylaxis of COVID–19, and since CMS is continuing to cover and pay authorized or approved products used for pre-exposure prophylaxis of COVID–19 under the Part B preventive vaccine benefit, we plan to propose long-term coding and payment rates for the administration of this product in future rulemaking, so long as the product meets these requirements. The current payment rates for Pemgarda and its administration can be found on the CMS Vaccine Pricing website under ''COVID–19 Vaccines & Monoclonal Antibodies''.[628] These payment rates are also listed below in Tables 51 and 52.

More information on our coding and payment policies for COVID–19 monoclonal antibodies is available at *https://www.cms.gov/monoclonal*.

We solicited comments on these policies. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our payment policies for COVID–19 monoclonal antibodies, and specifically our payment policies on monoclonal antibodies for PrEP for COVID–19. One commenter stated that they hope a code for therapeutic care can be implemented in the future.

Response: We thank commenters for their support of our policy and for partnering with CMS in our efforts to improve access to vaccines, monoclonal antibodies used for PrEP of COVID–19, and general preventive care for Medicare enrollees.

f. Summary of Payment Amounts for CY 2025

Due to the uncertainty surrounding the future of the EUA declaration for drugs and biological products for COVID–19, we are including Tables 51 and 52, which summarize the potential alternative preventive vaccine administration payment amounts under Medicare Part B at the time of the publication of this final rule. If the EUA declaration continues to be in effect on January 1, 2025, the payment rates in Table 51 will apply. If the EUA

[627] *https://www.fda.gov/media/177068/download?attachment.*

[628] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''COVID–19 Vaccines & Monoclonal Antibodies''.

declaration is terminated before January 1, 2025, the payment rates in Table 52 will apply.

For CY 2025, the growth rate of the 2017-based MEI is 3.5 percent with historical data through second quarter 2024. We proposed that if more recent data are subsequently available (for example, a more recent estimate of the MEI percentage increase), we would use such data, if appropriate, to determine the CY 2025 MEI percentage increase in the CY 2025 PFS final rule; we would apply that updated MEI percentage increase to the rates found in the Tables 51 and 52 where applicable. Therefore, in this final rule, the rates in Tables 51 and 52 represent our CY 2024 rates for the listed items, multiplied by 1.035

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TABLE 51: CY 2025 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2025

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$33.71	MEI	GAF
COVID-19 Vaccine[2,4]	$44.95	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.90	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis) [3,4,5]	N/A	N/A	N/A
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4]	N/A	N/A	N/A
Intravenous Infusion: Health Care Setting	$450	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.

[2] CPT code 90480.

[3] *https://www.cms.gov/monoclonal*.

[4] Beneficiary coinsurance and deductible are not applicable.

[5] As of the issuance of the CY 2025 PFS final rule, there are no monoclonal antibodies approved or authorized for the treatment or for post-exposure prophylaxis of COVID-19.

[6] The CY 2025 percentage increase of the 2017-based MEI is 3.5 percent, based on historical data through the 2nd quarter of 2024.

TABLE 52: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2025, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$33.71	MEI	GAF
COVID-19 Vaccine[2,4]	$33.71	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.90	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD[5]	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] CPT code 90480
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered. Beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] Please see section III.H.1.e. of this proposed rule.
[6] The CY 2025 percentage increase of the 2017-based MEI is 3.5 percent, based on historical data through the 2nd quarter of 2024.

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2. Revised Payment Policies for Hepatitis B Vaccine Administration

In section III.M of this final rule, we are finalizing our proposal to expand the list of individuals who are determined to be at high or intermediate risk of contracting hepatitis B at § 410.63 in order to improve access and utilization of hepatitis B vaccines. Specifically, we proposed to expand coverage of hepatitis B vaccinations by revising § 410.63(a)(2), Intermediate Risk Groups, by adding a new paragraph (a)(2)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series and individuals whose previous vaccination history is unknown. We believe that this final rule coverage change will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States, and is in the best interest of the Medicare program and its beneficiaries. Below, we discuss how the proposal to expand coverage may impact Part B payment policy for hepatitis B vaccines and administration.

a. Background

Section 2323 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) amended section 1861(s)(10) of the Act by adding subparagraph (B) to provide Medicare Part B coverage for the hepatitis B vaccine and its administration for those individuals who are at high or intermediate risk of contracting hepatitis B. The statute required the Secretary to determine, by regulations, criteria for identifying individuals who are at high or intermediate risk of contracting hepatitis B. In addition, section 2323 of the Deficit Reduction Act of 1984 added section 1833(k) of the Act, which states that the Secretary may provide for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services, instead of the amount of payment otherwise provided under Part B for the hepatitis B vaccine and its administration.

In the June 4, 1990 **Federal Register**, we issued a final rule to implement section 2323 of the Deficit Reduction Act of 1984 and the coverage provisions were codified in regulation at § 410.63(a) (55 FR 22785). In the preamble to the1990 rule, we stated that, ''[f]or Medicare payment purposes, the hepatitis B vaccine may be administered—upon the order of a doctor of medicine or osteopathy—by qualified staff of home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, HMOs, persons recognized under the 'incident to physician's services' provision of the law (section 1861(s)(2)(A) of the Act), as well as doctors of medicine and osteopathy.'' This policy is included in the Medicare Claims Processing Manual, Chapter 18, section 10.1.3.

In the CY 2013 PFS final rule (77 FR 69363), CMS amended the regulations at § 410.63(a) to include those diagnosed with diabetes mellitus in the list of groups at high risk of contracting hepatitis B. In the November 6, 2020 COVID–19 IFC (85 FR 71145), in preamble discussions surrounding the implementation of coverage and payment for the COVID–19 vaccine, we mentioned the unique coverage and payment requirements related the hepatitis B vaccine under Part B. We noted that, unlike pneumococcal, influenza and COVID–19 vaccines, hepatitis B vaccines require an assessment of a patient's risk of contracting hepatitis B. Because hepatitis B vaccinations claims needed a physician's order, they could not be

roster billed by mass immunizers. More information on the physician's order policy that is in effect for the administration of hepatitis B vaccines through CY 2024 can be found in the Medicare Benefit Policy Manual, Chapter 15, Section 50.4.4.2.

b. Revisions to Payment Policies for Hepatitis B Vaccinations

As discussed above, in section III.M of this final rule, we are finalizing a policy to provide coverage under Part B for hepatitis B vaccines and their administration for an expanded range of Medicare enrollees, as reflected in the revised § 410.63(a). We explain that Medicare coverage of hepatitis B vaccination is outdated in light of recent information about the risks of contracting hepatitis B, and that current research indicates that individuals who remain unvaccinated against hepatitis B are at intermediate risk of contracting hepatitis B virus. Under the new policy, an assessment of an individual's vaccination status can now be made without the clinical expertise of a physician. Thus, we will remove our policy in the manual that the administration of a Part B-covered hepatitis B vaccine be preceded by a doctor's order. A doctor's order will no longer be necessary for the administration of a hepatitis B vaccine under Part B, and we will also change our procedures to allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration.

Currently, instructions regarding hepatitis B vaccine administration under Part B are contained in CMS manual guidance. As there are changes to § 410.63(a) finalized in this rulemaking, we will make corresponding changes to guidance in the Medicare Benefit Policy Manual and Medicare Claims Processing Manual. Moreover, additional information on roster billing is available on the CMS web page at *https://www.cms.gov/roster-billing*.

We note that the current payment rates for HCPCS code G0010, ''*Administration of hepatitis b vaccine,*'' as finalized in the CY 2024 PFS final rule, can be found on the CMS Vaccine Pricing website under ''Seasonal Flu Vaccines''.[629] The payment rates for G0010, with the annual update applied for CY 2025, are available in Tables 51 and 52 in section III.H.1.f. of this final rule. More information on other policies related to the administration of G0010 can be found in the section preceding this one (section III.H.1. of this final rule), and revisions to payment policies for the administration of G0010 in RHCs and FQHCs can be found in the section immediately below (section III.H.2.c. of this final rule).

c. Revisions to Payment Policies for Hepatitis B Vaccinations in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

When section 2323 of the Deficit Reduction Act of 1984 added section 1861(s)(10)(B) to the Act to add Medicare Part B coverage for the hepatitis B vaccine and its administration, it limited that coverage to certain settings. In RHCs and FQHCs, the law specified at section 1833(a)(3)(A) of the Act that the vaccines mentioned at section 1861(s)(10)(A) of the Act—namely, pneumococcal and influenza (and later, COVID–19) vaccines—are not included in the all-inclusive payment rate for an RHC or FQHC visit but are reimbursed as a separate payment. Pneumococcal, influenza and COVID–19 vaccines and their administration are paid at 100 percent of reasonable cost when administered in an RHC or FQHC, in accordance with section 1833(a)(1)(B) of the Act. By contrast, hepatitis B vaccines and the cost of administration have been included in the capitated payment for an RHC or FQHC visit. RHCs and FQHC visits are generally paid at 80 percent of reasonable costs, and thus, they are subject to coinsurance for Medicare Part B enrollees. The Deficit Reduction Act of 1984 also added section 1833(k) to the Act, which states that, for hepatitis B vaccines and their administration as described at section 1861(s)(10)(B), the Secretary may provide for payment that ''reasonably reflects the general cost of efficiently providing such services,'' instead of the amount of payment otherwise dictated in statute.

In CY 2011 PFS final rule (75 FR 73418), we addressed the issue of coinsurance for hepatitis B vaccines and their administration in FQHCs. The CY 2011 PFS final rule, which implemented the expansion of preventive services in Medicare as mandated by the ACA, stated that effective January 1, 2011, Part B coinsurance on hepatitis B vaccinations was waived, as the vaccine and its administration were deemed ''preventive services'' per section 1861(ddd)(3)(A) of the Act as cross-referenced to section 1861(ww)(2) of the Act. (More information on preventive services is provided immediately below at section III.H.3. of this final rule). The CY 2011 PFS final rule codified this FQHC policy in regulation at § 405.2449. In the CY 2014 FQHC PPS final rule (79 FR 25474), at § 405.2410(b), we codified regulations regarding coinsurance in RHCs and FQHCs which exempt from coinsurance ''preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter'', which explicitly includes the hepatitis B vaccine. In the CY 2016 PFS final rule (80 FR 71088), we clarified that these waivers of cost-sharing (both coinsurance and deductible) for preventive services applied to RHCs as well, and we subsequently clarified in sub-regulatory guidance that these waivers apply to the administration of hepatitis B vaccines in RHC and FQHCs.[630] We note that FQHC services are always exempt from the Part B deductible, per section 1833(b)(4) of the Act.

Even though hepatitis B vaccines and their administration are deemed preventive services for which coinsurance (and deductible in RHCs) is waived, hepatitis B vaccines are still currently paid differently than other Part B vaccines in RHCs and FQHCs. Due to the statutory differences explained above, pneumococcal, influenza and COVID–19 vaccines and their administration are paid at 100 of reasonable cost in RHCs and FQHCs—that is, they are paid separately from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology—while hepatitis B vaccines and their administration are paid as part of the FQHCs PPS or the RHC AIR, which means that they are paid through changes to the facilities' capitated rate.

In light of the proposal to expand coverage for hepatitis B vaccination in section III.M. of this final rule, we proposed to use the aforementioned authority at section 1833(k) of the Act to align payment for hepatitis B vaccinations in RHCs and FQHCs with the payment for pneumococcal, influenza and COVID–19 vaccinations in those settings. That is, we proposed to pay for hepatitis B vaccines and their administration in RHCs and FQHCs at 100 percent of reasonable cost, separate

[629] *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price/vaccine-pricing*, under ''Seasonal Flu Vaccines;'' see links to the relevant year under ''Locality-Adjusted Payment Rates.''

[630] Updates were made to Chapter 13, section 220.1 of Medicare Benefit Policy Manual via Change Request 9864, R2186CP, December 9, 2016, ''Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates:'' *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R230BP.pdf.* Updates were also made to Chapter 9, section 60.3 of the Medicare Claims Processing Manual via Change Request 9397, R3434CP, December 31, 2015, ''Reorganization of Chapter 9:'' *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3434CP.pdf.*

from the FQHCs PPS and the RHC AIR methodology, for all populations identified for coverage at § 410.63(a). As is the case for pneumococcal, influenza and COVID–19 vaccine administration, under this proposal, a hepatitis B vaccine administration would not be considered an RHC or FQHC visit. We proposed that effective January 1, 2025, RHCs and FQHCs would bill for Part B hepatitis B vaccines in the same manner as they currently bill for pneumococcal, influenza and COVID–19 vaccines, that is, on their cost report.

We note that we are finalizing a policy above, in section III.B.5 of this final rule, to allow for billing and payment of all Part B preventive vaccines and their administration at the time of service in RHCs and FQHCs, with annual reconciliation on the facilities' cost reports. As explained there, the policy will be effective for dates of service on or after July 1, 2025, in order to allow time for implementation and necessary systems changes. Both the policy in section III.B.5 and this policy together support our goal of streamlining payment for all Part B vaccines across Part B settings of care. We believe that streamlining Part B vaccine and vaccine administration payments among care settings aligns with the stated goals of section 1833(k) of the Act, since those payment policy changes will allow for increased efficiency in Part B claims processing on both the part of the RHCs and FQHCs and on the part of CMS. We also believe that the increased efficiency will promote vaccine access, and thus health equity in general, in RHCs and FQHCs that already serve vulnerable populations.

To implement this policy regarding payment for hepatitis B vaccines and their administration in RHCs and FQHCs, we are also amending the regulations at § 405.2466(b)(1)(iv), to add hepatitis B vaccines to the list of vaccines covered in RHCs and FQHCs at 100 percent of reasonable cost. We are finalizing that regulation text as proposed. We plan to make corresponding changes to guidance in the Medicare Benefit Policy Manual, Chapter 13 and Medicare Claims Processing Manual, Chapter 9 and facilitate the necessary operational systems updates needed to implement these changes.

d. Regulations Concerning Hepatitis B Vaccines and Their Administration

Listed below are several Medicare Part B regulations that mention the hepatitis B vaccine and refer to § 410.63(a) for a definition of hepatitis B vaccine coverage. Since we proposed to revise § 410.63(a) in section III.M. of this final rule, we do not believe additional regulation text changes are needed to conform to the coverage proposal, as the update to the definition at § 410.63(a) will apply to the use of the definition in these regulations:

- Section 410.10(p).
- Section 410.57(d).
- Section 411.15(e)(3) and (k)(5).
- Section 414.707(a)(2)(iii).
- Section 414.904(e)(1).

In addition, we noted that there are no conforming regulation text changes needed to the payment regulations at § 410.152, paragraphs (h) and (l)(1), to conform to the coverage proposal.

We received public comments on all of these proposals regarding Hepatitis B vaccines and their administration. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported these proposals regarding payment for Hepatitis B vaccines and their administration. Commenters noted that removing the physician order requirement alleviates a long-standing barrier to hepatitis B vaccine coverage. One commenter noted that the payment change for hepatitis B vaccines in RHCs and FQHCs will provide easier access to those vaccines, and thus improve quality of life, for Medicare enrollees and those with disabilities who live in rural areas where accessing primary care is difficult.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to improve equity and access to hepatitis B vaccines, especially for those vulnerable populations that are served by RHCs and FQHCs. We agree that finalizing these proposals will alleviate barriers to accessing hepatitis B vaccinations for Medicare enrollees.

Comment: Some commenters voiced concerns about our proposal to remove the physician's order requirement for Hepatitis B vaccine administration under Part B. One commenter believes that this change will cause retail pharmacies to face greater compliance challenges, and the commenter asked CMS to provide examples of the medical documentation that a retail pharmacy may rely upon before deciding to administer the Hepatitis B vaccine to a Medicare enrollee. Other commenters voiced concerns about possible consequences of the removal of the physician order requirement, including the concern that a patient's primary or regular physician may not be aware of the administration of the Hepatitis B vaccine to their patient.

Response: As explained in section II.M. of this final rule, an individual whose vaccination history is unknown may receive the hepatitis B vaccine under these changes in coverage, meaning that a vaccination record is not needed. Therefore, no documentation is needed for a retail pharmacy to provide a Hepatitis B vaccine to a Medicare enrollee. In fact, we explained above that mass immunizers will be able to roster bill for hepatitis B vaccines and their administration. We advise mass immunizers to check the CMS roster billing web page at *https://www.cms.gov/roster-billing* for updates regarding the timing and implementation of roster billing for Hepatitis B vaccines.

Regarding commenters' concern that a patient's physician may not be aware of the administration of a hepatitis B vaccine by a mass immunizer, we note that CMS continually encourages and aims to facilitate care coordination between providers and other practitioners, and we do so in this case as well. We also note that in section II.M. of this final rule, we reference the CDC's guidance that it is not harmful to vaccinate people who are immune to hepatitis B virus because of current or previous infection or vaccination, nor does it increase the risk for adverse events.[1] Therefore, individuals may receive a covered vaccination series when their medical history is not available.

Comment: Some commenters asked that CMS expand the mass immunizer program to include all future Part B preventive vaccines.

Response: We did not make any proposals regarding future expansions of the Part B preventive vaccine benefit. Legislation would be necessary to expand Part B coverage for additional preventive vaccines under section 1861(s)(10) of the Act. These comments are outside the scope of our proposals.

3. Payment for Drugs Covered as Additional Preventive Services (§ 410.152)

a. Statutory Background

Section 101 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275) added section 1861(ddd)(1) and (2) of the Act to effectuate ''improvements to coverage of preventive services'' in the Medicare program. Under section 1861(ddd)(1) of the Act, Medicare Part B covers

[1] CDC. Viral hepatitis. FAQ for health professionals. Atlanta, GA: U.S. HHS, CDC; 2022. Retrieved from *https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

''additional preventive services'' that identify medical conditions or risk factors and that the Secretary determines are reasonable and necessary for: (A) the prevention or early detection of an illness or disability; (B) that are recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) that are appropriate for individuals entitled to benefits under Part A or enrolled under Part B. Section 1861(ddd)(2) of the Act states that, in making determinations under section 1861(ddd)(1) of the Act, the Secretary shall use the process for making National Coverage Determinations (NCD) in the Medicare program.

Section 101 of MIPPA also added section 1833(a)(1)(W) of the Act, which provides requirements for payment of additional preventive services. Section 1833(a)(1)(W)(i) establishes requirements for payment of additional preventive services that are clinical diagnostic laboratory tests, and section 1833(a)(1)(W)(ii) establishes requirements for payment of all other services. Section 1833(a)(1)(W)(ii) (as amended by section 4104 of the Affordable Care Act (Pub. L. 111–148) requires that the amount paid for the provision of all other additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph.

We noted that ''additional preventive services'' are a subset of ''preventive services'' under Medicare Part B, per section 1861(ddd)(3) and 1861(ww)(2)(O) of the Act, respectively. Section 1833(b)(1) of the Act states that the annual Part B deductible does not apply to preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population, and section 1833(a)(1)(Y) of the Act waives coinsurance for preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population. Based on all the above statutory authorities, there is no cost-sharing under Part B for additional preventive services for Medicare enrollees, that is, there is no applicable beneficiary coinsurance or deductible for these services.

The term ''preventive services'' is defined at § 410.2, and coverage for ''additional preventive services'' is delineated at § 410.64. At § 410.152(l), we list the Part B preventive services that are paid at 100 percent of the Medicare payment amount, that is, for which zero coinsurance is charged. There, at § 410.152(l)(11), we include ''additional preventive services identified for coverage through the national coverage determination (NCD) process''. At § 410.160(b), we list the Part B services that are not subject to the Part B annual deductible and do not count toward meeting that deductible, and ''additional preventive services identified for coverage through the national coverage determination (NCD) process'' is included there at § 410.160(b)(13).

The payment authority under section 1833(a)(1)(W)(ii) of the Act has not been utilized to date because CMS has not yet covered any additional preventive service that would require use of that payment authority. While CMS currently covers certain screenings and therapies as additional preventive services under the section 1861(ddd) of the Act, those screenings and therapies are currently paid under the existing PFS fee schedule for physician services. Furthermore, the Medicare Diabetes Prevention Program, described at section III.E of this final rule, uses section 1833(a)(1)(W)(ii) of the Act authority to waive the coinsurance and deductible as described above, but its payment policy is based on separate authorities under the model.

Specifically, we noted that CMS has not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. This was highlighted when CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. This proposed NCD announced CMS' intention to cover and pay for those drugs under section 1861(ddd) of the Act's additional preventive services authority, and the final NCD was released on September 30, 2024. For more information on the final NCD for PrEP for HIV drugs, please see *https://www.cms.gov/medicare/coverage/prep*.

We also noted that CMS covers and pays for Part B vaccines, which are also considered preventive services under sections 1861(ddd)(3) and 1861(ww)(2)(A) of the Act, but they have unique payment rates specified in statute at section 1842(o)(1)(A)(iv) of the Act (for more information, see above at section III.H.1.a. of this final rule).

b. Fee Schedule for Drugs Covered as Additional Preventive Services (DCAPS)

As discussed above, the authority at section 1833(a)(1)(W)(ii) of the Act provides for payment for additional preventive services, including drugs. This authority differs from the authority used to pay for drugs that are separately paid as drugs and biologicals under other Part B payment authorities. Specifically, payment for most drugs separately payable under Part B is authorized at section 1833(a)(1)(S) of the Act and outlined at section 1842(o)(1)(C) of the Act, and those payments are generally made according to the methodology described at section 1847A of the Act, which typically reflects a payment limit based on the Average Sales Price (ASP). In addition, because drugs covered as additional preventive services (hereinafter, DCAPS; we will use the term ''DCAPS drugs'' for the ease of the reader) are not described in section 1842(o)(1)(C) of the Act, provisions under section 1847A of the Act would not apply, including requirements for manufacturers to report ASP data to CMS on a quarterly basis (see sections 1847A(f) and 1927(b)(3)(A)(iii) of the Act). When manufacturers are not required to report the manufacturer's ASP for a drug, they may do so voluntarily, but the availability of voluntarily reported ASP data cannot be guaranteed, and the data may not reflect all available NDCs for the drug. However, we emphasize that DCAPS drugs that are also covered under Part B for non-preventive indications (that is, are also used for diagnosis or treatment) would be subject to ASP reporting requirements.

Above, we mentioned that section 1833(a)(1)(W)(ii) of the Act requires that the amount paid for the provision of additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph. For purposes of this policy, we refer to the amount determined under the fee schedule as the payment limit, which we discuss in detail below.

In the CY 2025 PFS proposed rule (89 FR 61931), we proposed a fee schedule for DCAPS drugs that uses existing Part B drug pricing mechanisms, because we believe that it is preferable to set all drug payment limits under Part B, including those for DCAPS, as consistently as possible. Accordingly, we proposed that the payment limit for a DCAPS drug be determined using the methodology described in section 1847A of the Act, or, if ASP data is not available for a particular drug, to use an alternative pricing mechanism, as described below. We proposed to update the fee schedule quarterly, on the same schedule as the ASP pricing file, which is updated each calendar quarter.

(1) Payment Limit Based on Section 1847A of the Act

To determine the payment limit for the applicable billing and payment code for a DCAPS drug under the fee schedule, we proposed to apply ASP methodology described in section 1847A of the Act when ASP data is available for the drug. We believe the use of ASP data would be preferable for determining the payment limit for DCAPS drug billing and payment codes for two reasons. First, this approach would determine the payment limit for these drugs in the same way as the payment limit is usually determined for other drugs that are separately payable under Part B, when possible. This would include the application of payment limit calculations for multiple source drugs, single source drugs and biologicals, and biosimilar biological products, as is done for products under section 1847A of the Act, for each applicable billing and payment code. Second, because section 1847A(c)(3) of the Act requires that calculation of the manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program), this would set a payment limit that would likely better reflect acquisition cost of the drug than list prices in available compendia (such as Wholesale Acquisition Cost (WAC)).

We proposed that CMS would determine the payment limit for DCAPS drugs as the amount that would result from application of ASP methodology in section 1847A of the Act only if ASP data for the drug is available for a given quarter (that is, positive manufacturer's ASP data is reported by the drug manufacturer, as explained in section III.A.2 of this final rule). We proposed that if ASP data is available for a DCAPS drug, the payment limit would be the amount described in section 1847A(b) of the Act, which is usually 106 percent of ASP.

(2) Payment Limit Based on National Average Drug Acquisition Cost (NADAC) Pricing

If ASP data for a DCAPS drug (as described in the previous section) is not available (as defined in the prior paragraph), we proposed to determine the payment limit for the applicable billing and payment code using the most recently published amount for the drug in Medicaid's NADAC survey (OMB control number 0938–1041).[631] When using NADAC data, we proposed to determine the payment limit per billing unit, which would be an average of NADAC prices for all NDCs for the drug. If a drug is available in generic and brand formulations, we proposed all NDCs will be averaged together to determine the payment limit.

Since the timing of ASP reporting and publishing has a two-quarter lag (for example, payment limits calculated using data reported from the first quarter of sales become effective two quarters later), we proposed that ''most recently published'' for purposes of this policy means the most recently updated NADAC survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[632] For example, in the calculation of the payment limit for dates of service in the third calendar quarter, if NADAC is used to determine the payment limit, we will use the most recent NADAC survey update available on the 30th day after the close of the first calendar quarter to determine the payment limit for the third quarter.

The NADAC survey provides a national drug pricing benchmark for certain drugs that is adequately comprehensive to serve as the first alternative pricing source in the case that ASP data is not available. CMS conducts surveys of retail community pharmacy prices to develop the NADAC pricing benchmark in the annual NADAC pricing file. The pricing benchmark is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. NADAC data is publicly available, and it can be accessed at *https://data.medicaid.gov/nadac*.

In the CY 2020 PFS final rule (84 FR 62655), we similarly finalized the use of NADAC pricing as a pricing alternative for oral drugs under the Part B Opioid Treatment Program (OTP) benefit when ASP data is not available. There, we stated that ''[s]urvey data on invoice prices provide the closest pricing metric to ASP that we are aware of.'' Because the previous statement continues to be true, it is an appropriate alternative in the pricing framework for DCAPS drugs when ASP data is not available.

(3) Payment Limit Based on the Federal Supply Schedule (FSS)

Since NADAC pricing is only available for drugs typically dispensed through retail community pharmacies, there could be circumstances in which ASP and NADAC data are not available for DCAPS drugs. Therefore, if both ASP and NADAC pricing data are not available for a DCAPS drug, we propose to use the most recently published and listed prices for pharmaceutical products in the FSS to calculate the payment limit for the applicable billing and payment code. In the same manner as discussed in the previous section, we propose that ''most recently published'' for purposes of this policy means the most recently updated FSS survey available 30 days after the close of the quarter for which ASP data would have been reported if it were available.[633] For example, in the calculation of the payment limit for dates of service in the third calendar quarter, if FSS is used to determine the payment limit, we will use the most recent FSS update available on the 30th day after the close of the first calendar quarter to determine the payment limit for the third quarter. When using the FSS, we will calculate the average price per billing unit (as described in the billing and payment code for the drug) for all NDCs listed for a drug.

Drug pricing information from the Veterans Affairs' (VA's) FSS pharmaceutical pricing database is publicly available at the NDC level and published at *https://www.va.gov/opal/nac/fss/pharmPrices.asp*. We proposed to use FSS data when ASP and NADAC data are not available because FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, including both self-administered drugs typically dispensed through retail community pharmacies and drugs administered incident to a physician's service. We believe that using FSS data to calculate the payment limit for DCAPS drugs is preferable to instructing MACs to determine DCAPS drug payment limits according to invoice (as discussed below), because invoice-based pricing requires MACs to manually process claims and is therefore burdensome to the MACs.

(4) Invoice Pricing

Finally, if ASP, NADAC, and FSS pricing are not available for a particular drug covered as an additional preventive service, then MACs will determine the payment for that drug according to invoice. Since one of the three above pricing mechanisms should be available in nearly all cases, we expect that invoice pricing would be necessary only in rare situations. Specifically, we believe that invoice

[631] *https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html.*

[632] 42 CFR 414.804(a)(5).

[633] 42 CFR 414.804(a)(5).

pricing would likely only be necessary for new drugs before pricing data is available.

To summarize, we proposed to establish a fee schedule using the following pricing mechanisms to determine the payment limit for DCAPS drugs under Part B, which would be updated quarterly:

(1) If ASP data is available for the DCAPS drug, the payment limit would be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);

(2) If ASP data is not available, the payment limit would be calculated using NADAC prices for the drug;

(3) If ASP data and NADAC prices are not available, the payment limit would be calculated using the FSS prices for the drug; and

(4) If ASP data, NADAC prices, and FSS prices are not available, payment limit would be the invoice price determined by the MAC.

We proposed to amend § 410.152 by adding paragraph (o) to establish the fee schedule and the pricing methodologies used to determine the payment limit for DCAPS drugs under Part B. In addition, to highlight that coinsurance does not apply to DCAPS drugs, we proposed to publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

We solicited public comment on the proposed fee schedule for drugs paid as additional preventive services.

The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of the general approach represented by our payment proposals for DCAPS drugs. Commenters supported potential expansions of coverage and payment for preventive services under Medicare Part B. Some commenters specifically noted and appreciated the waiver of cost-sharing for certain preventive services. Other commenters noted that they believe strengthening access to preventive services helps to ameliorate medical crises later downstream, especially for Medicare enrollees living with mental health and substance use conditions. Another commenter appreciated that once a DCAPS fee schedule is finalized, CMS can cover and pay for drugs without delay if CMS determines that a drug meets the criteria under section 1861(ddd)(1) of the Act.

Commenters also specifically supported our proposed fee schedule. Commenters noted that they appreciated our alignment of the fee schedule with payment policies for other Part B drugs. Many commenters supported our proposal to pay for DCAPS drugs based on section 1847A of the Act, if ASP data is available for the DCAPS drug. Commenters also supported our proposal to direct MACs to use invoice pricing as a last alternative for payment of DCAPS drugs.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to promote access to preventive health care for Medicare enrollees.

Comment: Several commenters requested that we reconsider our proposals regarding alternative payment mechanisms for DCAPS drugs if ASP data is not available for the drug. These commenters stated that they believe payment calculated according to NADAC or FSS pricing would likely result in underpayments that would not reflect the costs incurred by providers to acquire DCAPS drugs. Instead, these commenters recommended that we use pricing based on WAC as an alternative to payment according to ASP methodology. They stated that WAC is a publicly available benchmark, and that they believe WAC plus 3 percent provides a more predictable payment amount compared to other pricing metrics CMS proposed, including NADAC, FSS, and invoice pricing. Commenters noted that setting a price using WAC plus 3 percent is consistent with CMS payment policy for Part B drugs during the initial sales period when ASP data is not yet available, and thus they believe it is most sensible alternative for DCAPS drug payment.

Some commenters argued that the predictability of WAC would help providers manage their finances better, which they state is especially important for smaller practices or those in underserved areas. Other commenters claimed that WAC is a more accurate representation of the price paid by a pharmacy relative to NADAC pricing, since NADAC prices are based on pricing data that CMS receives from pharmacies, and thus they believe that the pricing data is somewhat lagged and inconsistent. These commenters also stated that, since FSS pricing is a negotiated price specifically for certain government programs, they believe that it does not reflect broader market prices and may be significantly lower than market prices. These commenters also believe that using WAC-based pricing will more effectively meet our stated goal of setting drug payment limits for DCAPS as consistently as possible with other payment mechanisms used in Part B.

One commenter specifically recommended that, if we do finalize the use of FSS pricing as an alternative pricing mechanism for DCAPS drugs, that we use the ''other government agencies'' (OGA) price, as opposed to other pricing used in the FSS.

Some commenters recommended that, in cases where a HCPCS code and/or ASP data is not available for a new DCAPS drug, CMS pay for the drug in the physician office setting at WAC plus 3 percent, in the same manner as separately payable Part B drugs as described above. Commenters explained that this would also ensure consistency for all drugs paid under Medicare Part B.

Other commenters generally called for CMS to ensure that the DCAPS fee schedule provides adequate payment to cover pharmacy acquisition and dispensing costs, and asked CMS to promote increased access to preventive drugs.

Response: We thank commenters for their feedback. We agree with commenters that an ASP-based payment limit is preferrable for DCAPS drugs, and the proposed DCAPS fee schedule is designed with that goal in mind. As mentioned above, section 1847A(c)(3) of the Act requires that calculation of the manufacturer's ASP for an NDC must include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program, discounts under the 340B Program, and rebates under the Part B and Part D Medicare inflation rebate program). Therefore, an ASP-based payment limit likely better reflects acquisition cost of the drug than list prices in available compendia, such as WAC.

Above, we mentioned that we stated in the CY 2020 PFS final rule (84 FR 62655) that we believe NADAC survey data on invoice prices provides the closest pricing metric to ASP-based payment limits that is available. We also mentioned above that FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, which is why we chose it as an additional alternative for DCAPS drug fee schedule pricing. Thus, our proposal explained that ASP, NADAC and FSS are all drug pricing options that aim to estimate the accurate acquisition cost of a drug, rather than WAC, which is a list price often higher than acquisition cost.

With regard to the comment that asked for clarification regarding FSS pricing, we clarify that the FSS price is the indeed the ''other government agencies'' (OGA) price. We also reiterate that both NADAC and FSS OGA pricing

are publicly available, and we provide website information earlier in this section of the final rule.

In addition, we reiterate that NADAC pricing is used as a payment alternative to ASP-based payment for drugs used in the Part B OTP benefit, and thus, our use of NADAC pricing aligns with payment policies under Part B. Section 1847A of the Act specifies that payment should be made for drugs under Medicare Part B using WAC in limited circumstances such as (1) during an initial period of when the first quarter of sales is unavailable for a drug or (2) for single-source drugs or biologicals whose ASP exceeds WAC. WAC is generally not used when ASP is unavailable beyond those circumstances.

However, we encourage drug manufacturers to submit ASP data to CMS (that is, positive manufacturer's ASP data is reported by the drug manufacturer, as explained in section III.A.2 of this final rule). We continue to believe that ASP-based payment limits are the most accurate drug pricing methodology that is available to CMS. Drug manufacturers can report manufacturer's ASP data to CMS on a quarterly basis in order ensure that payment limits are set based on ASP. More information on ASP reporting is available at *https://www.cms.gov/medicare/payment/part-b-drugs/asp-reporting.*

Comment: One commenter requested that CMS make pricing publicly available.

Response: We direct the commenter to section III.H.3.c. below, regarding DCAPS drug supply and administration fees. There, we state that CMS intends to make the DCAPS fee schedule publicly available by publishing the DCAPS fee schedule quarterly on the CMS website.

Comment: One commenter mentioned that our proposed payment calculations for DCAPS drugs included averaging across brand and generic drugs, where applicable. This commenter stated that they generally support CMS bundling items and services to the extent possible, but they requested that CMS monitor conditions to ensure that this does not have any unintended consequence on patient access to DCAPS drugs.

Response: We thank the commenter for raising this concern. In Chapter 17, section 20.1.3 and 20.4 of the Medicare Claims Processing Manual, we discuss calculations for pricing multiple-source drugs in Part B, as defined at section 1847A(c)(6)(C) of the Act, when the payment limits are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File. In those sections of the Medicare Claims Processing Manual, the pricing calculation for WAC and AWP respectively, is described as the lesser price of:

- The median of all generic forms of the drug or biological; or
- The lowest brand name product.

Based on the commenter's remarks and our historical Part B drug policies, we are persuaded to amend our proposed policy as to DCAPS pricing calculations. We proposed to average together all NDCs of a drug if a drug is available in generic and brand formulations to determine the payment limit. However, in light of commenters' feedback, we are finalizing a DCAPS drug pricing policy to treat brand and generic drugs in a similar manner to the description in the Medicare Claims Processing Manual, Chapter 17, sections 20.1.3 and 20.4, as described above. We believe this will avoid the unintended consequences referenced by the commenter, and thus not create a differential pricing barrier for patients between brand and generic DCAPS drugs, and that pricing for those drugs is not unintentionally inflated. We believe that this longstanding payment approach will appropriately use NADAC and FSS pricing to determine payment limits for DCAPS drugs for which brands and generics are marketed.

Therefore, when calculating the price for multiple-source DCAPS drugs using NADAC or FSS OGA pricing, we will use the lesser price of:

- The median of all generic forms of the drug; or
- The lowest brand name product.

Comment: Many commenters provided suggestions, feedback, and comments on the Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, published on July 12, 2023, as the NCD was not yet finalized as of the end of the comment period for the CY 2025 PFS proposed rule on September 9, 2024. Comments included requests to ease the transition of PrEP for HIV drugs from Part D to Part B, the role of pharmacies and pharmacists in supplying PrEP for HIV drugs under Part B, and concerns regarding access to, adequate coverage for, and beneficiary protections for PrEP for HIV drugs. One commenter expressed concern regarding payment for PrEP for HIV drugs under Part B in the interim period between the commencement of coverage and the DCAPS payment policy taking effect on January 1, 2025. Another commenter requested that CMS clarify 340B reporting requirements for PrEP for HIV drugs covered and paid under Part B. Some commenters also requested that CMS simplify coding and billing for PrEP for HIV drugs and supply fees. One commenter requested that CMS extend these DCAPS coverage and payment policies to all provider-administered HIV treatments. Another commenter asked that CMS align coverage policies with the USPSTF's 2023 recommendation for the Prevention of Acquisition of HIV: Preexposure Prophylaxis, and asked CMS to create a safe harbor for PrEP products in the first year following transition from Part D to Part B.

Response: This DCAPS fee schedule has been established to apply to any current and future drugs covered as additional preventive services under 1861(ddd)(1) of the Act, effective January 1, 2025. These proposals did not address specifics regarding the NCD for PrEP for HIV drugs, and therefore, the additional comments on the proposed NCD are out of the scope of these proposals. The public comment period on the proposed NCD for PrEP for HIV drugs was from January 12, 2023–February 11, 2023. The final NCD was released on September 30, 2024, and is available at *https://www.cms.gov/medicare/coverage/prep.*

We thank commenters for their feedback regarding Medicare Part B payment for PrEP for HIV drugs. We direct interested parties to *https://www.cms.gov/medicare/coverage/prep* for more information on the final NCD and the transition of PrEP for HIV coverage and payment from Part D to Part B. This CMS PrEP web page contains and/or will contain additional guidance on implementation of PrEP for HIV coverage under Part B, including coding and billing information, payments for PrEP for HIV for the period of September 30–December 31, 2024, and the implementation of the DCAPS fee schedule for PrEP for HIV drugs, which will be effective January 1, 2025, upon this final rule's publication. Payment information for the period of September 30–December 31, 2024, is out of scope of this final rule because this final rule is effective January 1, 2025. However, we will continue to update the CMS PrEP web page as we prepare to implement the DCAPS fee schedule beginning January 1, 2025. We share commenters' priority of ensuring patient access to DCAPS drugs, and as we continue to implement the final NCD, we will continue to communicate updates regarding payment for PrEP for HIV drugs under Part B.

We note that comments regarding USPSTF recommendations for coverage of PrEP for HIV drugs, ''safe harbor''

regulations, the role of pharmacists in supplying PrEP for HIV drugs, and 340B reporting requirements, are out of the scope of these payment policy proposals.

Comment: Commenters had additional suggestions regarding the ''additional preventive services'' benefit category. One commenter suggested that CMS should consult with interested parties to determine what other services should be considered ''preventive.'' Some commenters had questions regarding coverage and payment for DCAPS drugs under Medicare Advantage and Medicare Prescription Drug Plans.

Response: We did not make any proposals regarding expanding preventive coverage under Medicare Part B, and we did not make any proposals regarding DCAPS drug coverage in Medicare Parts C and D. These comments are outside of the scope of our proposals.

After consideration of public comments, we are finalizing these DCAPS drugs policies mostly as proposed, with the modification to our policy regarding brand and generic drugs, as described in the responses above, and summarized below. We are establishing a fee schedule using the following pricing mechanisms to determine the payment limit for DCAPS drugs under Part B, which will be updated and published on the CMS website quarterly:

(1) If ASP data is available for the DCAPS drug, the payment limit would be determined based on the methodology under section 1847A(b) of the Act (usually 106 percent of ASP);

(2) If ASP data is not available, the payment limit would be calculated using NADAC prices for the drug;

(3) If ASP data and NADAC prices are not available, the payment limit would be calculated using the FSS prices for the drug; and

(4) If ASP data, NADAC prices, and FSS prices are not available, payment limit would be the invoice price determined by the MAC.

In this final rule, we are clarifying that the FSS price is the ''other government agencies'' price. We are also finalizing the policy we described above, that for purposes of NADAC and FSS price calculations for DCAPS drugs pricing, we will treat brand and generic drugs in a similar manner to the description in the Medicare Claims Processing Manual, Chapter 17, sections 20.1.3 and 20.4. Thus, when calculating the price for multiple-source DCAPS drugs using NADAC or FSS OGA pricing, we will use the lesser price of:

- The median of all generic forms of the drug; or
- The lowest brand name product.

We are amending § 410.152 by adding paragraph (o) to establish this fee schedule and the pricing methodologies used to determine the payment limits for DCAPS drugs under Part B. In addition, to highlight that coinsurance does not apply to DCAPS drugs, we will publish the payment limits for DCAPS drugs along with other separately payable Part B drugs on the ASP pricing file.

c. Payment for Supplying and Administration of Drugs Under the Additional Preventive Services Benefit

As explained above, DCAPS drugs are subject to payment under section 1833(a)(1)(W)(ii) of the Act. Because the fee schedule authorized under such section has not yet been established, and since DCAPS drugs are not covered by Part B under the same authority as other separately payable Part B drugs that would provide for administration or supplying fees, there is no existing policy regarding payment for the administration of DCAPS drugs or the supplying of DCAPS drugs by suppliers and providers. In a similar manner to the DCAPS drug pricing mechanisms described above, we proposed administration and supplying fees for DCAPS drugs that mirror existing policies under the PFS and Part B drug payment. We anticipate that an NCD that adds drugs to the additional preventive services benefit would include coverage for the supplying or administration of the drug, as appropriate, and those fees would therefore be considered payment for additional preventive services as well. (For example, supply and administration fees are included as part of the final NCD for PrEP for HIV drugs, found at *https://www.cms.gov/medicare/coverage/prep*.) Therefore, we proposed payment limits for the supply and administration of DCAPS drugs to be included on the DCAPS fee schedule. As stated above, section 1833(a)(1)(W)(ii) of the Act requires that the amount paid for the provision of additional preventive services is 100 percent of the lesser of the actual charge for the service, or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph. That is, the amount paid for the administration or supplying of the DCAPS drug will be the lesser of either the actual charge for the service or the payment limit.

For drugs that are supplied by a pharmacy, we proposed that the fee schedule include a payment limit for a supplying fee that is similar to the supplying fee for other Part B-covered drugs dispensed from a pharmacy, to allow for consistency among similar payments in Part B. These other groups of drugs covered under Part B include immunosuppressives, oral anti-cancer, and oral anti-emetic drugs, and supplying fees for these drugs are described at 42 CFR part 414, subpart L (§§ 414.1000 and 414.1001). Generally, Medicare pays $24 for the first prescription of one of these drugs supplied by a pharmacy in a 30-day period, and pays $16 for each subsequent prescription, after the first one, supplied in that 30-day period.[634] We proposed similar payment limits for supplying fees for DCAPS drugs. Specifically, we proposed that CMS will establish payment limit of $24 to a pharmacy for the first DCAPS prescription that the pharmacy supplies to a beneficiary in a 30-day period, and a payment limit of $16 to a pharmacy for all subsequent DCAPS prescriptions that the pharmacy supplies to a beneficiary in that 30-day period. We proposed that the same fees would apply regardless of the number of days' supply that is dispensed.

As discussed in section III.A.4.c of this final rule, further study regarding the supplying fees for certain drugs paid under Part B (for example, immunosuppressive drugs) is needed and we did not propose to make any changes to the supplying fee amounts at this time (meaning the current 30-day supplying fees would apply to any amount of days' supply). The dispensing and supplying fees under Part B (§ 414.1001) have been shown to be higher than dispensing fees paid in the commercial market.[635] So, until additional study is done regarding input costs for dispensing drugs billed to Medicare Part B and subsequent notice-and-comment rulemaking can be done, if appropriate, in response to such information, we aim to continue the current fee schedule for such Part B drugs regardless of the days' supply dispensed. Therefore, we proposed to use the same approach for payment limits that are paid to pharmacies that supply DCAPS prescriptions.

For drugs that are administered by a physician or a non-physician practitioner, we proposed that the fee schedule include a payment limit for

[634] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf*.

[635] *https://www.pcmanet.org/rx-research-corner/mandating-pharmacy-reimbursement-increase-spending/08/31/2021/#:#:text=The%20average%20dispensing%20fee%20in,the%20state's%20Medicaid%20FFS%20rate.*.

such administration that aligns with the administration fee for other drugs provided as incident to physician services, as paid according to the PFS. To operationalize this, we proposed that CMS determine the payment limit for administration of a DCAPS drug provided incident to a physician service via a crosswalk to an existing, corresponding drug administration code under the PFS. Exact details on coding and corresponding crosswalks would be included on the published DCAPS fee schedule once DCAPS drugs are finalized for coverage via the NCD process. The fee schedule will be published quarterly on the CMS website and implemented in the Medicare claims processing systems.

No cost sharing would apply for the administration or supplying of DCAPS drugs, because we proposed that such administration or supplying will be considered an additional preventive service, and as explained above, there is no cost-sharing for any additional preventive services under section 1833(a)(1)(W) of the Act. We proposed to codify these policies at the newly added § 410.152(o).

We noted that with regard to the July 12, 2023 Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, in section II.E.4.b. of this final rule, in item 37, we proposed national rates for HCPCS code G0012 (*Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle*) that are crosswalked from CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Please see that section of the final rule for more information on finalized coding for PrEP for HIV administration. For more information on the final NCD for PrEP for HIV drugs, please see *https://www.cms.gov/medicare/coverage/prep*.

We solicited comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters were supportive of our proposals to set payment limits for DCAPS drug supplying fees that are similar to the supplying fees for other Part B-covered drugs dispensed from a pharmacy. Commenters appreciated our efforts to align payments across health care settings and to allow for consistency among similar payments in Part B.

Response: We thank commenters for their support of our proposals and for partnering with CMS in our efforts to improve access to preventive health care for Medicare enrollees.

Comment: One commenter noted the Medicare Payment Advisory Commission's (MedPAC) 2016 Report to the Congress, in which MedPAC recommended that CMS reduce Part B drug supply fees to match those of other payers, as Medicare supply fees have been found to be substantially higher than those paid by other payers.[636] This commenter recommended that CMS revisit its Part B drug supplying and dispensing fee rates and reduce them to levels similar to other payers.

Response: In section III.A.4.c of this final rule, further study the supplying fees for certain drugs paid under Part B in needed. We take this comment into consideration for future policymaking. Any future changes to supply fees will be proposed via notice-and-comment rulemaking.

Comment: One commenter, commenting specifically on the NCD for PrEP for HIV drugs, asked CMS to consider a higher supplying fee to help cover pharmacy costs inflicted by the coverage transition. The commenter recommended that CMS consider the existing supply fees for immunosuppressive therapy during the first 30-day period following a transplant. This commenter also recommended that supply fees be regularly updated and that CMS ensure that the fees reasonably and accurately reflect the additional effort necessary for pharmacies to acquire and dispense DCAPS drugs.

Response: Further study the supplying fees for certain drugs paid under Part B is needed. We will take this comment into consideration as part of that further study. Any future changes to supply fees will be proposed via notice-and-comment rulemaking.

For more information on supply fees for PrEP for HIV drugs, please see *https://www.cms.gov/medicare/coverage/prep*. This CMS PrEP for HIV web page contains information on the final NCD, the transition of PrEP for HIV coverage and payment from Part D to Part B, and additional guidance on implementation of PrEP for HIV coverage under Part B, including supply fees.

[636] Medicare Payment Advisory Commission. 2016. Report to the Congress: Medicare and the health care delivery system. Washington, DC: MedPAC. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*.

d. Payment for Drugs Covered as Additional Preventive Services in RHCs and FQHCs

Above, we mentioned that section 4104 of the ACA amended payment for additional preventive services, to increase payment to the lesser of 100 percent of charges, or the amount determined under a fee schedule established by the Secretary, per section 1833(a)(1)(W)(ii) of the Act. This change waived coinsurance for additional preventive services. Section 4104 of the ACA also removed several other barriers to access to preventive services in Medicare. Specifically, section 4104 of the ACA amended section 1833 of the Act to waive the deductible for preventive services at section 1833(b)(1) of the Act, and to waive coinsurance for preventive services that are recommended with a grade of A or B by the USPSTF for any indication or population by adding section 1833(a)(1)(Y) of the Act. We also mentioned above that ''additional preventive services'' are a subset of ''preventive services'' under Medicare Part B, per section 1861(ddd)(3) and 1861(ww)(2)(O) of the Act, respectively.

In the CY 2011 PFS final rule, we interpreted the above waivers of cost-sharing for preventive services to apply to FQHCs (75 FR 73417); we note that FQHC services were already exempt from the Part B deductible, per section 1833(b)(4) of the Act. The CY 2011 PFS final rule codified this FQHC policy in regulation at § 405.2449 (75 FR 73613), and in sub-regulatory guidance, we clarified that these waivers of cost-sharing for preventive services applied to RHCs as well.[637] In the CY 2014 FQHC PPS final rule (79 FR 25474), at § 405.2410(b), we codified regulations regarding coinsurance in RHCs and FQHCs, ''[E]xcept for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter.'' In the CY 2016 PFS final rule (80 FR 71088), we clarified explicitly that these waivers of cost-sharing (that is, both coinsurance and deductible) for preventive services applied to RHCs.

In the previous sections of III.H.3. of this final rule, we discussed drugs covered as additional preventive services (henceforth ''DCAPS drugs,'' for the ease of the reader). In this section, we clarify that drugs covered as additional preventive services, and any accompanying administration and

[637] Change Request 7208, R2186CP, 03/28/2011 Waiver of Coinsurance and Deductible for Preventive Services in Rural Health Clinics (RHCs), Section 4104 of Affordable Care Act (ACA): *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2186cp.pdf*.

supplying fees, are not subject to cost-sharing in RHCs and FQHCs. Since DCAPS drugs and the services to administer and supply them are all considered additional preventive services, as explained in the previous section, they are paid at 100 percent of the Medicare payment amount in RHCs and FQHCs per §§ 405.2410 and 410.152(l) and they are paid on a claim-by-claim basis.

In addition, we proposed that DCAPS drugs, when administered and supplied in an RHC or FQHC, as well as any administration and supply fee for those drugs, will be paid according to the fee schedule payment limits described above at section III.H.3.b. of this final rule. Since regulations at § 405.2460 allow the payment limitations set out in Part 410 to apply to payment for services provided by RHCs and FQHCs, we believe it is consistent with our current RHC and FQHC payment policies to apply the proposed DCAPS fee schedule payment limits, as discussed above, to those same DCAPS drugs when furnished in an RHC or FQHC. Those payment limits are described earlier in section III.H.3.b. and will be codified at § 410.152(o)(1). We proposed to codify this RHC/FQHC DCAPS policy in regulation as well, at a new § 405.2464(h).

The following is a summary of the comments we received and our responses.

Comment: Commenters supported this DCAPS policy for RHCs and FQHCs. Some commenters specifically noted and appreciated the waiver of cost-sharing for additional preventive services in RHCs and FQHCs. One commenter stated that the proposed DCAPS fee schedule would ensure that RHCs and FQHCs are adequately reimbursed for providing PrEP for HIV drugs to their clients, and this could reduce disparities, since RHCs and FQHCs serve clients from communities with disproportionately low rates of PrEP for HIV drug access. Another commenter noted that RHCs and FQHCs did not receive separate payment for other physician-administered drugs in the past, and this DCAPS payment policy supports RHCs and FQHCs and ensures their financial sustainability.

Response: We thank commenters for partnering with CMS in our efforts to improve access to preventive health care for Medicare enrollees, especially for those vulnerable populations that are served by RHCs and FQHCs. We look forward to continuing our work with all our partners to continue facilitating increased access to preventive health care for both Medicare enrollees and all Americans.

Comment: Some commenters aligned their comments with those on the DCAPS fee schedule in general, as described above in section III.H.3.b. These commenters agreed with our proposal to apply the proposed DCAPS fee schedule payment limits to DCAPS drugs when furnished in the RHC or FQHC setting, though they support WAC-based payment as an alternative to ASP methodology when ASP data is not available for a DCAPS drug.

Response: Please see our response to similar comments mentioned in section III.H.3.b. There, we mentioned that we stated in the CY 2020 PFS final rule (84 FR 62655) that we believe NADAC survey data on invoice prices provides the closest pricing metric to ASP methodology that is available. We also mentioned above that FSS data is one of the few existing options for drug pricing that includes a wide variety of drug formulations, which is why we chose it as an additional alternative for DCAPS drug fee schedule pricing. Thus, our proposal explained that ASP, NADAC and FSS are all drug pricing options that aim to estimate the accurate acquisition cost of a drug, rather than WAC, which is a list price.

At the outset, we encourage drug manufacturers to submit ASP data to CMS (that is, positive manufacturer's ASP data is reported by the drug manufacturer, as explained in section III.A.2 of this final rule). We continue to believe that ASP is the most accurate drug pricing source available to CMS because it reflects the sale price net of discounts as described in section 1847A(c)(3) of the Act. Since other pricing sources (that is, NADAC, FSS, and invoice pricing) are only used in the absence of ASP data, commenters' concerns about these other sources can be mitigated by reporting manufacturer's ASP data to CMS on a quarterly basis. More information on ASP reporting at *https://www.cms.gov/medicare/payment/part-b-drugs/asp-reporting*.

Comment: Several commenters requested that CMS clarify certain operational aspects of the provision of DCAPs drugs in RHCs and FQHCs. These commenters asked if there are a specific ways health centers will be able to access DCAPS drugs. These commenters also asked if any other drugs are being considered for coverage as DCAPS drugs, and if there are other drugs, will CMS publish a list. One commenter asked if there are other DCAPS policies that community health centers and other safety net providers should be aware of. Another commenter asked if RHC and FQHC DCAPS claims should be submitted on a UB–04 or a 1500, and they also asked CMS to clarify if DCAPS would generate additional reimbursement if performed on the same day as another qualifying RHC encounter. Other commenters asked CMS to ensure that RHCs and FQHCs are paid for DCAPS drugs and any administration and supplying fee at 100% of the Medicare payment amount.

Response: As described above in section III.H.3.a. of this final rule, section 1861(ddd)(2) of the Act states that, in making determinations under section 1861(ddd)(1) of the Act, the Secretary should use the process for making National Coverage Determinations (NCD) in the Medicare program. Therefore, any drugs that are being considered for DCAPS coverage will be announced via a proposed NCD and posted for public comment in the Medicare Coverage Database, found at *https://www.cms.gov/medicare-coverage-database/search.aspx*.

All other guidance for RHCs and FQHCs regarding DCAPS drugs will be provided in sub-regulatory guidance and posted on the CMS RHC (*https://www.cms.gov/center/provider-type/rural-health-clinics-center*) and FQHC (*https://www.cms.gov/medicare/payment/prospective-payment-systems/federally-qualified-health-centers-fqhc-center*) websites. For example, current guidance for RHC and FQHC coverage and payment for PrEP for HIV drugs, which are currently the only DCAPS drugs, can be found at the top of each of those websites as of the publication of this final rule.

We also note that we state above in section III.H.3.c., regarding DCAPS drug supply and administration fees, that CMS intends to make the DCAPS fee schedule publicly available by publishing the DCAPS fee schedule quarterly on the CMS website.

Above, we explain that since DCAPS drugs and the services to administer and supply them are all considered additional preventive services, as explained in the previous section, they are paid at 100 percent of the Medicare payment amount in RHCs and FQHCs per §§ 405.2410 and 410.152(l) and they are paid on a claim-by-claim basis. Therefore, we have finalized a policy that payment to RHCs and FQHCs for DCAPS drugs and their supplying and administration, and fees is separate from, that is, paid in addition to the RHC AIR and FQHC PPS. Finally, we note that DCAPS drugs and their supplying and administration fees, when provided by RHCs and FQHCs, would be reported on the UB 04.

Comment: Similar to the general comments on the proposed DCAPS fee schedule, as described above in section

III.H.3.b, several commenters provided feedback on the Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention, published on July 12, 2023, as the NCD was not yet finalized as of the end of the comment period for the CY 2025 PFS proposed rule on September 9, 2024. These comments included concerns regarding the transition of PrEP for HIV drugs from Part D to Part B, and concerns regarding access to, adequate coverage for, and beneficiary protections for PrEP for HIV drugs.

Response: This DCAPS fee schedule has been established to apply to any current and future drugs covered as additional preventive services under section 1861(ddd)(1) of the Act. These proposals do not address specifics regarding the NCD for PrEP for HIV drugs, and therefore, additional comments on the proposed NCD are out of the scope of these proposals. The public comment period on the proposed NCD for PrEP for HIV coverage under Medicare Part B was from January 12, 2023–February 11, 2023. Additional comments on the proposed NCD are out of the scope of this proposal. The final NCD was released on September 30, 2024, and is available at *https://www.cms.gov/medicare/coverage/prep*. We direct interested parties to *https://www.cms.gov/medicare/coverage/prep* for more information on the final NCD and the transition of PrEP for HIV coverage and payment from Part D to Part B.

After consideration of public comments, we are finalizing these policies as proposed. Finalized DCAPS fee schedule information can be found in section III.H.3.b. of this final rule. DCAPS drugs and the services to administer and supply them are paid at 100 percent of the Medicare payment amount, that is, the amounts on the DCAPS fee schedule, in RHCs and FQHCs, and they are paid on a claim-by-claim basis. We are codifying this RHC/FQHC DCAPS policy in regulation at a new § 405.2464(h).

I. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established new requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs covered under Part B and Part D faster than the rate of inflation. Drug manufacturers are required to pay rebates to Medicare if prices for certain drugs covered under Part B increase faster than the rate of inflation for a calendar quarter beginning with the first quarter of 2023; drug manufacturers are required to pay rebates to Medicare if prices for certain drugs covered under Part D increase faster than the rate of inflation over a 12-month period, starting with the 12-month period that began October 1, 2022.

Section 11101 of the IRA amended section 1847A of the Act by adding a new subsection (i), which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the specified amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B.

Section 11102 of the IRA added section 1860D–14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D–14B(b)(3) of the Act. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act (that is, brand name drugs), generic drugs approved under section 505(j) of the FD&C Act that meet certain statutory criteria (that is, sole source generic drugs), and biologicals licensed under section 351 of the Public Health Service Act (PHS), including biosimilars.

Under the IRA, certain statutory requirements vary for implementation of the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. For example, section 1847A(i) of the Act requires CMS to calculate Part B drug inflation rebates for a calendar quarter, whereas section 1860D–14B of the Act requires CMS to calculate Part D drug inflation rebates for a 12-month applicable period. With respect to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, CMS must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, CMS has until September 30, 2025, to invoice manufacturer for rebates. In contrast, under section 1860D–14B(a) of the Act, CMS must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), CMS has until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs used to calculate the rebate amounts for Part B and Part D. As a result, CMS proposed to use different methodologies to calculate inflation rebates for Part B rebatable drugs and Part D rebatable drugs. However, CMS has attempted to align policies across the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate Program to the extent possible.

b. Summary of Proposed Policies for the Medicare Prescription Drug Inflation Rebate Program

In the CY 2025 Physician Fee Schedule (PFS) proposed rule (89 FR 61934), we proposed to codify policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program [638]

[638] Medicare Part B Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf*; Medicare Part D Drug Inflation Rebate Revised Guidance: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf* (collectively referred

(collectively referred to as the ''Medicare Prescription Drug Inflation Rebate Program'') in regulatory text. Specifically, we proposed to codify with limited modification policies set forth in guidance for the Medicare Prescription Drug Inflation Rebate Program by adding new parts 427 and 428 to title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively, and welcomed comments on these proposed provisions.

In addition, we proposed new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Proposed § 427.201(b) provided that CMS will compare the payment amount in the quarterly pricing files published by CMS to the inflation-adjusted payment amount for a given quarter when determining whether the criteria for a coinsurance adjustment are met.
- Proposed § 427.302(c)(3) provided that for a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020 but with a first marketed date after December 1, 2020, the payment amount benchmark quarter for such drug is the third full calendar quarter after the drug's first marketed date. Proposed § 427.302(c)(4) further provided that for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter is the third full calendar quarter after the drug is assigned a billing and payment code other than a NOC code.
- Proposed § 427.303(b)(1)(i) provided that CMS will remove 340B units for professional claims with dates of service during 2024 (in addition to 2023) submitted by Medicare suppliers that are covered entities listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System as participating in the 340B Program, by using National Provider Identifiers and/or Medicare Provider numbers to identify these suppliers and the claims submitted with such identifiers.
- Proposed § 427.303(b)(5) provided that CMS will remove units of refundable single-dose container or single-use package drugs subject to discarded drug refunds, from the calculation of rebate amounts, generally in the reconciliation process.
- Proposed § 427.501 described CMS' method and process for reconciliation of a rebate amount for a Part B rebatable drug, including the circumstances that may trigger such a reconciliation.
- Proposed § 427.600 established a civil money penalty process in accordance with section 1847A(i)(7) of the Act to address when a manufacturer of a Part B rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable calendar quarter.
- Proposed § 427.10 provided that, were any provision of part 427 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions will be severable from part 427 and the invalidity or unenforceability will not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

We also proposed new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Proposed § 428.202(c)(3) provided that if a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, does not have AMP data reported under section 1927(b)(3) of the Act for any quarters during the period beginning on January 1, 2021 and ending on September 30, 2021, CMS will identify the payment amount benchmark period as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP reported. Proposed § 428.202(c)(4) further provided that for a Part D rebatable drug first approved or licensed after October 1, 2021 (that is, a subsequently approved drug), for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3), the payment amount benchmark period will be the first calendar year in which such drug has at least 1 quarter of AMP reported. We also solicited comments on alternative policies to address certain instances in which AMP are not reported for certain NDC–9s of a Part D rebatable drug.
- Proposed § 428.203(b)(2) provided that, for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program. To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, we proposed that CMS will use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. We proposed that CMS may apply adjustment(s) to these data as needed. We also solicited comments on alternative policies for collecting and using 340B data to calculate rebate amounts for Part D rebatable drugs.
- Proposed § 428.401 described CMS' method and process for reconciliation of a rebate amount for a Part D rebatable drug, including the circumstances that may trigger such a reconciliation.
- Proposed § 428.500 established a civil money penalty process in accordance with section 1860D–14B(e) of the Act to address when a manufacturer of a Part D rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug for such applicable period.
- Proposed § 428.10 provided that, were any provision of part 428 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions will be severable from this part and the invalidity or unenforceability will not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

In the CY 2025 PFS proposed rule (89 FR 61936), we proposed that unless otherwise specified, the provisions herein will apply, with respect to Part B rebatable drugs, for all calendar quarters beginning with January 1, 2023, and with respect to Part D rebatable drugs, for all applicable periods beginning with October 1, 2022. We stated that the IRA directs the Secretary to calculate rebate amounts for Part B rebatable drugs beginning on January 1, 2023, and Part D rebatable drugs beginning on October 1, 2022, using pricing data from past periods of time, including benchmark data from periods prior to the statute's enactment. In some cases, the time periods during which prices are subject to rebates began as early as several weeks after the IRA was enacted. In recognition of this timing, section 1860D–14B(h) of the Act specifically requires CMS to use program instruction to implement the Medicare Part D Drug Inflation Rebate Program for 2022, 2023, and 2024. Similarly, the existing provision at

to as the ''revised guidance''). These revised guidance documents, published December 14, 2023, implemented policies relating to the Medicare Prescription Drug Inflation Rebate Program for 2022, 2023, and 2024. CMS also published guidance on the use of the 340B modifier to report separately payable Part B drugs and biologicals acquired under the 340B program (Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier, *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance*.pdf).

section 1847A(c)(5)(C) of the Act, provides authority for CMS to implement the Medicare Part B Drug Inflation Rebate Program using program instruction or other guidance. In addition, sections 1847A(i)(1)(C) and 1860D–14B(a)(3) of the Act, as added by the IRA, permit the Secretary to delay the issuance of Rebate Reports for certain initial calendar quarters and applicable periods until 2025.

We further stated in the CY 2025 PFS proposed rule (89 FR 61936) that section 1871(e)(1)(A) of the Act provides that a substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act may not apply retroactively unless the Secretary has determined that such retroactive application is necessary to comply with statutory requirements or that failure to apply such policies retroactively would be contrary to the public interest. To the extent any proposed provisions in this section III.I. of this rule are considered to apply retroactively, we stated in the CY 2025 PFS proposed rule that CMS has determined that such retroactive application would be both necessary to establish policies to implement the statutory requirements that CMS perform various calculations that involve pricing activities from prior periods and also consistent with the statutory provisions expressly allowing the agency to delay the issuance of rebate reports for initial applicable periods until 2025. In addition, such retroactive application will be in the public interest because it would ensure that the proposed regulations address the same time periods and manufacturer pricing conduct addressed in the IRA and will promote consistency and continuity in program implementation.

We received public comments on the proposed provisions, as well as general comments on the CY 2025 PFS proposed rule. The following is a summary of the general comments we received and our responses; comments and responses on specific provisions are discussed in the subsections below.

Comment: A couple of commenters offered general support for CMS' proposed policies for the Medicare Part B Drug Inflation Rebate Program. One commenter supported CMS' proposed policies—and the IRA more broadly—to help address the prices of prescription drugs furnished to Medicare beneficiaries. One commenter expressed concern about potential unintentional effects of the IRA on certain specialties. However, this commenter did not expand on this statement.

Response: We thank the commenters who expressed support for CMS' proposed policies for the Medicare Part B Drug Inflation Rebate Program. We refer the commenter that expressed concern about the IRA's potential unintentional effects to the CMS IRA mailbox (*IRARebateandNegotiation@cms.hhs.gov*), which CMS established to receive queries related to the implementation of the Medicare Part B and Part D Drug Inflation Rebate Programs and the Medicare Drug Price Negotiation Program.

Comment: One commenter urged CMS to continue to evaluate the full impact of the IRA on access to medicine, including the Medicare Prescription Drug Inflation Rebate Program and the Medicare Drug Price Negotiation Program, noting specifically that the Medicare Drug Price Negotiation Program may have unintended consequences on the economic incentives to develop medicines.

Response: We appreciate this commenter's concern. As discussed in later sections of this final rule, we will monitor certain provisions of the Medicare Part B and Part D Drug Inflation Rebate Programs, including the status of Part B and Part D rebatable drugs on the FDA's shortage list. The commenter's suggestion to monitor the full impact of the IRA, including the impact of the Medicare Drug Price Negotiation Program, on access to medicine is beyond the scope of this final rule.

Comment: One commenter wrote that CMS did not provide sufficient detail for interested parties to meaningfully comment on various proposed policies, including but not limited to the definition of ''misreporting'' at § 427.501(d)(2)(ii) and alternative methodologies for calculating the benchmark period in cases where AMP is not reported. This commenter recommended CMS publish a second proposed rule containing concrete policy proposals that would allow interested parties to meaningfully comment.

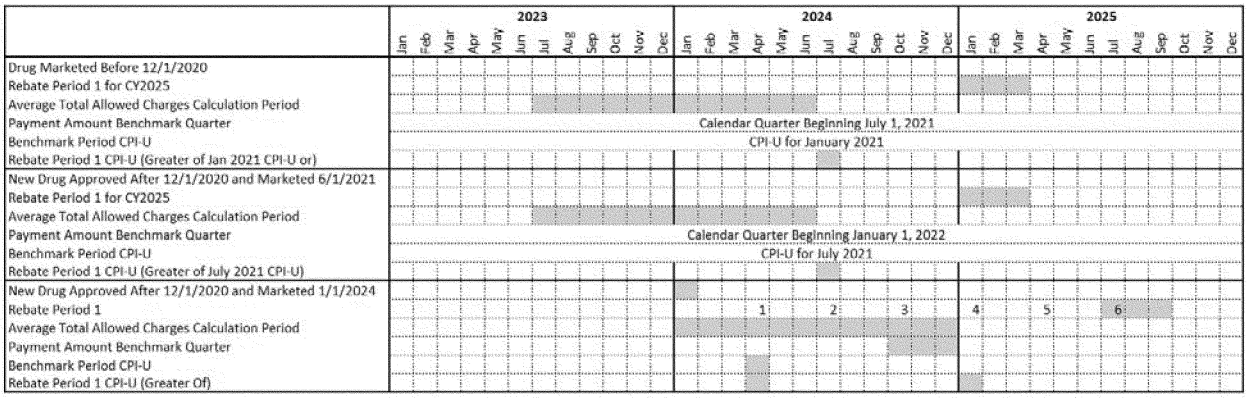
Response: We disagree with the commenter's assertion that the proposed rule did not include sufficient detail to allow interested parties to meaningfully comment on our proposed Medicare Prescription Drug Inflation Rebate Program policies, and, where applicable, the alternative approaches considered. Under the Administrative Procedure Act (APA), in proposed rulemaking, agencies are required to include either the terms or substance of the proposal or a description of the subjects and issues involved. The CY 2025 PFS proposed rule contained sufficient information on our policy proposals to implement the rebate provisions set forth in statute and the alternatives considered to put interested parties on notice of the policies that might be adopted in this final rule and afford them a meaningful opportunity to comment. As evidenced by the comments received in response to the CY 2025 PFS proposed rule, interested parties had a full opportunity to share their views on our proposals and the alternatives considered. We have considered these public comments in developing our policies for this final rule.

After consideration of the public comments received, we are finalizing, with modifications, the proposed policies for the Medicare Prescription Drug Inflation Rebate Program.

c. Timeline of Key Dates for the Medicare Prescription Drug Inflation Rebate Program

As sections 1847A(i)(2)(C) and 1860D–14B(a)(3) of the Act allow for delayed reporting and invoicing of rebates amounts for applicable calendar quarters in 2023 and 2024 for Part B rebatable drugs and the first two applicable periods for Part D rebatable drugs, as proposed, Figures B–I 1 and B–I 2 provide example timelines for how rebates will be calculated for applicable calendar quarters and one applicable period in calendar year 2025. Figures B–I1 and B–I2 also depict how the rebate period and components of the rebate calculation may shift based on the marketing and approval dates for a Part B or Part D rebatable drug.

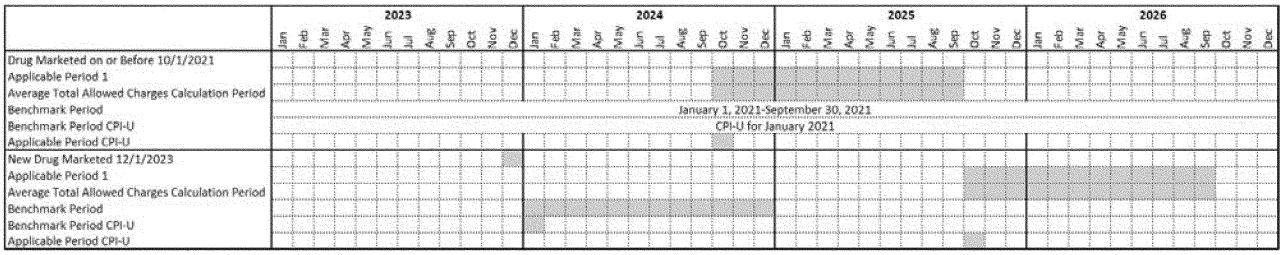
FIGURE B-I1: Summary of Proposed Data Timelines for Part B Drug Inflation Rebate Provisions for Calendar Year 2025[a]



[a] This graphic is an illustrative example of how rebates for quarters in calendar year 2025 will be calculated.

Note: In the case of subsequently approved drugs, a Part B rebatable drug's first applicable calendar quarter will begin the sixth full calendar quarter (denoted with the numbers in the figure) after the day the drug was first marketed or the first quarter of 2023, whichever is later. The Rebate Period CPI-U is the greater of the benchmark period CPI-U or the CPI-U of the first month of the quarter two quarters prior to the rebate period.

FIGURE B-I2: Summary of Proposed Data Timelines for Part D Drug Inflation Rebate Provisions for Calendar Year 2025[a]



[a] *This graphic is an illustrative example of how rebates for one applicable period including months in calendar year 2025 will be calculated.*

As proposed, Table 53 describes a summary timeline for inflation rebate amount reports and deadlines for applicable calendar quarters in calendar year 2025 and thereafter for Part B rebates and for the Part D rebate applicable period beginning on October 1, 2024, and applicable periods thereafter.

TABLE 53: Summary of Proposed Part B and D Drug Inflation Rebate Amount Reports and Deadlines[a]

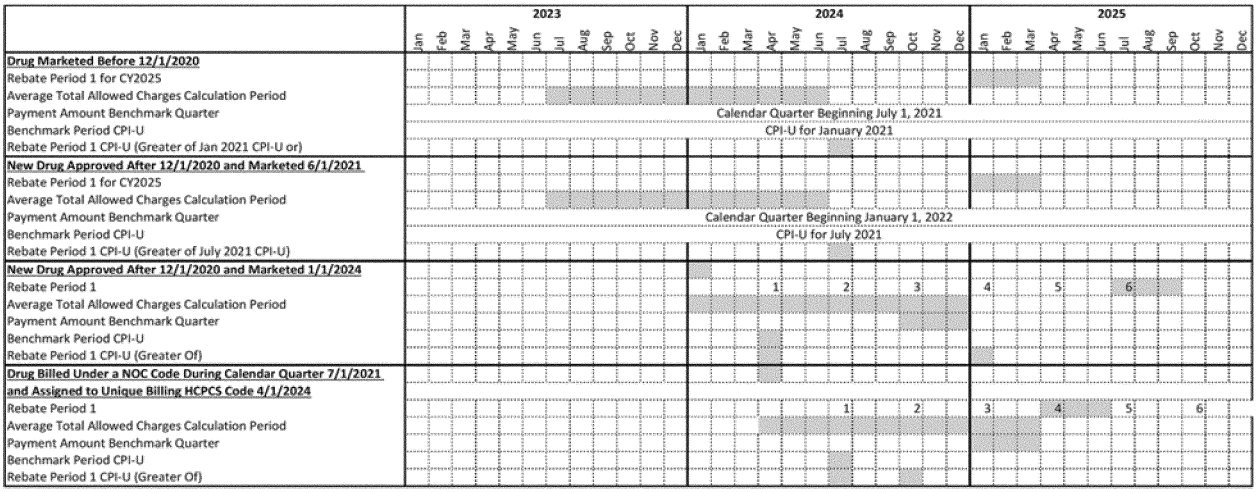
Milestone	Timing/Deadline
Part B Rebate – CMS must invoice manufacturers not later than 6 months after the end of each calendar quarter	
Preliminary Rebate Report sent to Manufacturers	Not later than 5 months after the end of the calendar quarter
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 6 months after the end of the calendar quarter
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
Preliminary Reconciliation Rebate Report sent to Manufacturers	Not later than 11 months after receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Reconciliation Rebate Report
Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Reconciliation Rebate Report
Part D Rebate – CMS must invoice manufacturers not later than 9 months after the end of each applicable period	
Preliminary Rebate Report sent to Manufacturers	Not later than 8 months after the end of the applicable period
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary Rebate Report
Rebate Report sent to Manufacturers	Not later than 9 months after the end of the applicable period
Manufacturer Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the Rebate Report
First Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 11 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the First Reconciliation Preliminary Rebate Report
First Reconciliation Rebate Report sent to Manufacturers	Not later than 12 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the First Reconciliation Rebate Report
Second Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 35 months after the receipt of the Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error should be submitted to CMS not later than 10 calendar days following receipt of the Second Reconciliation Preliminary Rebate Report
Second Reconciliation Rebate Report sent to Manufacturers	Not later than 36 months after the receipt of the Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Second Reconciliation Rebate Report

[a] *The months referred to in these timelines represent calendar months. This means, for example, that if a Preliminary Rebate Report is issued on August 15, 2027, the Rebate Report could be issued up until September 30, 2027.*

We did not receive public comments on the summary timelines. We are adding an amendment to section II.I.1.c. of this final rule to update Figure B–I3: Summary of Proposed Data Timelines for Part B Drug Inflation Rebate Provisions for Calendar Year 2025 as follows. We are adding an example to Figure B–I3 to illustrate how rebates for quarters in calendar year 2025 will be calculated for drugs billed under a NOC code during calendar quarter July 1,

2021 and assigned to a unique billing and payment code on April 1, 2024.

FIGURE B-I3: Provisions for Calendar Year 2025[a]



[a] This graphic is an illustrative example of how rebates for quarters in calendar year 2025 will be calculated.

Note: In the case of subsequently approved drugs, a Part B rebatable drug's first applicable calendar quarter will begin the sixth full calendar quarter (denoted with the numbers in the figure) after the day the drug was first marketed or the first quarter of 2023, whichever is later. For a drug billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the effective date of the drug's assigned billing and payment code other than a NOC code, whichever is later, the drug will be included on the first applicable calendar quarter the earliest applicable calendar quarter that follows the payment amount benchmark quarter. The Rebate Period CPI-U is the greater of the benchmark period CPI-U or the CPI-U of the first month of the quarter 2 quarters prior to the rebate period.

2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 427.20)

At § 427.20, we proposed to codify the definitions of terms consistent with the meanings given in section 1847A(i) of the Act or established in the revised Medicare Part B Drug Inflation Rebate Guidance, as applicable, as well as new definitions based on policies detailed in the proposed rule.

We proposed definitions for the following terms found in section 1847A of the Act:

- ''Benchmark period CPI–U''.
- ''Biosimilar biological product''.
- ''Inflation-adjusted payment amount''.
- ''Manufacturer''.
- ''Part B rebatable drug''.
- ''Payment amount benchmark quarter''.
- ''Payment amount in the payment amount benchmark quarter''.
- ''Rebate period CPI–U''.
- ''Single source drug or biological product''.
- ''Specified amount''.
- ''Subsequently approved drug''.
- ''Unit''.

Further, we proposed to codify at § 427.20 definitions established in the revised Medicare Part B Drug Inflation Rebate Guidance and new definitions based on policies detailed in the proposed rule for the following terms:

- ''Allowed charges''.
- ''Applicable calendar quarter''.
- ''Applicable threshold''.
- ''Average sales price (ASP)''.
- ''Billing and payment code''.
- ''Billing unit''.
- ''CPI–U''.[639]
- ''FDA application''.
- ''Final action claim''.
- ''First marketed date''.
- ''Grouped billing and payment code''.
- ''National Drug Code'' (NDC).
- ''Not Otherwise Classified (NOC) code''.

We have added definitions for the following terms to make a technical clarification as described in section III.I.2.d.iii. of this final rule and based on public comments received and summarized under section III.I.2.d.ii. of this final rule.

- ''Billing and payment code FDA approval or licensure date''.
- ''Sold or marketed''.

After consideration of public comments, we are finalizing, with modifications, the definitions proposed at § 427.20.

b. Determination of Part B Rebatable Drugs (§§ 427.100 Through 427.101)

i. Definitions

In proposed § 427.100, we proposed to define the following terms applicable to subpart B (§§ 427.100 through 427.101):

- ''EUA Declaration''.
- ''Individual who uses such a drug or biological''.

We did not receive comments on these proposed definitions. We are finalizing these definitions as proposed at § 427.100.

[639] These data are referenced to 1982–84=100—that is, the average of pricing data for the 36 months from 1982 through 1984 serve as the basis for the index and are assigned a value of 100. These data are not seasonally adjusted.

ii. Identification of Part B Rebatable Drugs

Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' in part, as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act), for which payment is made under Part B. The definitions for a biosimilar biological product and a qualifying biosimilar biological product are codified at § 414.902.

At § 427.101(a), we proposed to codify the policies established in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify Part B rebatable drugs by (1) identifying the applicable billing and payment code for each single source drug or biological product, including biosimilar biological products, for which payment is made under Part B and (2) excluding any billing and payment code corresponding to a drug or biological product in excluded product categories or that have average total allowed charges below an applicable threshold, to be codified at § 427.101(b) and (c), respectively.[640]

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.101(a).

iii. Excluded Product Categories

Section 1847A(i)(2)(A) of the Act excludes qualifying biosimilar biological products (as defined in section 1847A(b)(8)(B)(iii) of the Act) from the definition of a Part B rebatable drug. As such, at § 427.101(b)(1) we proposed to codify the policy established in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude such products from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates.

Section 1847A(i)(2)(A) of the Act defines a Part B rebatable drug as a ''single source drug or biological (as defined in [section 1847A(c)(6)(D) of the Act]),'' which requires that a single source drug not be a multiple source drug. We have interpreted section 1847A(c)(6)(C)(ii) of the Act to mean that single source drugs or biological products are treated as multiple source drugs if they were within the same billing and payment code as of October 1, 2003. Accordingly, at § 427.101(b)(2), we proposed to codify the existing policy established in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude drugs and biological products set forth in section 1847A(c)(6)(C)(ii) of the Act from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates.

For drugs and biological products that are billed using a HCPCS code that represents a Not Otherwise Classified (NOC) code, we have a process to determine the allowed payment amount for such billing and payment codes; however, current Medicare claims data do not allow CMS to determine the average total allowed charges for such drug or biological product for a year per individual that uses such a drug or biological product or to identify units billed. CMS must perform these steps to determine if a drug or biological product is a Part B rebatable drug. Therefore, at § 427.101(b)(3), we proposed to codify the policy in section 30.1 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude drugs and biological products that are billed using a billing and payment code that represents a NOC code or claims for such drugs and biological products when no other billing and payment code is applicable. We noted that few Part B drugs and biological products are billed with such codes and the quarterly process for updating billing and payment codes, including establishing new billing and payment codes, provides an existing mechanism for CMS to minimize the number of Part B rebatable drugs that are billed with such codes. As discussed at §§ 90.2 and 90.3 in Chapter 17 of the Medicare Claims Processing Manual, NOC codes are generally used to bill Medicare for new-to-market, FDA-approved drug products until a specific billing and payment code is assigned; and so, CMS expects that the impact of this exclusion will be limited.[641]

Consistent with section 303(h) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, radiopharmaceutical drugs and biologicals are not paid under section 1847A of the Act. Manufacturers of radiopharmaceutical drugs and biologicals are therefore not required to report ASP under section 1927(b)(3) of the Act and are not otherwise required to report ASP data to CMS for separately payable radiopharmaceutical drugs and biologicals. In addition, different payment methodologies across the outpatient setting result in data variations that could inappropriately trigger an inflation rebate amount due to methodological differences in reimbursement. Therefore, at § 427.101(b)(4) we proposed to codify the revised Medicare Part B Drug Inflation Rebate Guidance policy (as set forth in section 30.1) that excludes separately payable radiopharmaceutical drugs and biologicals for the purposes of identifying Part B rebatable drugs. Additionally, we proposed to codify the existing policy not to subject these units to the inflation-adjusted beneficiary coinsurance at § 427.201(c) as described further in the following section of this rule.[642]

We aim to create a consistent coding and payment approach for the suite of products currently referred to as skin substitutes as stated in section 30.1 of revised Medicare Part B Drug Inflation Rebate Guidance. In the CY 2024 PFS proposed rule, CMS solicited comments on potential changes to payment for skin substitutes. In the CY 2024 PFS final rule, we acknowledged the comments received in response to this solicitation and stated that CMS would take these comments into consideration for future rulemaking.[643] At § 427.101(b)(5) we proposed to codify existing policy to exclude cellular- and tissue-based products that aid wound healing, currently referred to as skin substitutes, for the purposes of identifying Part B rebatable drugs. In addition, we proposed not to subject these products to the beneficiary coinsurance adjustment at § 427.201(c).

Section 1847A(i)(2)(A) of the Act excludes from the definition of a Part B rebatable drug a drug or biological if, as determined by the Secretary, the average total allowed charges for such drug or biological product under Part B for a year per individual who uses such a drug or biological product are less than $100. Section 1847A(i)(2)(B) of the Act

[640] The billing and payment codes used to identify drugs covered under Part B are Healthcare Common Procedure Coding System (HCPCS) codes. For more information on HCPCS codes and how they are applied, see ''HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURESHCPCS'' at *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.*

[641] *See: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf.*

[642] In the CY 2025 PFS proposed rule, we also proposed to clarify how radiopharmaceuticals are paid for in the physician's office and to codify these policies in regulation. Specifically, we proposed to clarify that for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs can determine payment limits for radiopharmaceuticals based on any methodology in place on or prior to November 2003.

[643] See 88 FR 78818, November 16, 2023 (*https://www.federalregister.gov/public-inspection/2023-24184/medicare-and-medicaid-programs-calendar-year-2024-payment-policies-under-the-physician-fee-schedule*).

provides that the $100 amount for 2023 will be increased for 2024 and subsequent years by the percentage change in the CPI–U for the 12-month period ending with June of the previous year, rounded to the nearest multiple of $10. Therefore, at § 427.101(b)(6) we proposed to codify the policy established in revised Medicare Part B Drug Inflation Rebate Guidance to exclude from the definition of a Part B rebatable drug those drugs and biologicals for which the Part B average total allowed charges for a year per individual who uses such drug or biological is below the applicable threshold.

Section 1847A(i)(2)(A)(ii) of the Act excludes vaccines set forth in subparagraph (A) or (B) of section 1861(s)(10) of the Act from the definition of a Part B rebatable drug. Such vaccines include the pneumococcal vaccine, the influenza vaccine, the COVID–19 vaccine; and the hepatitis B vaccine when furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations). As such, at § 427.101(b)(7), we proposed to codify the existing policy established in section 30.3 of the revised Medicare Part B Drug Inflation Rebate Guidance to exclude vaccines set forth in subparagraph (A) or (B) of section 1861(s)(10) of the Act from the definition of a Part B rebatable drug and not subject them to Part B inflation rebates. In addition, with respect to monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19, which are covered and paid for under section 1861(s)(10) of the Act, we proposed to exclude these products from the definition of Part B rebatable drugs for applicable quarters through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products is terminated. For monoclonal antibodies that are used for pre-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act, we proposed to exclude these products from the definition of Part B rebatable drug for applicable calendar quarters even after the year in which the EUA Declaration ends, as long as these products have an FDA-approved application or license after the EUA Declaration is terminated.

Finally, Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under 505(j) of the FD&C Act do not meet the definition of ''single source drug or biological product,'' as defined under section 1847A(c)(6)(D) of the Act, and thus, are not Part B rebatable drugs. We proposed to codify this exclusion at § 427.101(b)(8).

We received public comments on these proposed provisions to exclude skin substitutes and separately payable radiopharmaceutical drugs and biologicals from the identification of a Part B rebatable drug. The following is a summary of the comments we received and our responses.

Comment: One commenter appreciated CMS' proposal regarding the suite of products referred to as skin substitutes for the purposes of identifying Part B rebatable drugs. This commenter recommended CMS finalize this proposal to not consider skin substitutes Part B rebatable drugs. Additionally, this commenter recommended CMS clarify that because skin substitutes are not single source drugs, biological products, or biosimilar biological products they cannot be considered Part B rebatable drugs.

Response: We thank this commenter for their input and are finalizing as proposed. At this time, skin substitutes are excluded from the regulatory definition of a Part B rebatable drug.

Comment: One commenter supported CMS' proposal to codify existing policy that separately payable radiopharmaceutical products are excluded from the definition of a Part B rebatable drug and, as such, are not subject to the inflation-adjusted beneficiary coinsurance, and recommended CMS finalize this proposal.

Response: We thank this commenter for their feedback. As described in the CY 2025 PFS proposed rule, we will exclude separately payable radiopharmaceutical drugs and biologicals for the purposes of identifying Part B rebatable drugs and not subject these products to the inflation-adjusted beneficiary coinsurance.

After consideration of public comments, we are finalizing as proposed our proposal at § 427.101(b) to exclude certain product categories from the definition of a Part B rebatable drug.

iv. Drugs and Biological Products With Average Total Allowed Charges Below the Applicable Threshold

Under section 1847A(i)(2) of the Act, drugs and biological products, for which the average total allowed charges for such drug or biological under Part B for a year per individual who uses such drug or biological are below the applicable threshold, as determined by the Secretary, are excluded from the definition of Part B rebatable drugs. As explained in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS uses the term ''applicable threshold'' to mean $100 for all 4 calendar quarters in 2023. For all 4 calendar quarters in 2024, the applicable threshold will be $100 as increased in accordance with section 1847A(i)(2)(B) of the Act. For calendar quarters in 2025 and beyond, the applicable threshold will be equal to the unrounded applicable threshold calculated for the prior calendar year, increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

At § 427.101(c), we proposed to codify policies from the revised Medicare Part B Drug Inflation Rebate Guidance to exclude these drugs from the definition of a Part B rebatable drug. To do so, in accordance with the statute, for each applicable calendar quarter, we proposed to identify drugs and biological products with Part B average total allowed charges for a year per individual that uses such a drug or biological product below the applicable threshold.

At § 427.101(c)(1), we proposed that to identify the average total allowed charges for a year per individual, for each Part B rebatable drug, CMS will:

- For single source drugs and biological products assigned to only one billing and payment code, sum the allowed charges from final action claims greater than $0 and divide the summed amount by the number of individuals who use such a drug or biological.
- For single source drugs and biological products assigned to more than one billing and payment code, sum the allowed charges from final action claims greater than $0 for all billing and payment codes and divide the summed amount by the number of individuals who use such a drug or biological.

CMS may move a drug or biological product from a grouped billing and payment code to a unique billing and payment code in instances where the drug is either approved through the pathway established under section 505(b)(2) of the FD&C Act (hereinafter ''section 505(b)(2) drug products'') that CMS initially assigned to the same billing and payment code as its reference drug for a period of time, or the drug was previously a multiple source drug but is now a single source drug that was moved to its own billing and payment code. There may be instances where a single source drug or biological product was previously crosswalked to a grouped billing and payment code (other than a NOC code) during the *full* year. In such instances, we proposed to calculate the average

total allowed charges per individual per year for the drug using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year. Such instances will apply to section 505(b)(2) drug products, drugs that were previously multiple source drugs where all other drugs under the same billing and payment code were discontinued (applicable only if the sole remaining product was not approved under an ANDA), and to any other situations where a drug was previously in a grouped billing and payment code (other than a NOC code).

Finally, there may be instances where a single source drug or biological product was initially billed under a grouped billing and payment code (other than a NOC code) and was later billed under a unique billing and payment code for *some* of the year. In such instances, we proposed to calculate the average total allowed charges per individual for a year by: summing the total allowed charges billed under the unique billing and payment code for the drug with dates of service on or after the Medicare effective date for this unique billing and payment code and identifying the individuals on those claims; summing the total allowed charges on claims billed under the previously grouped billing and payment code and identifying the individuals with claims prior to the unique billing and payment code's effective date; and then summing the total allowed charges under both billing and payment codes across the full year and dividing by the total number of individuals (de-duplicated for those individuals identified under both the previously grouped billing and payment code and the unique billing and payment code). If the average total allowed charges for a year per individual who uses such drug or biological product are less than the applicable threshold, we proposed to exclude the billing and payment code for that calendar quarter. We solicited comment on this proposed implementation of the exclusion for drugs and biologicals with average total allowed charges below the applicable threshold.

We proposed at § 427.101(c)(2) to calculate the applicable threshold as follows:

- For applicable calendar quarters in 2023, the applicable threshold is equal to $100.
- For applicable calendar quarters in 2024, the applicable threshold is equal to $100 increased by the percentage increase in the CPI–U for the 12-month period ending with June of 2023.
- For applicable calendar quarters in each subsequent calendar year, the applicable threshold is equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.
- If the resulting amount from these calculations is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.[644]

Accordingly, the formula to determine the applicable threshold for calendar quarters in 2024 is $100 *multiplied by* (CPI–U for June 2023 *divided by* CPI–U for June 2022) (apply rounding to the nearest multiple of $10). To illustrate, the 2024 threshold is: $100 \times (305.109/296.311) = 102.969178$ (which rounds down to $100 after applying CMS rounding) so the threshold for calendar quarters in 2024 = $100.

For the purposes of this calculation, we proposed that ''a year'' means the 4 consecutive calendar quarters beginning 6 calendar quarters before the applicable calendar quarter. We also proposed using final action claims from the Medicare fee-for-service claims repository to identify claims where separate payment was allowed for the applicable HCPCS code for dates of service within a year. Drugs and biological products that do not meet the applicable threshold are not considered Part B rebatable drugs. For example, for the calendar quarter beginning July 1, 2025, CMS will use available final action Medicare Part B claims with dates of service beginning January 1, 2024, and ending December 31, 2024, because January 1, 2024, is the beginning of the calendar quarter that is 6 quarters before the applicable calendar quarter beginning on July 1, 2025.

At § 427.101(c)(3), we proposed to codify the policies and methodological steps as described in section 30.2 of the revised Medicare Part B Drug Inflation Rebate Guidance for excluding drugs and biological products with average total allowed charges below the applicable threshold at the billing and payment code level. For each applicable calendar quarter, we will identify the applicable billing and payment codes for drugs and biological products with average total allowed charges for a year per individual less than the applicable threshold and exclude such drugs and biological products from the definition of Part B rebatable drug in accordance with proposed § 427.101(b)(6). When a single source drug or biological product with average total allowed charges below the applicable threshold is assigned to a unique billing and payment code, we will exclude the assigned billing and payment code for the applicable calendar quarter. There also may be instances where a single source drug or biological product is assigned to more than one billing and payment code during a year and the average total allowed charges for a year per individual that uses such drug or biological product are less than the applicable threshold. In such instances, we proposed to exclude all assigned billing and payment codes for such single source drug or biological product for that applicable calendar quarter.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.101(c).

c. Inflation-Adjusted Beneficiary Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation (§§ 427.200 Through 427.201)

Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug. In the CY 2024 Hospital Outpatient Prospective Payment System (OPPS) final rule and the CY 2024 PFS final rule, CMS codified this inflation-adjusted coinsurance amount at §§ 419.41(e), 410.152(m), and 489.30(b)(6), respectively.

Beginning with the April 2023 quarterly pricing files, the applicable beneficiary coinsurance percentage is shown for each HCPCS code in the pricing files that are posted on the CMS website. For example, the ASP Pricing files are posted at *https://www.cms.gov/*

[644] CMS will round down any amount less than $5 over a multiple of $10 to that multiple of $10, and round up any amount $5 or more over a multiple of $10 to the next multiple of $10.

medicare/payment/part-b-drugs/asp-pricing-files. The applicable beneficiary coinsurance percentage for certain drugs and biologicals used predominantly in the hospital outpatient setting are listed in the Hospital Outpatient Prospective Payment System (OPPS) Addenda A and B, which can be found at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*. The applicable beneficiary coinsurance percentage for certain drugs and biologicals used predominantly in the ambulatory surgical center setting are listed in the ASC Addendum, which can be found at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda*. The percentage is expressed as two digits with three decimal places, for example, 18.760. If an adjusted beneficiary coinsurance does not apply, the percentage would show as 20.000.

Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between the payment limit and the inflation-adjusted coinsurance amount. Consistent with the clarification in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance and with the application of sequestration in the context of Medicare payment and beneficiary coinsurance in general, we note that the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152.

In the CY 2025 PFS proposed rule (89 FR 61942), we proposed to adopt new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined at § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. This new provision includes references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). We further proposed at § 427.201(c) that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Additionally, we proposed at § 427.201(b) that CMS will use the published payment amount in quarterly pricing files [645] [646] [647] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. This proposed approach deviates from the rebate calculation approach proposed at § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ. The approach proposed at § 427.201(b) will be used only to determine whether there should be a coinsurance adjustment and will not impact the applicability or calculation of inflation rebates. We believe this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts.

As stated in the CY 2025 PFS proposed rule (89 FR 61942), our intent with this proposed policy is to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount. Though the payment amount is generally based on the same provisions as the specified amount, there may be situations where the payment amount is updated or adjusted under other provisions of 1847A of the Act, such as when ASP data are not available under section 1847A(c)(5)(B). For example, if the specified amount is very low due to negative ASP data and the payment amount is updated using other available data resulting in a payment amount that exceeds the inflation-adjusted payment amount, beneficiaries will not receive the benefit of adjusted coinsurance. There may also be situations where the payment amount is lower than the inflation-adjusted payment amount, but the specified amount is higher than the inflation-adjusted payment amount. In such a situation, if the ''specified amount'' was used as the comparator to determine whether coinsurance should be adjusted, beneficiaries will pay a coinsurance *higher* than 20 percent, because 20 percent of the inflation-adjusted payment amount will be higher than 20 percent of the payment amount. As such, we proposed to codify at § 427.201(b) that we will compare the published payment amount in the quarterly pricing files published by CMS to determine whether a coinsurance adjustment applies. This policy will provide an adjusted beneficiary coinsurance amount only when the payment amount for a Part B rebatable drug exceeds the inflation-adjusted payment amount in a given quarter.

We believe this approach is valid and gives effect to the differing statutory language in sections 1847A(i)(3)(A), 1847A(i)(5), and 1833(a)(1)(EE) of the Act, which sets forth the coinsurance adjustment for Part B rebatable drugs. Unlike the ''specified amount'' in section 1847A(i)(3)(A) of the Act, sections 1847A(i)(5) and 1833(a)(1)(EE) of the Act both refer to a ''payment amount.'' Fundamentally, a payment amount cannot be a negative number; if the specified amount and payment amount were the same amount, it would result in situations where the payment amount at section 1833(a)(1)(EE) of the Act was a negative number. Rather, we believe that the term ''payment amount'' in both sections 1847A(i)(5) and 1833(a)(1)(EE) of the Act is most naturally read to include the amount, as updated and adjusted for the purposes of providing payment to providers, that CMS publishes as the payment amount in quarterly pricing files; and that section 1833(a)(1)(EE) of the Act operates to adjust the *percentage* of such payment amount. Furthermore, section 1847A(i)(5)(B) of the Act provides the Secretary with discretion to apply the adjusted coinsurance percentage to the payment amount that would otherwise apply under section 1847A(b)(1)(B) or (C) of the Act. Lastly, sections 1847A(i)(8)(D) and (E) of the Act preclude administrative and judicial review of the computation of the adjusted coinsurance and amounts paid to the provider under section 1833(a)(1)(EE) of the Act.

In summary, we proposed CMS will use the payment amount in quarterly pricing files to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance, the calculation to determine the adjusted Medicare

[645] See: *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files*.

[646] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*.

[647] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda*.

payment (if applicable) will not be adjusted for sequestration, and drugs excluded from the identification of Part B rebatable drugs will not be subject to the inflation-adjusted beneficiary coinsurance.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal to adjust beneficiary coinsurance when applicable. Additionally, one of these commenters noted that CMS' intent to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount could be particularly important in situations where the ASP is very low or negative and CMS must use other data to calculate the payment amount.

Response: We thank commenters for their support.

Comment: One commenter recommended that CMS use the manufacturer-calculated specified amount for inflation rebate amounts and when calculating payment amounts for coinsurance adjustment, noting that using consistent sources across these calculations would avoid triggering inflation rebates in scenarios when there was no price increase.

Response: We believe our proposed methodology for calculating the inflation-adjusted beneficiary coinsurance, which deviates from the rebate calculation approach proposed at § 427.302, is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts. As previously described, there may be situations where the payment amount is updated or adjusted under other provisions of 1847A of the Act, such as when ASP data are not available under section 1847A(c)(5)(B) of the Act. Such a situation could occur if the payment amount is lower than the inflation-adjusted payment amount, but the specified amount is higher than the inflation-adjusted payment amount, which could cause beneficiaries to pay a coinsurance greater than 20 percent.

Comment: One commenter expressed concern that the proposed change to the methodology for determining whether coinsurance should be adjusted focuses too heavily on the volume of Part B drugs dispensed instead of on the impact of inflation on a person enrolled in Medicare. This commenter encouraged CMS to consider a similar strategy used in the Medicare Part D Drug Inflation Rebate Program that uses the CPI–U during a specific period to calculate an inflation-based rebate.

Response: We thank the commenter for this feedback. We did not propose to determine whether to adjust the beneficiary coinsurance based on the volume of Part B drugs administered. As noted, CMS proposed to compare the published payment amount in CMS quarterly pricing files to the inflation-adjusted payment amount to determine which is higher. We believe our proposed methodology is consistent with sections 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the ''specified amount'' used to determine rebate amounts. We also note that similar to the Medicare Part D Drug Inflation Rebate Program, CMS uses CPI-Us for specific periods to calculate the inflation rebate for the Medicare Part B Drug Inflation Rebate Program.

Comment: One commenter recommended that CMS provide additional guidance to Medicare Advantage (MA) plans on how Part B rebatable drugs will be reimbursed. The same commenter stated that CMS should increase payments to MA plans for the reduced coinsurance collected from beneficiaries under the adjusted beneficiary coinsurance policy described in section 1847A(i)(5) of the Act. The commenter asked CMS to establish a mechanism to reimburse MA plans for these losses.

Response: As part of MA rate development, CMS assumes prices for drugs covered under Part B will not materially exceed the inflation-adjusted payment amounts under section 1847A(i) of the Act. Therefore, no adjustments to projected Part B FFS expenditures to account for inflation rebates are necessary. Any potential losses from inflation rebates should be accounted for in the bids MA organizations submit to CMS.

Comment: One commenter requested CMS provide additional guidance to MA plans on how to operationalize the coinsurance adjustment as the rebatable drug price changes quarterly. The commenter did not specify any particular clarification that CMS should provide. The commenter also stated it would be helpful to understand how CMS will account for the reduction in cost sharing in MA plan reimbursements.

Response: MA plans should consult the HPMS memoranda, ''Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Contract Year 2023 Medicare Advantage and Section 1876 Cost Plans,'' dated November 7, 2022,[648] and ''Frequently Asked Questions: Inflation Reduction Act Changes to Cost Sharing for Part B Drugs for Medicare Advantage and Section 1876 Cost Plans,'' dated July 13, 2023,[649] for information. MA organizations must account for Part B rebatable drug coinsurance adjustments under section 1847A(i) of the Act in the bids MA organizations submit to CMS. Section 1853 of the Act sets forth how the MA capitation rates and benchmarks are set based on FFS per capita costs.

After consideration of public comments, we are finalizing our proposal as proposed at §§ 427.200 and 427.201.

d. Determination of the Rebate Amount for Part B Rebatable Drugs (§§ 427.300 Through 427.304)

i. Definitions

In proposed § 427.300, we proposed to define the following terms applicable to subpart D (§§ 427.300 through 427.304):

- ''340B Program''.
- ''Refundable single-use dose container or single-use package drug''.

We did not receive comments on these proposed definitions. We are finalizing these definitions as proposed at § 427.100.

ii. Calculation of the Total Part B Rebate Amount To Be Paid by Manufacturers

Section 1847A(i)(3) of the Act specifies the calculation of the rebate amount for a Part B rebatable drug assigned to a billing and payment code for an applicable calendar quarter for which a manufacturer must pay a rebate. We proposed to codify the rebate calculation, as established in revised Medicare Part B Drug Inflation Rebate Guidance,[650] as the estimated amount is equal to the product of the total number of billing units determined in accordance with section 1847A(i)(3)(B) of the Act (proposed at § 427.303) and the amount (if any) by which the specified amount (proposed at § 427.302(b)) exceeds the inflation-adjusted payment amount determined

[648] *https://mabenefitsmailbox.lmi.org/MABenefitsMailbox/S3Browser/GetFile?path=CY2023%20Part%20C%20IRA%20Memorandum%2011-7-2022.pdf.*

[649] *https://www.cms.gov/files/document/ira-part-b-rebatable-drugs-and-insulin-faq.pdf.*

[650] See: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.*

in accordance with section 1847A(i)(3)(C) of the Act (proposed at § 427.302(g)) for the drug or biological product for an applicable calendar quarter. The Part B drug inflation rebate amount calculated in accordance with this subpart is subject to adjustment based on any reductions in accordance with subpart E of this part or any reconciliations in accordance with subpart F of this part.

Because Part B rebatable drugs are single source drugs or biologicals, they typically will have one manufacturer. However, a Part B rebatable drug could have more than one manufacturer. For example, a Part B rebatable drug could be produced by one or more manufacturer(s) that is a repackager or relabeler. Multiple manufacturers of a rebatable drug also could occur in the case of one or more authorized generic products that are marketed under the same FDA-approval as the original FDA applicant. In such instances, all the NDCs for the drug typically are assigned to the same billing and payment code(s), and each manufacturer is responsible for reporting ASP data to CMS. When calculating the rebate owed by manufacturers for a rebatable drug that has more than one manufacturer, we proposed to codify the policy from section 50.13 of the revised Medicare Part B Drug Inflation Rebate Guidance to multiply the total rebate amount calculated for the billing and payment code by the following quotient:

(Sum of the individual manufacturer's billing units sold during the applicable calendar quarter for all NDCs of the manufacturer assigned to the billing and payment code, as reported in the ASP data submissions) *divided by* (Sum of all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code, as reported in the ASP data submissions)

We received public comments on this calculation approach. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed concern that CMS' proposal to allocate Part B inflation rebates when there are multiple manufacturers in a billing and payment code does not appropriately assign rebate liability. One commenter noted that the proposed methodology assumes that each NDC is equally responsible for driving the amount of an increase in the payment amount for the benchmark period and that the policy has the potential to assign rebate liability to a manufacturer whose individual pricing for its respective NDC(s) increased at or below the rate of inflation. One commenter recommended CMS revise its methodology to assess rebate liability against each manufacturer only in proportion to its actual responsibility for triggering the inflation rebate. A few commenters opposed the proposed methodology, which they noted could result in a manufacturer owing a rebate even when ASP growth for the manufacturer's own NDC has been lower than inflation.

Some commenters offered more specific recommendations, stating CMS should calculate inflation rebate liability at the NDC–11 level for billing and payment codes comprised of NDCs from multiple manufacturers. Additionally, these commenters recommended CMS require providers to report associated product NDC–11s on Part B claim forms and to reject claims without NDC–11s. These commenters maintained that requiring NDC–11s on Part B claim forms would mitigate situations in which one manufacturer would be subject to an inflation rebate due to the ASP growth of another manufacturer.

Response: We appreciate commenters sharing their concerns and recommendations. As we stated in the revised Medicare Part B Drug Inflation Rebate Guidance [651] on page 37, CMS maintains that it will apportion the Part B rebate amount among manufacturers by dividing the sum of each manufacturer's reported ASP units sold during the rebate quarter by the sum of all manufacturer-reported ASP units sold during the rebate quarter for all NDCs of the rebatable drug assigned to the billing and payment code. We believe this approach appropriately apportions rebate liability for NDCs assigned to a grouped billing and payment code using data available to CMS. We also believe that calculating Part B inflation rebates at the billing and payment code level, rather than at the NDC–11 level as some commenters recommended, is consistent with section 1847A(i)(3)(A) of the Act, which specifies how the rebate amount is calculated. Additionally, single source drugs are typically assigned unique HCPCS codes.

Additionally, calculating Part B inflation rebates at the NDC–11 level would require imposing new requirements on the claims submission process to require reporting of the NDC–11 on Part B claims, which would increase the administrative burden associated with the claims submission process. At this time, we will not require NDC–11s on Part B claims and we will continue to calculate Part B rebates at the HCPCS level per our proposed approach. We will continue to evaluate the potential for NDC–11 reporting in connection with our ongoing assessment of potential changes to Part B claims and billing. The comment regarding the use of NDC–11s in situations in which a provider inadvertently submits a claim for payment under Part B for a self-administered formulation rather than the physician-administered formulation is outside the scope of this final rule.

Comment: One commenter reported that it identified at least one circumstance where the majority of ASP units for an NDC in a billing and payment code are packaged into a payment amount that includes another item or service and are not separately payable (such as those paid under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)), and noted that units attributed to that NDC should not be used to apportion rebate liability. The commenter recommended CMS clarify its methodology to exclude NDCs for which the number of ASP-reported units are subject to bundled payment.

Response: We thank the commenter for sharing this information. We are aware of the circumstance the commenter raised. Under such a circumstance, we will apportion the Part B rebate amount as described at § 427.301(b) and section 50.13 of the revised Medicare Part B Drug Inflation Rebate Guidance. In this particular circumstance, the NDCs in the bundled code are also in the non-bundled code, thus the ASP reporting for the NDCs will be applied to only the non-bundled code, since the bundled code is not separately payable. CMS will use this information to apportion liability since CMS cannot determine how many units by NDC are being administered in the bundled vs. non-bundled code. Further, at this time, we will not require NDC–11s on Part B claims because CMS has not fully assessed the breadth of changes to Part B claims and billing. CMS also notes that as proposed at § 427.303(b)(3) and as stated in the revised Medicare Part B Drug Inflation Rebate Guidance on page 38, in accordance with section 1847A(i)(3)(B)(ii)(II) of the Act, CMS will exclude units of drugs ''that are packaged into the payment amount for an item or service and are not separately payable.'' We also note that claim lines

[651] See: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.*

for drugs for which payment is bundled under the ESRD PPS would not have a Medicare allowed amount that is greater than zero, and so such units will be excluded.

After consideration of public comments, for the reasons stated above, we believe that calculating Part B inflation rebates at the billing and payment code level is consistent with section 1847A(i)(3)(A) of the Act. Therefore, we are finalizing our proposals as proposed at § 427.301(b).

As discussed in the CY 2025 PFS proposed rule (89 FR 61943), based on further review, we have observed that there are several instances where there are multiple manufacturers in a billing and payment code and the ASP data, including the number of units sold, for all or some manufacturers' NDCs within a billing and payment code may be negative, zero, or missing. To enable CMS to calculate the respective rebate amounts attributable to each manufacturer when the ASP units are negative, zero, or missing, we solicited comments on the new proposed policies outlined below and any other alternative options.

(1) Scenarios in Which All NDCs Within a Billing and Payment Code Have Missing, Negative, or Equal to Zero ASP Units

If there are NDCs of multiple manufacturers in a billing and payment code, to determine the respective rebate amount when the manufacturer-reported ASP units for all NDCs are either missing, negative, or equal to zero but there is a positive rebate amount calculated for the Part B rebatable drug, we proposed to: (1) apportion a $0 rebate amount when the manufacturer-reported units for all NDCs are missing for NDCs not sold or marketed during the applicable calendar quarter, NDCs with negative manufacturer-reported ASP units during the applicable calendar quarter, and/or NDCs with manufacturer-reported ASP units equal to zero during the applicable calendar quarter; and (2) equally apportion a positive rebate amount to each NDC that was sold or marketed during the applicable calendar quarter and that lack manufacturer-reported ASP units for the applicable calendar quarter. If the NDCs within a billing and payment code have a mix of missing ASP units, negative ASP units, and/or zero ASP units, CMS will apportion a $0 rebate amount to each NDC with missing units that are not sold or marketed during the applicable calendar quarter, each NDC with negative units, and each NDC with units equal to zero, and CMS will equally apportion a positive rebate amount to NDCs with missing units that were sold or marketed during the applicable quarter by dividing the total rebate amount for the grouped billing and payment code by the total number of such NDCs within the billing and payment code. We understand that this approach would treat missing units for NDCs not sold or marketed during the applicable calendar quarter, negative units, and units equal to zero as representing zero sales, and we solicited comments on the extent to which this approach could potentially exclude from rebate liability a manufacturer of a drug that did have sales in that quarter (for example, if negative units represent price concessions). In addition, we solicited comments on the extent to which, in a scenario with a billing and payment code with multiple manufacturers, a single manufacturer that lacks reported ASP units could assume full rebate liability for the entire billing and payment code if the manufacturer's NDCs lack reported ASP units and were sold or marketed during the applicable calendar quarter.

We also considered several alternative policies for attributing rebate amounts to each respective manufacturer in this scenario, including: (1) using the reported ASP units from the calendar quarter prior to the applicable calendar quarter; (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable calendar quarter (for example, an average of the previous 4 calendar quarters); and (3) validation of ASP data based on review of AMP data in combination with one of the aforementioned alternative proposed policies to determine inflation rebate amounts. However, we have observed that ASP units are often missing, negative, or equal to zero for several quarters in a four-quarter lookback, so including additional quarters may not necessarily yield additional data that could be used to apportion inflation rebate amounts (and could complicate the calculation of an average by introducing a mix of missing units, negative units, or units equal to zero within a single NDC). In addition, the AMP validation of ASP sales could add another layer of complexity and potential bias as AMP data represent only sales to retail community pharmacies, and ASP data represent all sales of a drug. We solicited comments on these alternatives.

(2) Scenarios in Which Some (But Not All) NDCs Have Missing, Negative, or Equal to Zero ASP Units

When some NDCs within a grouped billing and payment code lack manufacturer-reported ASP units, have negative manufacturer-reported units, or have manufacturer-reported ASP units equal to zero, we proposed to: (1) apportion a $0 rebate amount to each NDC that was not sold or marketed during the applicable calendar quarter that lacks manufacturer-reported ASP units during the applicable calendar quarter, each NDC with negative manufacturer-reported ASP unit for the applicable calendar quarter, and each NDC with manufacturer-reported ASP units equal to zero for the applicable calendar quarter; (2) assign ASP units equal to the lowest positive number of manufacturer-reported ASP units for any NDC in the grouped billing and payment code to each NDC that was sold or marketed during the applicable calendar quarter and for which the respective NDC lacks manufacturer-reported ASP units; and (3) apportion rebate amounts across NDCs that were sold or marketed during the applicable calendar quarter and for which each respective NDC lacks manufacturer-reported ASP units during the applicable calendar quarter and NDCs that were sold or marketed during the applicable calendar quarter and for which respective NDCs have positive manufacturer-reported units in accordance with the policy outlined in section 50.13 of the revised Medicare Part B Drug Inflation Rebate Guidance. We solicited comments on the extent to which, in a scenario where NDCs of multiple manufacturers are assigned to the same billing and payment code, a single manufacturer that accounts for all positive ASP units could potentially be responsible for the full rebate amount for the entire billing and payment code.

We also considered proposing other alternative policies for attributing rebate amounts to each respective manufacturer in this scenario, including: (1) review of historical ASP data to identify the most recent calendar quarter with positive ASP units for any of the NDCs with missing units, negative units, or units equal to zero in the applicable calendar quarter and allocation of financial responsibility across NDCs with positive ASP units in that quarter (excluding NDCs without positive units in that quarter); (2) using an average of units sold based on sales data for several calendar quarters prior to the applicable quarter (for example, an average of the previous four calendar quarters); (3) apportionment of rebates based on units at the NDC–9 level rather than the NDC–11 level; and (4) apportionment of rebates to only those manufacturers within a HCPCS code

that reported positive ASP units for the applicable calendar quarter.

We elected not to propose use of a historical lookback approach (under options 1 and 2) because ASP units are often missing, negative, or equal to zero for the most recent calendar quarter and/or over several quarters in a four-quarter lookback period, and so including additional quarters may not necessarily yield additional data that could be used to apportion inflation rebate amounts (and could complicate the calculation of an average by introducing a mix of missing units, negative units, or units equal to zero, and positive units within a single NDC). We also understand that a historical lookback approach could create outliers that could affect the resulting allocation. When evaluating option 3, CMS observed that ASP units are often missing, negative, or equal to zero for several calendar quarters when aggregating units sold at the NDC–9 level. Consequently, this approach may not necessarily yield additional data that could be used to apportion inflation rebate amounts and doing so would differ from our general policy on using NDC–11s as set forth in the revised guidance. Finally, we decided not to propose apportioning the full rebate amount to only those manufacturers that reported positive ASP units within a billing and payment code under option 4, as we questioned whether that policy could inadvertently disfavor manufacturers that reported units while benefiting manufacturers that did not report ASP data. We stated that we would continue to evaluate these alternative policy approaches for apportioning rebate liability and may adopt changes to this proposed policy in the final rule.

CMS reminded manufacturers of their reporting obligations under sections 1847A(f)(2) and 1927(b) of the Act and that failure to provide timely information may result in penalties as detailed in sections 1847A(d)(4)(B) and (C) and 1927(b)(3)(C)(i) of the Act.

We solicited comments on these proposals as well as alternative policy options on how CMS could apportion rebate amounts among multiple manufacturers' NDCs that lacked ASP units, reported negative units, and/or reported units equal to zero for NDCs.

We received public comments on these proposals and alternatives considered. The following is a summary of the comments we received and our responses.

Comment: A few commenters noted that their recommendation to require NDC–11s on Part B claim forms would allow CMS to validate ASP units for NDCs in a billing and payment code comprised of drugs from multiple manufacturers, particularly for drugs with negative or zero reported ASP but with sales during the applicable quarter. One of these commenters added that collecting NDC–11s would negate the need for CMS to develop an approach to allocate rebate amounts across multiple manufacturers in a billing and payment code with all or some negative, zero, or missing ASP units because CMS would have the actual number of units dispensed in Part B during applicable quarter for each manufacturer.

Response: CMS thanks the commenters for sharing this information. As we previously responded, calculating Part B inflation rebates at the NDC–11 level would require imposing new requirements on the claims submission process to require reporting of the NDC–11 and corresponding quantities on Part B claims, which would increase the administrative burden associated with the claims submission process. Additionally, modifications to Medicare systems would be needed to capture this information. At this time, we will not require NDC–11s on Part B claims and we will continue to calculate Part B rebates at the HCPCS level per our proposed approach that we are finalizing in this rule.

Comment: A couple of commenters recommended CMS provide greater clarity on how it plans to apportion the rebate amount in situations in which all or some NDCs within a billing and payment code have missing ASP units, negative ASP units, or ASP units equal to zero. In particular, these commenters requested that CMS define the terms sold or marketed, noting that CMS' proposal depends on whether NDCs are sold or marketed during the applicable quarter, however, CMS did not define when a drug is considered sold or marketed during the applicable calendar quarter in the proposed rule.

Response: We appreciate this feedback. We agree with the commenter's suggestion to define when a drug is considered sold or marketed during the applicable calendar quarter and are modifying the list of definitions at § 427.20. In this final rule, we have defined ''sold or marketed'' at § 427.20 as follows: means, with respect to an NDC, that the NDC has either a date of first sale identified using ASP data reported by NDC–11 to CMS by a manufacturer required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, or an NDC Directory start marketing date prior to or during the applicable calendar quarter and meets any of the following criteria: (1) the NDC has units reported for the rebate quarter; (2) the end marketing date is during the rebate quarter; (3) the end marketing date is after the rebate quarter; or (4) the end marketing date is missing.

After consideration of public comments, in this final rule, we are finalizing a methodology to calculate the respective rebate amounts attributable to each manufacturer when the ASP units are missing, negative, or equal to zero for the applicable calendar quarter. For this final rule, we are adding § 427.301(c) to describe how CMS will apportion the Part B rebate amount when there are multiple NDCs in a grouped billing and payment code and when manufacturer-reported ASP units for such NDCs lack manufacturer-reported ASP units during the applicable calendar quarter, have negative manufacturer-reported ASP units during the applicable calendar quarter, or have manufacturer-reported ASP units equal to zero during the applicable calendar quarter.

iii. Calculation of the Per Unit Part B Drug Rebate Amount

(1) Identification of the Specified Amount for the Applicable Calendar Quarter

In the calculation of the rebate amount for a Part B rebatable drug, we are statutorily required to compare the inflation-adjusted payment amount to the specified amount, which is the amount set forth in section 1847A(i)(3)(A)(ii)(I) of the Act. The statute requires CMS to impose an inflation rebate if the specified amount exceeds the inflation-adjusted payment amount. We proposed to codify at § 427.302(a) the policy established in revised Medicare Part B Drug Inflation Rebate Guidance to calculate the Part B per unit rebate amount for the applicable calendar quarter by determining the amount by which the specified amount exceeds the inflation-adjusted payment amount, after accounting for exclusions under § 427.303(b). We proposed to codify the current operational steps for calculating Part B inflation rebates as described in section 50 of the revised Medicare Part B Drug Inflation Rebate Guidance.

At § 427.302(b), we proposed to codify the policy established in section 50.2 of the revised Medicare Part B Drug Inflation Rebate Guidance on how to calculate the specified amount for the applicable calendar quarter. The ''specified amount'' refers to the amount specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act, as applicable. In general, section

1847A(i)(3)(A)(ii)(I)(aa) and (bb) of the Act cross-reference provisions governing quarterly payment limits for single source drugs and biological products that are typically, but not always, reflected in the quarterly pricing files. Specifically, the specified amount for single source drugs and biological products is 106 percent of the amount determined under section 1847A(b)(4) of the Act—that is, the lesser of ASP or WAC—for the applicable calendar quarter. For biosimilar biological products, the specified amount is the payment amount under section 1847A(b)(1)(C) of the Act, which is based on 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product.

At § 427.302(b)(1), we proposed that the first applicable calendar quarter for a Part B rebatable drug will be the earliest applicable calendar quarter that follows the payment amount benchmark quarter identified at § 427.302(c)(1) through (5).

Additionally, for the purposes of determining the rebate amount for a Part B rebatable drug, based on further consideration of data availability in specific circumstances, we proposed to clarify the policy established in section 50 of the revised Medicare Part B Drug Inflation Rebate Guidance and use the most updated price information reported by manufacturers, determined in accordance with section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act as applicable, as the specified amount for the applicable calendar quarter for each HCPCS code identified in accordance with § 427.101. That is, we will use the most updated price information reported by manufacturers to compare whether 106 percent of WAC or 106 percent of ASP is less, and will use the lower value for the specified amount. In circumstances in which all NDCs in the HCPCS code have neither manufacturer-reported ASP nor WAC price data available for the applicable calendar quarter, we proposed to use WAC price data from other public sources, if available, to calculate 106 percent of WAC, which will serve as the specified amount. We proposed to adopt this approach regardless of whether there is a price substitution for Medicare's payment during the quarter or whether other policies cause the published payment limit to differ from the specified amount. In circumstances in which negative or zero manufacturer ASP data is reported for all NDCs for a given quarter, that negative or zero ASP amount will be used to compare 106 percent of WAC to 106 percent of ASP to determine the lower value for use as the specified amount. CMS believes these proposals on treatment of missing pricing data and treatment of pricing differences between reported prices and the published payment limit for a billing and payment code will further clarify the application of the specified amount in the calendar quarter and are consistent with the requirements set forth in section 1847A(i)(3)(A)(ii)(I) of the Act. CMS solicited comments on this policy.

We received public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: One commenter expressed support for CMS' proposal to determine the specified amount by comparing whether 106 percent of ASP or 106 percent of WAC is lower. However, this commenter disagreed with CMS using WAC when determining a product's specified amount when reported ASP is zero or negative because the specified amount refers to the payment amount determined in accordance with section 1847A(i)(3)(A)(ii)(I) of the Act, which directs CMS to use the lesser of the product's ASP or WAC plus 6 percent. The commenter noted that using WAC in the context of inflation rebates is inappropriate because inflation rebates are intended to address rising drug prices.

Response: We believe this commenter misunderstood our proposal. In the CY 2025 PFS proposed rule (89 FR 61945), we proposed to compare whether 106 percent of WAC or 106 percent of ASP is less using the most updated price information reported by manufacturers, and then to use the lower value for the specified amount. We also proposed that, in circumstances in which negative or zero manufacturer ASP data is reported for all NDCs for a given quarter, the negative or zero ASP amount will be used when comparing 106 percent of WAC to 106 percent of ASP to determine the lower value for use as the specified amount. That is, the specified amount in such circumstances will be the lower of 106 percent of the negative or zero ASP or 106 percent of WAC. We believe the proposals on the treatment of missing or negative pricing data for a billing and payment code clarify the application of the specified amount in the calendar quarter and are consistent with the requirements set forth in section 1847A(i)(3)(A)(ii)(I) of the Act.

After consideration of public comments, we are finalizing our proposal as proposed with modifications at § 427.302(b). We are making a technical correction to § 427.302(b)(1) to clarify that the first applicable calendar quarter for a Part B rebatable drug will be the later of the third full calendar quarter after the payment amount benchmark quarter identified in § 427.302(c)(1) through (5) or the calendar quarter beginning January 1, 2023. We also are making a technical correction by adding § 427.302(b)(2) to state that for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the effective date of the drug's assigned billing and payment code other than a NOC code, whichever is later, the first applicable calendar quarter will be the first full calendar quarter that follows the payment amount benchmark quarter identified in § 427.302(c)(1) through (5). Finally, with the addition of § 427.302(b)(2) as previously described, we are revising a paragraph reference to be § 427.302(b)(3).

(2) Identification of the Payment Amount Benchmark Quarter

At § 427.302(c), we proposed to codify policies from section 50.3 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify the applicable payment amount benchmark quarter. Specifically, for drugs first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the payment amount benchmark quarter would be the calendar quarter beginning July 1, 2021. For subsequently approved drugs—that is, drugs approved or licensed by the FDA after December 1, 2020—the payment amount benchmark quarter would be the third full calendar quarter after a drug's first marketed date. Additionally, there may be cases where a drug was first approved or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020, and the drug lacks ASP or WAC data to calculate the payment amount for the applicable calendar quarter beginning July 1, 2021. Under the policy applicable to drugs approved or licensed and with a first marketed date before December 1, 2020, such drugs would not have data to calculate the payment amount in the payment amount benchmark quarter. In these cases, we proposed to treat such drugs in the same manner as we would treat subsequently approved drugs and identify the payment amount benchmark quarter as the third full calendar quarter after a drug's first marketed date. We solicited comments on this policy proposal and specifically on our proposal to treat drugs approved

or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020 as subsequently approved drugs.

For Part B rebatable drugs that were billed under a NOC code during the payment amount benchmark quarter, CMS stated in the revised Medicare Part B Drug Inflation Rebate Guidance that it would use the third full quarter after a drug was assigned a unique HCPCS code as the payment amount benchmark quarter. In this rulemaking, we proposed to determine the payment amount benchmark quarter as follows: for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, we proposed that the payment amount benchmark quarter be the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code. We solicited comments on these proposals.

We noted in the CY 2025 PFS proposed rule (89 FR 61945) that we continue to consider whether there is a need to identify additional or modified methodologies to appropriately determine the payment amount benchmark quarter for products with insufficient pricing data in the payment amount benchmark quarter or that otherwise do not fall squarely into the categories otherwise described at § 427.302(c) and in a manner that enables the calculation of rebate amounts consistent with section 1847A(i)(3) of the Act.

In the CY 2025 PFS proposed rule (89 FR 61945), we noted that we have determined that ASP data are the most appropriate for identifying (1) the day on which the drug was first marketed and (2) which calendar quarter is the third full calendar quarter thereafter as the payment amount benchmark quarter for drugs first approved or licensed by the FDA after December 1, 2020, or licensed on or before December 1, 2020, but with a first marketed date after December 1, 2020. We also noted that we have determined that it is most appropriate and administratively feasible to identify the first marketed date as the date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application.

Additionally, we noted in the CY 2025 PFS proposed rule (89 FR 61945) that we believe ASP data are accurate and reliable because manufacturers attest to the accuracy of their submitted data and have the ability to update these data quarterly. Therefore, at § 427.302(c), we proposed to codify existing policy from the revised Medicare Part B Drug Inflation Rebate Guidance on the identification of the payment amount benchmark quarter for each Part B rebatable drug. CMS will use the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code for that Part B rebatable drug as of the applicable calendar quarter have ever been marketed. The earliest first marketed date will apply to all NDCs within a billing and payment code and to all products and package sizes marketed under the same FDA-approved application. If the original NDC on which the first marketed date is based is terminated, the first marketed date for the associated billing and payment code would remain the same. By defining the first marketed date for the Part B rebatable drug at the level of the product's FDA approval, CMS will retain the same first marketed date for the billing and payment code even if the NDCs and/or billing and payment codes used to bill for the Part B rebatable drug change over time. In addition, when the date of first sale is missing from ASP data, we proposed to identify the first marketed date from alternative public sources, such as the National Institutes of Health's DailyMed.

Table 54 in this section provides an example, for illustration purposes only, of the application of first marketed date based on the earliest date of first sale of any NDC ever marketed under any NDA or BLA under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have ever been marketed. In the example, NDC1 (marketed under NDA 000000) is first sold on January 15, 2022, and NDC2 (also marketed under NDA 000000) is first sold on October 15, 2023. Both NDCs are assigned to HCPCS code X0000, and no other NDCs are or have been assigned to HCPCS code X0000. NDC1 and NDC2 are the only NDCs marketed under NDA 000000. The first marketed date for HCPCS code X0000 would be January 15, 2022, because that date is the earliest date of first sale for any NDC marketed under any NDA or BLA under which any NDC ever assigned to that HCPCS code was marketed as of the calendar quarter. If NDC2 was subsequently assigned to a new HCPCS code Y0000, the first marketed date for HCPCS Y0000 would similarly be January 15, 2022, because that is the earliest date of first sale for any NDC (NDC1) marketed under any NDA (NDA 000000) under which any NDC ever assigned to HCPCS code Y0000 (NDC2) was marketed. In cases when NDCs that are marketed under different NDA/BLAs are assigned to the same HCPCS code, using the example in the table in this section, NDC3 (the only NDC marketed under NDA 111111) was first sold on November 1, 2024, and first billed under HCPCS Y0000. The first marketed date for HCPCS Y0000 would remain January 15, 2022, as noted, given that HCPCS Y0000 includes NDC2, marketed under NDA 000000, for which the earliest date of first sale for any NDC marketed thereunder is NDC1's date of first sale (January 15, 2022). NDC3 was later assigned to a new HCPCS code Z0000. The first marketed date for HCPCS code Z0000 would be November 1, 2024, because that is the earliest date of first sale for any NDC ever marketed under NDA 111111, which is the only NDA ever associated with Z0000 as of the calendar quarter.

TABLE 54: Example of Application of First Marketed Date at the FDA Approval Level

Calendar Quarter	HCPCS Code	NDC	FDA Application Number	Date of First Sale for NDC	HCPCS Code Effective Date	Date of First Sale for Any NDC in NDA/BLA	First Marketed Date
2023 Q2	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
2023 Q3	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2023 Q4	X0000	NDC1	000000	1/15/2022	4/1/2023	1/15/2022	1/15/2022
		NDC2	000000	10/15/2023	4/1/2023	1/15/2022	
2024 Q1	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q2	X0000	NDC2	000000	10/15/2023	4/1/2023	1/15/2022	1/15/2022
2024 Q3	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
2024 Q4	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
		NDC3	111111	11/1/2024	7/1/2024	11/1/2024	
2025 Q1	Y0000	NDC2	000000	10/15/2023	7/1/2024	1/15/2022	1/15/2022
	Z0000	NDC3	111111	11/1/2024	1/1/2025	11/1/2024	11/1/2024

We did not receive public comments on this provision to identify the payment amount benchmark quarter for each Part B rebatable drug.

After further consideration of the provision, we are finalizing, with modification, an amendment to § 427.302(c) to specify that to identify the applicable payment amount benchmark quarter, we also will use the earliest approval or licensure date for any FDA application associated with any NDC ever assigned to the billing and payment code. We are making this modification because we identified an example scenario in which an NDC previously assigned to a billing and payment code had a first marketed date in June 1992 (that is, before December 1, 2020), but the FDA applications with NDCs currently in the billing and payment code were approved after December 1, 2020. Prior to CMS adding the modification, this billing and payment code would have met the definition of a subsequently approved drug under § 427.20 and been subject to the payment amount benchmark quarter identification method at § 427.302(c)(2), which would have meant the payment amount benchmark quarter would be the third full calendar quarter after the first marketed date—that is, a payment amount benchmark quarter in 1993. This outcome would have been inconsistent with the policy described in the proposed rule. By defining and referencing the billing and payment code FDA approval or licensure date using the same FDA applications used to identify the first marketed date for associated NDCs, the regulatory text better reflects our original intent to avoid incongruous results and retain the same approval or licensure date for the billing and payment code even if an NDC is removed from the billing and payment code. As finalized with such modification, the billing and payment code in the above scenario will have a first marketed date in 1992 and a first approval date *before* December 1, 2020, and thus will have a payment amount benchmark quarter of July 1–September 30, 2021 under § 427.302(c)(1).

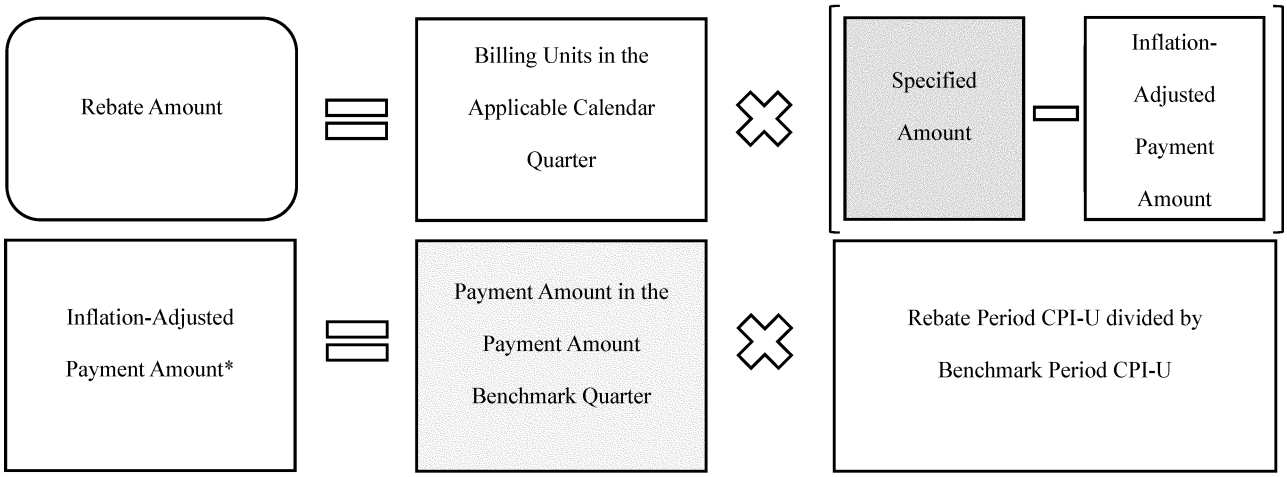
(3) Identification of Payment Amount in the Payment Amount Benchmark Quarter

Section 1847A(i)(3)(C) of the Act specifies use of the ''payment amount for the billing and payment code for such drug in the payment amount benchmark quarter'' (''payment amount in the payment amount benchmark quarter'') in the determination of the inflation-adjusted payment amount. While the specified amount and the payment amount in the payment amount benchmark quarter are similar, the statutory requirements for determining these two amounts differ. The specified amount for a Part B rebatable drug, as set forth in section 1847A(i)(3)(A)(ii)(I) of the Act, is based on item (aa) (that is, lesser of ASP+6 percent or WAC+6 percent) or (bb) (that is, 100 percent of the ASP for the biosimilar biological product plus 6 percent of the lesser of ASP or WAC for the reference biological product). The payment amount in the payment amount benchmark quarter under section 1847A(i)(3)(C)(i) of the Act is based on various provisions within section 1847A of the Act (for example, the lesser of 106 percent ASP or WAC, WAC+3 percent, and price substitutions). To identify the payment amount in the payment amount benchmark quarter for the Part B rebatable drug by billing and payment code, at § 427.302(d), we proposed to codify the policies established in section 50.4 of the revised Medicare Part B Drug Inflation Rebate Guidance. CMS will use the published payment limit (as available) for the billing and payment code for the applicable payment amount benchmark quarter determined in accordance with section 1847A of the Act. If a published payment limit is not available for the applicable payment amount benchmark quarters, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC. If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of identifying the payment amount in the payment amount benchmark quarter, CMS will consider to be the payment amount for the payment amount benchmark quarter. Table 55 and Figure B–I4 illustrate the specified amount and payment amount in the payment amount benchmark quarter.

TABLE 55: Comparison of Specified Amount and Payment Amount in the Payment Amount Benchmark Quarter

Specified Amount		Payment Amount in the Payment Amount Benchmark Quarter	
Purpose in Rebate Calculation	**Pricing Methodology Under 1847A(i)(3)(A)(ii)(I)**	**Purpose in Rebate Calculation**	**Pricing Methodology Under 1847A(i)(3)(C)(i)**
Part B amount described under 1847A(i)(3)(A)(ii)(I) for the calendar quarter in which a rebate may be assessed	• Lesser of ASP+6% or WAC+6% • In the case of a biosimilar biological product, 100% of ASP for the biosimilar biological product + 6% of the lesser of ASP or WAC for the reference biological product	Part B published payment limit for the payment amount benchmark quarter, which is generally the quarter beginning July 1, 2021	• Various Part B pricing provisions consistent with section 1847A of the Act

FIGURE B-I4: Use of the Specified Amount and the Payment Amount in the Benchmark Quarter in Rebate Calculations



* See the section Determination of the Inflation Adjusted Payment Amount for information about identification and calculation of the inflation-adjusted payment amount.

We note that there may be situations when a Part B rebatable drug was previously billed under a grouped billing and payment code during the benchmark quarter and later billed under a unique billing and payment code, such as certain section 505(b)(2) drug products and single source drugs that were previously multiple source drugs. For example, a multiple source drug approved under an NDA may become a single source drug if all other therapeutically equivalent drugs are no longer marketed and the now-single source NDA is later shifted into a separately payable code. To identify the payment amount in the payment amount benchmark quarter for such drugs, we proposed to codify policy established in section 50.4 of the Medicare Part B Drug Inflation Rebate Guidance and identify the grouped billing and payment code payment limit used by CMS for the payment amount in the payment amount benchmark quarter and use that payment limit for the benchmark quarter.

Finally, consistent with the policy established in section 50.4 of the revised Medicare Part B Drug Inflation Rebate Guidance, we will not apply a sequestration reduction to the payment amount in the payment amount benchmark quarter as part of the methodology to calculate a Part B inflation rebate amount.

Comment: A couple of commenters expressed concern about the metric CMS is using to determine the payment amount in the payment amount benchmark quarter. One commenter expressed concern about Part B rebatable drugs that were not in a grouped billing and payment code as of October 1, 2003, but were in a grouped billing and payment code as of July 1, 2021 and were later assigned to a unique billing and payment code. For these drugs, the commenter wrote that the benchmark payment amount reflects the grouped billing and payment code; however, the drug's price in any given quarter reflects the drug's unique billing and payment code payment amount. The implications of this, according to the commenter, are that the payment amount in the payment amount

benchmark quarter may be low because it accounts for all drugs in a grouped billing and payment code, making it seem like the drug's price has increased more than it actually has. Further, this commenter wrote that CMS is measuring the drug's current payment amount (based on unique billing and payment code) against the past, lower grouped billing and payment code. To address this concern, the commenter recommended CMS apply a drug-specific benchmark measurement for Part B rebatable drugs that moved from a grouped billing and payment code to a unique code and then calculate the payment amount in the payment amount benchmark quarter based on how the calculation would have been made if the drug had been assigned to a unique code before the payment amount benchmark quarter. The commenter added that this approach would more accurately reflect real price increases for drugs previously in grouped billing and payment codes. Additionally, another commenter recommended that CMS use the manufacturer calculated specified amount instead of the ''published payment limit'' for grouped billing and payment codes.

Response: We appreciate these commenters raising these concerns. We believe that in situations when a Part B rebatable drug was previously billed under a grouped billing and payment code during the benchmark quarter and later billed under a unique billing and payment code, using the payment limit for the grouped billing and payment code payment is in accordance with section 1847A(i)(3)(C)(i) of the Act. This provision sets forth the payment amount in the payment amount benchmark quarter and is based on various provisions within section 1847A of the Act (for example, the lesser of 106 percent ASP or WAC, WAC+3 percent, and price substitutions). We also note that single source drugs or biological products that were within the same billing and payment code as of October 1, 2003 are treated as multiple-source drugs, per section 1847A(c)(6)(C)(ii) of the Act, and will be excluded from the definition of a Part B rebatable drug as proposed at § 427.101(b)(2).

After consideration of public comments on this proposed provision, we are finalizing our proposal as proposed at § 427.302(d).

(4) Identification of the Benchmark Period CPI–U

For each Part B rebatable drug by HCPCS code, the statute requires CMS to identify the applicable benchmark period CPI–U. In accordance with section 1847A(i)(3)(E) of the Act, the benchmark period CPI–U for drugs first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, is the CPI–U for January 2021, which is 261.582.[652] We proposed to codify at § 427.302(e) policies established in section 50.5 of the revised Medicare Part B Drug Inflation Rebate Guidance. Specifically, the benchmark period CPI–U for drugs first approved or licensed on or before December 1, 2020, with a first marketed date after December 1, 2020, will be the CPI–U for the first month of the third full calendar quarter after a drug's first marketed date. Additionally, we proposed to codify policies in revised guidance that the benchmark period CPI–U for subsequently approved drugs will be the first month of the first full calendar quarter after a drug's first marketed date in accordance with section 1847A(i)(4)(A) of the Act. Furthermore, we proposed to determine the benchmark period CPI–U for certain drugs previously billed under NOC codes as follows: For a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, we proposed that the benchmark period CPI–U will be first month of the third full calendar quarter after the drug is assigned a billing and payment code other than a NOC code.

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended that CMS align the payment amount benchmark quarter and the benchmark quarter CPI–U for drugs approved on or before December 1, 2020, but with a first marketed date after December 1, 2020. CMS proposed that for a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, but with a first marketed date after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date. Specifically, these commenters recommended CMS treat the benchmark quarter CPI–U in the same manner as CMS' approach for subsequently approved drugs. For subsequently approved drugs, CMS proposed that the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date in accordance with section 1847A(i)(4)(A) of the Act. One commenter noted that revising the policy to align the benchmark quarter CPI–Us for such drugs would provide consistency for manufacturers.

One of these commenters also made a similar recommendation for Part B rebatable drugs previous billed under a NOC code—that CMS should take a consistent approach for such drugs and identify the benchmark period CPI–U as the first full calendar quarter after the day on which the drug was first marketed as it does for subsequently approved drugs.

Response: We thank these commenters for their feedback. We agree with these commenters' recommendations. We have revised this policy to align the payment amount benchmark period CPI–U and to maintain a consistent approach for all Part B rebatable drugs. For example, both for drugs first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020 (§ 427.302(e)(1)) and for subsequently approved drugs (§ 427.302(e)(2)), there are two quarters between the payment amount benchmark quarter and the benchmark period CPI–U identified under statute. To align the approaches, we are revising the CPI–U date at § 427.302(e)(3) and (e)(4) to reflect the same two-quarter difference. We consider this revision a correction rather than a material policy change. At § 427.302(e)(3), CMS is finalizing the policy that for a Part B rebatable drug first approved or licensed by FDA on or before December 1, 2020, and with a first marketed date after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date. Also, at § 427.302(e)(4), for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

Comment: One commenter recommended that CMS clarify that it will provide timely notification to manufacturers when CMS assigns a drug to a new billing and payment code to allow manufacturers to prepare for any impact to inflation rebate calculation for that drug.

Response: We appreciate this suggestion. We refer manufacturers to CMS' HCPCS Quarterly Update website,

[652] CMS retrieved the January 2021 CPI–U from bls.gov on March 22, 2024.

where we post all HCPCS Level II updates.[653] These files are fully searchable and sortable. We also note that additional information about HCPCS coding procedures[654] also is available on the CMS' HCPCS Quarterly Update website.

After consideration of public comments, we are finalizing the provision at § 427.302(d) as proposed and are finalizing, with modifications, an amendment to § 427.302(e)(3), to use the first month of the first full calendar quarter after a drug's first marketed date as the benchmark period CPI–U for drugs first approved or licensed on or before December 1, 2020, and with a first marketed date after December 1, 2020. Additionally, we are finalizing, with modifications, an amendment to § 427.302(e)(4), to use the first month of the first full calendar quarter after the drug is assigned a billing and payment code other than a NOC code as the benchmark period CPI–U for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full quarter after such drug's first marketed date, whichever is later.

(5) Identification of the Rebate Period CPI–U

As specified in section 1847A(i)(3)(F) of the Act, at § 427.302(f), we proposed to codify the policy described in section 50.6 of the revised Medicare Part B Drug Inflation Rebate Guidance, that the rebate period CPI–U means the greater of the benchmark period CPI–U index level and the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters prior to the applicable calendar quarter in which the Part B rebatable drug is furnished. CMS will retrieve the CPI–U index level information from *bls.gov*.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.302(f).

(6) Determination of the Inflation-Adjusted Payment Amount

Section 1847A(i)(3)(C) of the Act specifies the determination of the inflation-adjusted payment amount. At § 427.302(g), we proposed to codify the policy established in section 50.7 of revised Medicare Part B Drug Inflation Rebate Guidance for determining the inflation-adjusted payment amount in accordance with this section of the Act. For each applicable calendar quarter and for each Part B rebatable drug by billing and payment code, we proposed to use the payment amount in the payment amount benchmark quarter (per § 427.302(d)), benchmark period CPI–U (per § 427.302(e)), and rebate period CPI–U (per § 427.302(f)) to identify the inflation-adjusted payment amount. Specifically, we will calculate the inflation-adjusted payment amount by dividing the rebate period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the payment amount in the payment amount benchmark quarter.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.302(g).

iv. Determination of Total Number of Billing Units

For calendar quarters starting on or after January 1, 2023, we proposed at § 427.303 to codify policies established in section 50.8 of the revised Medicare Part B Drug Inflation Rebate Guidance to determine the number of billing units for each Part B rebatable drug by HCPCS code. Section 1847A(i)(3)(B) of the Act describes the total number of billing units of Part B rebatable drugs that should be included in the rebate calculation. These billing units include the number of billing units for the HCPCS code of the Part B rebatable drug furnished during the relevant calendar quarter minus billing units of drugs with respect to which the manufacturer provides a discount under the 340B Program, billing units with respect to which the manufacturer could have paid a Medicaid rebate, and billing units that are packaged into the payment amount for an item or service and are not separately payable. We further proposed codifying policy set forth in revised Medicare Part B Drug Inflation Rebate Guidance at § 427.303 to exclude billing units when a drug is no longer a Part B rebatable drug.

After identifying Part B rebatable drugs by HCPCS code (in accordance with policy proposed at §§ 427.10, 427.20, and 427.100 through 427.101) using final action claims in the CMS Medicare fee-for-service claims repository, we proposed to codify existing policy in the revised Medicare Part B Drug Inflation Rebate Guidance at § 427.303 to determine the total number of billing units for each HCPCS code as follows. We proposed to identify claim lines for such HCPCS code for dates of service in the calendar quarter, exclude billing units in claim specified in section 1847A(i)(3)(B)(ii) of the Act, as applicable, and sum the number of billing units in the remaining claim lines for which Medicare payment was allowed and greater than zero. Including billing units where Medicare payment was allowed would ensure that billing units for which Medicare and some beneficiaries have financial liability would be counted in the total number of billing units.

We proposed to codify the policy in the revised Medicare Part B Drug Inflation Rebate Guidance at § 427.303 and will perform this process at least 3 months after the end of a calendar quarter to allow time for claims to be submitted, processed, and finalized. Subpart F described the proposed rebate process, including reports of rebate amounts, suggestion of error, and restatements. We solicited comment on the following proposed policies, including whether any additional units should be excluded from the rebate amount calculation.

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter recommended CMS also exclude units from other federal programs such as units purchased under the Federal Supply Schedule, as these units already have statutory discounts.

Response: In response to the request that CMS also exclude units from other Federal programs, section 1847A(i)(3)(B) of the Act prescribes that the total number of units is based on the number of units furnished in a calendar quarter, excluding units of drugs with respect to which the manufacturer provides a discount under the 340B Program, units with respect to which the manufacturer pays a Medicaid rebate, or units that are packaged into the payment amount for an item or service and are not separately payable. In addition, CMS will exclude units when a drug is no longer a Part B rebatable drug. CMS declines to adopt the commenter's recommendation to exclude units from other federal programs, such as units purchased under the Federal Supply Schedule.

After consideration of public comments, we are finalizing our proposal as proposed at § 427.303 to exclude specified units from Part B inflation rebate calculations. We note that, in the Medicare Part D Drug Inflation Rebate Program provisions, we finalized at § 428.203(b)(3) that CMS will exclude units from the total number of units dispensed of a Part D rebatable drug when those units are associated with a Part D rebatable drug that has been billed as compounded. We have not made equivalent modifications in

[653] See: *https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update.*

[654] CMS, HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURES, December 2022, *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.*

the Medicare Part B Drug Inflation Rebate Program provisions because drugs covered under Part B that are billed as compounds should be reported with HCPCS code J7999, which is a NOC code.[655] Because products billed under a NOC code are not considered Part B rebatable drugs, as finalized at § 427.101(b)(3), drugs covered under Part B that are billed as compounds are by default already excluded from Part B inflation rebate calculations. For the same reason, it is unnecessary to modify § 427.101(c) to explicitly exclude drugs covered under Part B that are billed as compounds from the calculation of the average total allowed charges used to exclude drugs and biological products with average total allowed charges below the applicable threshold.

(1) Units of Drugs Acquired Through the 340B Program

Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes billing units of drugs for which the manufacturer provides a discount under the 340B Program from the billing units of drugs for which a manufacturer may otherwise have a Part B inflation rebate liability. We proposed codifying the policy described in section 50.8.1 of the revised Medicare Part B Drug Inflation Rebate Guidance at § 427.303 to remove separately payable billing units in claim lines that are billed with the ''JG'' or ''TB'' modifiers from identified final action claim lines.

In the CY 2025 PFS proposed rule, CMS sought to codify the removal of units of drugs for which the manufacturer provides a discount under the 340B Program from Part B inflation rebate calculations based on certain prior CMS policies set forth in this paragraph related to the identification of claims for such drugs. On December 20, 2022, CMS issued program guidance that requires all 340B covered entities to include the ''JG'' or ''TB'' modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B Program with dates of service beginning no later than January 1, 2024.[656] Furthermore, in the CY 2024 OPPS final rule (88 FR 81791 through 81792), CMS finalized a policy to utilize a single 340B modifier (''TB''), requiring hospitals that currently report the ''JG'' modifier to use the ''TB'' modifier beginning January 1, 2025. As described in the final rule, in CY 2024, these hospitals can choose to continue to use the ''JG'' modifier or choose to transition to the use of ''TB'' modifier during that year. On December 14, 2023, CMS updated the December 20, 2022 guidance titled ''Part B Inflation Rebate Guidance: Use of the 340B Modifiers'' to align with the updated single modifier requirement.[657]

We proposed at § 427.303(b)(1)(i) to exclude separately payable billing units in claim lines for professional claims with dates of service during 2023 from suppliers that are covered entities listed by the HRSA 340B Office of Pharmacy Affairs Information System (OPAIS) as participating in the 340B Program. CMS will use National Provider Identifier (NPI) numbers and/or Medicare Provider Numbers (MPN) to identify these suppliers and the claims submitted with such identifiers. We proposed to continue this approach for professional claims with dates of service during 2024. For institutional claims through 2024, we proposed to remove units in all institutional claim lines that were billed with the ''JG'' or ''TB'' modifiers. Consistent with the CMS updated 340B modifier guidance, we proposed at § 427.303(b)(1)(iii) to exclude separately payable billing units in claim lines for institutional providers with the ''JG'' and ''TB'' modifiers from identified final action claims with dates of service through December 31, 2024. We proposed to codify policies established in section 50.8.1 of the revised Medicare Part B Drug Inflation Rebate Guidance at § 427.303(b)(1)(iii) by excluding separately payable billing units in claim lines with the ''TB'' modifier from identified final action claims with dates of service on or after January 1, 2025. We proposed to use these modifiers to identify and exclude billing units for which a discount was acquired under the 340B Program because the ''TB'' modifier is an existing mechanism used to identify drugs acquired through the 340B Program and familiar to most 340B covered entities paid under the OPPS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter recommended CMS provide manufacturers with claim-level data so that manufacturers may verify rebate reports and validate that 340B units are not included in inflation rebate calculations. Another commenter asked CMS to share claim-level data to prevent duplicate discounts and noted that the commenter found modifiers did not consistently identify duplicate claims.

Response: CMS declines to provide claim-level data to manufacturers regarding the 340B Program or other statutory exclusions of units from rebate counts as CMS does not believe this is necessary to operate the program at this time. Providing manufacturers with extracts of claim-level data regarding the 340B Program or other statutory exclusions of units from rebate counts at a cadence that aligns with timing for Rebate Reports such that a manufacturer could use the data to validate their Reports would be a complex undertaking for the agency. Additionally, providing claim-level data raises considerations on potential impact to other interested parties such as pharmacies and plans or Pharmacy Benefit Managers (PBMs). Based on CMS' engagement with interested parties, there is no consensus on what they consider to be essential data fields to verify rebate reports and validate removal of 340B units without risk of disclosure of protected health information or other sensitive or confidential information. Finally, while the statute requires manufacturers to pay a Part B inflation rebate on drugs with prices that exceed inflation for an applicable calendar quarter, there are no statutory requirements for the provision of claim-level data or 340B data to manufacturers to fulfill their obligation to pay a Part B inflation rebate. The Rebate Reports and reconciliation policy described at § 427.502 of this final rule will allow manufacturers to review results of rebate calculations and raise a mathematical error during the Suggestion of Error period described at § 427.503, thereby not requiring validation of 340B data.

Comment: A couple of commenters requested CMS specify that accurate use of the ''JG'' or ''TB'' modifier is required for a Part B claim to be complete and reimbursable. Some commenters suggested that CMS require Medicare Administrative Contractors (MACs) to reject claims as incomplete if they do not include a 340B or non-340B modifier (that is, to identify that a drug was not purchased under the 340B Program).

Some commenters recommended that CMS conduct audits to ensure covered entities' adherence to program requirements and to comprehensively exclude the appropriate units from inflation rebate calculations. A few commenters suggested the audit process include penalties for non-compliant covered entities and recalculations of inflation rebate obligations when needed. One commenter asked CMS to

[655] See: *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59576&ver=7.*

[656] See: *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

[657] See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.*

publish specific penalties for non-compliance with program requirements, instead of providing a statement that covered entities are subject to the False Claims Act.

Response: We thank commenters for their feedback. The December 20, 2022 Part B Inflation Rebate Guidance: 340B Modifier [658] program guidance requires all 340B covered entities to include the ''JG'' or ''TB'' modifier, as applicable, on separately payable claim lines for drugs acquired through the 340B Program with dates of service beginning no later than January 1, 2024. This guidance was revised in the December 14, 2023 Revised Part B Inflation Rebate Guidance: 340B Modifier [659] program guidance, which maintains the modifier requirement but aligns it to policy in the CY 2024 OPPS final rule (88 FR 81791 through 81792).

Providers and suppliers are required to maintain current knowledge of Medicare billing policies and to submit accurate claims. Providers and suppliers are also required to maintain all documentation to support the validity of the services reported on the claim and ensure this information is available upon request. CMS expects providers and suppliers to submit accurate claims, to utilize the correct modifiers, and to correct any claim that omits a required modifier. CMS believes existing penalties are sufficient to promote provider and supplier compliance with these requirements. CMS intends for all rebate calculations to be as accurate and is providing a process for manufacturers to review rebate calculations, as described at § 427.501. Section 1847A(i)(8) of the Act precludes administrative or judicial review of the determination of units under this program, the determination of whether a drug is a Part B rebatable drug, and the calculation of the rebate amount.

Comment: Some commenters recommended that CMS adopt use of a non-340B modifier to identify Part B drugs not acquired through the 340B Program. Commenters stated that a non-340B modifier paired with the existing ''JG'' [660] and ''TB'' modifiers will allow for program integrity and comprehensive identification and removal of 340B units from Part B inflation rebate calculations. Commenters stated this approach would align with CMS' approach for the Part B discarded drug modifier JZ, where providers and suppliers submit a claim with the JZ modifier if there are no discarded amounts from single-dose container or single-use package drugs. One commenter stated that in the absence of a claims clearinghouse to identify and verify 340B claims, CMS should continue investigating methods to improve identification of 340B claims at the point of sale and to require modifiers for non-340B claims.

Response: At this time, CMS does not believe a modifier is needed to report drugs or biological products that were not purchased under the 340B Program. Based on available data at the time of this rulemaking, CMS does not have evidence that providers and suppliers are frequently omitting the ''JG'' and ''TB'' modifiers on a claim for a Part B drug purchased under the 340B Program. CMS continues to believe the requirement under the updated 340B modifier guidance and CY 2024 OPPS/ASC final rule for providers and suppliers to use a 340B modifier will provide the data required to identify and exclude 340B units from Part B inflation rebates.[661] [662]

Comment: A few commenters asked CMS to establish a clearinghouse model to identify 340B units and exclude these units from inflation rebate calculations. One commenter stated their ideal approach would be an independent entity serving as a clearinghouse for claims data. Commenters stated a clearinghouse would facilitate the identification of 340B claims, prevent duplicate discounts, and provide transparency. One commenter requested that CMS take an active role in ensuring the validity of data submitted to the clearinghouse and not rely only on attestations from covered entities. The same commenter recommended CMS provide covered entities with a set of data fields they must submit to the clearinghouse.

Response: We believe that requiring a claims modifier, as described in the December 20, 2022 Part B Inflation Rebate Guidance: 340B Modifier [663] program guidance and revised in the December 14, 2023 Revised Part B Inflation Rebate Guidance: 340B Modifier [664] program guidance, will provide the necessary data to exclude 340B units from Part B inflation rebates for institutional claims with dates of service starting in calendar year 2024. For professional claims with dates of service during 2023 and 2024, CMS will also remove all units in claims from suppliers that are covered entities listed by the HRSA 340B OPAIS as participating in the 340B Program. CMS will use NPIs and/or MPNs to identify these suppliers and the claims submitted with such identifiers. In this final rule, CMS clarified that we will use other fields in the OPAIS (such as name and address) to identify covered entities submitting professional claims with separately payable 340B units if NPI or MPN is not available. For institutional claims with dates of service during 2023, CMS will remove units in all institutional claim lines that were billed with the ''JG'' or ''TB'' modifiers and all other units in institutional claims submitted by 340B covered entities not paid under OPPS billing separately payable claim lines for drugs acquired under the 340B Program.

We decline to adopt the commenters' suggestion to adopt a clearinghouse model for identification and removal of 340B units from Part B claims on the basis that covered entities are knowledgeable of the 340B modifier requirements and current billing patterns reveal these modifiers are being reported on professional and institutional claims in CY 2023 and CY 2024. At this time, we do not have evidence to suggest a change in approach is necessary.

Comment: One commenter noted that CMS' proposed policy for excluding 340B units on professional claims with dates of service in 2023 and 2024 relies on NPIs and asked CMS to clarify that claims submitted without NPIs would be excluded from the calculation of inflation rebates.

Response: All providers and suppliers are required to report an NPI on a Medicare claim as required under § 424.506(c). For professional claims with dates of service in CY 2023 and CY 2024, CMS will use NPIs and/or MPNs to identify covered entities submitting professional claims with separately payable 340B units so that these units

[658] See: *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

[659] See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.*

[660] The ''JG'' modifier will be discontinued on December 31, 2024. All covered entities must transition to use the ''TB'' modifier for dates of service on or after January 1, 2025.

[661] See: *https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatientprospective-payment-and-ambulatory-surgical-center-payment.* See: *https://www.federalregister.gov/public-inspection/2023-24293/medicare-program-hospital-outpatientprospective-payment-and-ambulatory-surgical-center-payment.*

[662] See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.* See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.*

[663] See: *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

[664] See: *https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf.*

can be excluded from rebate calculations. In this final rule, CMS is clarifying that we will use other fields in the OPAIS (such as name and address) to identify covered entities submitting professional claims with separately payable 340B units if NPI or MPN is not available.

Comment: A few commenters requested CMS coordinate with HRSA to prevent the duplication of 340B discounts and possibly overstated inflation rebate obligations due to 340B units not being wholly excluded.

Response: CMS intends to continue to consult with HRSA for technical assistance with the 340B pricing databases and to ensure that the inflation rebate policies remove 340B units as required by statute.

Comment: A few commenters asked that CMS clarify that the 340B claims modifier requirement applies to all drugs covered under Medicare Part B, including Human Immunodeficiency Virus (HIV) pre-exposure prophylaxis (PrEP) drugs if an NCD is finalized for these drugs.

Response: On September 30, 2024 CMS determined that PrEP using antiretroviral drugs to prevent HIV is reasonable and necessary for the prevention of an illness or disability and will cover these drugs as an additional preventive service under Medicare Part B.[665] We clarify that the 340B modifier requirement applies to such antiretroviral drugs when covered under Part B for non-preventive purposes (that is, when used for diagnosis or treatment). Given the timing of the NCD in connection with the timing for development of this rulemaking, CMS intends to address whether Drugs Covered as Additional Preventive Services (DCAPS) would be Part B rebatable drugs in future policymaking.

Comment: One commenter expressed concern that the removal of 340B units from calculations could lead to higher costs for drugs commonly used by HIV patients.

Response: We appreciate the commenter's concern about drug costs for HIV patients. Section 1847A(i)(3)(B)(ii)(I) of the Act establishes that 340B units are removed from the Part B inflation rebate calculation.

After consideration of public comments, we are finalizing this provision with a few modifications.

We proposed at § 427.303(b)(1)(i) to exclude separately payable billing units in claim lines for professional claims with dates of service during 2023 from suppliers that are covered entities listed by the HRSA 340B OPAIS as participating in the 340B Program. CMS will use NPIs and/or MPNs to identify these suppliers and the claims submitted with such identifiers. In this final rule, CMS is noting that if NPIs and MPNs are not available from these suppliers and claims, it will use other fields available in OPAIS, such as name and address. As some covered entities in the OPAIS do not provide an NPI or MPN, using other fields in OPAIS will allow CMS to identify those covered entities and exclude their claims for separately payable drugs acquired under the 340B Program. CMS is further clarifying in this final rule that we will also remove units in all professional claim lines for dates of service during 2023 that were billed with the ''JG'' or ''TB'' modifiers. As use of the JG or TB modifier was not required for some covered entities until January 1, 2024, this approach will allow CMS to comprehensively exclude units of separately payable drugs acquired under the 340B Program from professional claims. In our proposal to codify policies described in the revised guidance, we inadvertently omitted a reference to our exclusion policy for all professional claims; the clarification herein is intended to ensure consistency with the policy described in the revised guidance. As we proposed in the CY 2025 PFS proposed rule, we will continue this approach for professional claims with dates of service during 2024.

We are adding language specifying that for institutional claims with dates of service during 2023, in addition to removing units in all institutional claim lines that were billed with the ''JG'' or ''TB'' modifiers, we will remove units in institutional claims from covered entities that are critical access hospitals and Maryland waiver hospitals. As critical access hospitals and Maryland waiver hospitals were not required to use the JG or TB modifier before January 1, 2024, CMS cannot use these modifiers to accurately remove units in institutional claims with dates of service during 2023 for these hospital types. In our proposal to codify prior policies described in the Part B revised guidance, we inadvertently omitted a reference to the exclusion of units in institutional claims submitted by covered entity critical access hospitals, Maryland waiver hospitals, and non-excepted off-campus provider-based departments (PBDs) billing separately payable claim lines for drugs acquired under the 340B Program for claims with dates of service from January 1, 2023 through December 31, 2023. Because critical access hospitals and Maryland waiver hospitals were not required to report ''JG'' or ''TB'' modifiers during 2023, the omission of such reference in the proposed regulatory text at § 427.303(b)(1)(ii) would not capture 340B units by such covered entities. Beginning January 1, 2024, all covered entities were required to report the ''JG'' or ''TB'' modifier. We do not specifically reference non-excepted off-campus provider-based departments (PBDs) in § 427.303(b)(1)(ii) and in this final rule because these entities were required to use a modifier for separately payable drugs before the December 20, 2022 program guidance requiring use of the ''JG'' or ''TB'' modifier for all 340B covered entities beginning on January 1, 2024. Therefore, separately payable drugs acquired under the 340B Program billed by non-excepted off-campus PBDs in 2023 can be identified with the ''JG'' or ''TB'' modifier and would be excluded from rebate calculations.

We are also finalizing an amendment to § 427.303(b)(1)(iii) to state that we will exclude from rebate calculations separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers for claims with dates of service from January 1, 2024 through December 31, 2024. We are also finalizing an amendment to § 427.303(b)(1)(iv) to state that we will exclude from rebate calculations separately payable billing units in claim lines for institutional claims that are billed with the ''TB'' modifier for claims with dates of service on or after January 1, 2025.

CMS views these amendments as merely technical changes to improve operations in fulfillment of our statutory obligation to exclude 340B units under the Medicare Part B Drug Inflation Rebate Program; therefore, CMS believes that the revised regulatory text of § 427.303(b)(1) more accurately reflects our policies described in the Medicare Part B Drug Inflation Rebate Revised Guidance.

(2) Units With a Rebate Under Section 1927 of the Social Security Act

To receive payment under Medicaid for covered outpatient drugs, manufacturers must participate in the Medicaid Drug Rebate Program (MDRP) (that is, have a drug rebate agreement in effect with the Secretary of HHS) and are required to report certain pricing and drug product information and pay Medicaid drug rebates for covered outpatient drugs furnished and paid for under the Medicaid State plan. States

[665] See: *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310&fromTracking=Y&doctype=all&timeframe=30&sortBy=updated&bc=20.*

invoice manufacturers no later than 60 days after the end of each calendar quarter on the number of units of each dosage form and strength of each covered outpatient drug furnished and paid for under the State plan. This invoice includes units of covered outpatient drugs that are furnished to dually eligible beneficiaries when the claim for the drug is paid for by Medicare Part B and the beneficiary's cost sharing is covered by Medicaid. To determine unit counts for rebate calculations, at this time, at § 427.303(b)(2), we proposed codifying our policy described in revised Medicare Part B Drug Inflation Rebate Guidance in section 50.8.2 to exclude billing units from claims with dates of service during a month within a calendar quarter when the Medicare beneficiary has Medicaid coverage that may provide cost-sharing assistance. These are Qualified Medicare Beneficiary (QMB) Plus, Specified Low-Income Medicare Beneficiary (SLMB) Plus, QMB-only beneficiaries, and other full dually eligible beneficiaries. We further proposed codifying the policy in revised guidance that billing units for Part B rebatable drugs furnished to Medicare beneficiaries with Medicaid coverage that does not include cost-sharing assistance (that is, SLMB Only, Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries) be included in rebate calculations. CMS will identify the months for which a beneficiary has Medicaid coverage with cost-sharing assistance using available information (for example the State MMA File of dually eligible beneficiaries) at the time the rebate amount is being calculated for a calendar quarter. We proposed codifying this policy as manufacturers pay rebates through the Medicaid Drug Rebate Program on units of covered outpatient drugs that are furnished to dually eligible beneficiaries when the claim for the drug is paid for by Medicare Part B and the beneficiary's cost sharing is covered by Medicaid.

We also considered excluding all units furnished to dually eligible individuals but did not propose this alternative because it would result in the over exclusion of units.

Comment: One commenter supported the proposal to exclude units subject to rebates under the MDRP that are furnished to dually eligible beneficiaries when the claim is paid by Medicare Part B and the beneficiary's cost sharing is covered by Medicaid.

Response: We appreciate this commenter's support.

After consideration of public comments, we are finalizing as proposed at § 427.303(b)(2).

(3) Units That Are Packaged Into the Payment Amount for an Item or Service and Are Not Separately Payable

As described earlier in this section, we proposed codifying our policy in section 50.8.3 of revised Medicare Part B Drug Inflation Rebate Guidance and only include claim lines with a Medicare allowed amount greater than zero. Because we proposed at § 427.303(b)(3) identifying billing units for separately payable claim lines for Part B rebatable drugs only, no further action would be necessary to exclude billing units that are packaged into the payment amount for an item or service and are not separately payable, such as drugs for which payment is packaged under the OPPS, or the Ambulatory Surgical Center (ASC) payment system, or those furnished in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting. CMS notes that claim lines for drugs for which payment is bundled under the ESRD PPS would not have a Medicare allowed amount that is greater than zero and such units would therefore be excluded.

We also noted in the CY 2025 PFS proposed rule (89 FR 61949) that in accordance with policies established in the CY 2024 OPPS/ASC final rule and codified in regulatory text at 88 FR 81540, CMS will except biosimilar biological products from the OPPS threshold packaging policy when their reference biological products are separately paid. This means that CMS will pay separately for these biosimilar biological products even if their per-day cost is below the threshold packaging policy. Because units of these biosimilar biological products are not packaged into the payment amount for an item or service and are separately payable, they will be included in the Part B inflation rebate calculation if they are not qualifying biosimilar biological products.

Comment: One commenter supported CMS' proposal to exclude bundled units from the calculation of the Medicare Part B inflation rebate.

Response: We appreciate this commenter's support.

After consideration of public comments, we are finalizing as proposed at § 427.303(b)(3).

(4) Units When a Drug Is No Longer a Part B Rebatable Drug

As described in section 1847A(i)(2) of the Act, multiple source drugs are not Part B rebatable drugs. A single source drug that is a Part B rebatable drug could become a multiple source drug at the start of or during a calendar quarter. In such cases, at § 427.303(b)(4), we proposed codifying policy in section 50.8.4 of the revised Medicare Part B Drug Inflation Rebate Guidance to identify the first marketed date, as described at § 427.20, of a drug product that is rated as therapeutically equivalent to such a drug under FDA's most recent publication of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the FDA Orange Book [666]) and determine whether the drug is no longer a Part B rebatable drug. At § 427.303(b)(4), we proposed to exclude billing units of such drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter. We further proposed codifying policy that CMS may consult with the FDA for technical assistance in instances where there is ambiguity as to whether a new product is therapeutically equivalent. Units furnished on or after the calendar month of the first marketed date will be excluded from the units identified in accordance with § 427.303(b)(4)(iii).

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.303(b)(4).

(5) Operational Considerations Related to the Inclusion of Units Furnished to Beneficiaries Who Are Enrolled in Medicare Advantage (MA) Plans

Section 1847A(i) of the Act requires the manufacturer of a Part B rebatable drug to pay a rebate that, generally, is calculated based on the total number of billing units of that drug that were furnished in a calendar quarter, multiplied by the excess specified amount for the drug over a statutorily defined inflation-adjusted payment amount. The inclusion in this calculation of billing units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans poses significant operational complexities. We did not propose to establish a policy on treatment of MA units in the calculation of Part B inflation rebates due to operational considerations, but we stated that we may establish policy on this issue in future rulemaking. We solicited comments on this approach.

We did not make any proposals associated with the treatment of MA units for Part B rebate calculations;

[666] Accessible via *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.*

however, we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Some commenters recommended CMS clarify in final rulemaking that MA units cannot be included in Part B inflation rebates and that CMS does not intend to issue rulemaking in the future to the contrary.

Response: At this time, CMS will not include MA units in Part B inflation rebates. CMS may revisit the inclusion of billing units of drugs that are furnished to Medicare beneficiaries who are enrolled in MA plans under Medicare Part C in future rulemaking.

Comment: Some commenters interpreted section 1847(i)(2)(A) of the Act to expressly define a Part B rebatable drug as a drug for which payment is made under Medicare Part B and, therefore, in the view of the commenters, to exclude units of drugs furnished under MA. Some commenters also asserted that CMS has set precedent through other Agency policy that interprets the scope of section 1847A to cover only Part B, not Part C. As an example, one commenter notes that section 1847A(a)(1) of the Act says that the ASP-based methodology in this section of the statute applies to drugs described in section 1842(o)(1)(C) of the Act. This reference applies to certain types of drugs furnished after 2004 ''for which payment has been made under this part.'' The commenter says that CMS interpreted this language to apply to only drugs paid for under Part B and did not interpret it to mean requiring MA plans use the ASP-based methodology to pay for drugs furnished to plan enrollees. One commenter stated that CMS does not explain the basis for its belief that the statute could extend to Part C.

Response: Because CMS believes that operational changes would likely be necessary to include MA units, at this time, CMS will not include MA units in the calculation of Part B rebates. CMS may address the issue of whether to include MA units in the calculation of Part B rebates in future policymaking and would solicit and consider public comments on this issue at that time.

Comment: Some commenters stated that units of rebatable drugs furnished under MA should be excluded from Part B rebatable drugs because they are not separately payable. These commenters noted that under section 1847A(i)(1)(B) of the Act, units that are packaged into the payment amount for an item or service and are not separately payable are excluded from the calculation of the total number of units to apply Part B rebates. Commenters stated that Part B drugs are not separately payable within MA, as CMS makes capitated payments to plans.

Response: As noted in the response above, CMS will not include MA units in the calculation of Part B rebates at this time due to operational considerations. CMS may address this issue in future policymaking and would solicit and consider public comments on this issue at that time.

(6) Units Subject to Discarded Drug Refunds

At § 427.303(b)(5), we proposed a policy addressing the interaction between Part B inflation rebates and billing units of discarded drugs. Under the Infrastructure Investment and Jobs Act of 2021, section 90004, manufacturers are required to provide a refund to CMS for certain discarded amounts from separately payable single-dose container or single-use package drugs beginning January 1, 2023. To implement the discarded drugs refund provision of the Infrastructure Investment and Jobs Act of 2021, in the CY 2023 PFS final rule (87 FR 69711 through 69719), CMS finalized the requirement that providers and suppliers use the ''JW'' claim modifier for all separately payable drugs with discarded amounts of drugs from a single-dose container or from a single-use package for Part B claims that bill for drugs and biological products to report discarded amounts. CMS also finalized a requirement for providers and suppliers to use the ''JZ'' modifier on claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts to attest that no amount of drug was discarded and eligible for payment.[667] As of October 1, 2023, claims for drugs from single-dose containers that do not use the modifiers as appropriate may be returned until claims are properly resubmitted.

Although section 1847A(i)(3)(B)(ii) of the Act does not require that billing units of discarded drugs be excluded from Part B inflation rebates, we proposed to exclude billing units of discarded drugs that are subject to discarded drug refunds from Part B inflation rebates. CMS believes not applying Part B inflation rebates to billing units of discarded drugs for which a refund is owed would balance fairness for manufacturers that owe refunds for billing units of discarded drugs with the need to fulfill the requirements of section 11101 of the IRA.

As new policy not established in section 50.8.6 of the revised Medicare Part B Drug Inflation Rebate Guidance, we proposed to exclude billing units of a refundable single-dose container or single-use package drug as defined at § 414.902 (hereinafter referred to as ''refundable drug'') subject to discarded drug refunds, from the calculation of rebate amounts during the reconciliation process except for calendar quarters in calendar year 2023. In the CY 2024 PFS final rule (codified at § 414.940), CMS finalized a policy to send annual refund reports for discarded drug refunds for the 4 quarters of a calendar year at or around the time it sends Part B Inflation Rebate Reports for the first quarter of the following calendar year. Therefore, CMS invoices manufacturers for discarded drug refunds on an annual basis but CMS is required to invoice manufacturers for Part B inflation rebates on a quarterly basis.

Under the timeline for processing discarded drug refunds, data to determine which billing units of discarded drugs are subject to discarded drug refunds generally will not be available until after CMS issues the Rebate Report to the manufacturer. Due to these data limitations, we proposed to include all discarded billing units, including units of a refundable drug subject to the discarded drug refund (as defined at § 414.940), in the calculation of billing units for the Preliminary Rebate Report and the Rebate Report. We proposed to use data available during the reconciliation process to exclude billing units of discarded drugs that are subject to discarded drug refunds from the calculation of the rebate amount.

For calendar quarters in calendar year 2023, we proposed to exclude billing units of a refundable drug subject to discarded drug refunds from the calculation of the rebate amount before CMS issues the Rebate Report to the manufacturer. As permitted by section 1847A(i)(1)(C) of the Act, CMS is delaying reporting of rebate information required by section 1847A(i)(1)(A) of the Act for calendar quarters in calendar years 2023 and 2024 until no later than September 30, 2025. Under this timeline for calendar quarters in calendar year 2023, CMS will have data available regarding which billing units are subject to discarded drug refunds when CMS sends the Preliminary Rebate Report and Rebate Report in 2025 for calendar quarters in calendar year 2023 and can exclude these billing units from the

[667] See 87 FR 2512, November 18, 2022 (*https://www.federalregister.gov/d/2022-23873/p-2512*).

calculation of the rebate amount in these reports.

We solicited comments on the proposed approach to excluding billing units of a refundable drug subject to discarded drug refunds from the calculation of Part B inflation rebate amounts during the reconciliation process, except for calendar quarters in calendar year 2023.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported or recommended CMS finalize its proposal to exclude billing units of a refundable drug subject to a discarded drug refunds from the calculation of Part B inflation rebate amounts during the reconciliation process, except for calendar quarters in calendar year 2023.

Response: We thank these commenters for their input and support for the proposed policy.

Comment: A few commenters noted that under section 1847A(i)(2)(A) of the Act, a Part B rebatable drug is defined as ''a single-source drug or biological . . . for which payment is made under this part.'' These commenters claimed that, since manufacturers provide refunds to CMS for Part B payment on these units through the discarded drug refund under section 1847A(h) of the Act, these units should not be eligible for inclusion in Part B rebates. A couple of commenters noted that the calculation of total units subject to Part B rebates is based on units ''furnished'' to Medicare beneficiaries during an applicable calendar quarter. Commenters contended that, since the units of discarded drugs subject to refunds are not furnished to Medicare beneficiaries, these units should be excluded from the calculation of units subject to Part B rebates.

Response: We thank these commenters for the input. However, as we stated in revised Medicare Part B Drug Inflation Rebate Guidance on page 31, we disagree with the commenters' interpretation of the statute that because manufacturers refund CMS for some of the allowed payment for discarded drugs, these units of drugs are not eligible for inclusion in Part B inflation rebates. Section 1847A(i)(3)(B) of the Act prescribes that the total number of units of a rebatable drug is determined by the number of units furnished in an applicable calendar quarter, excluding units of drugs with respect to which the manufacturer provides a discount under the 340B Program, units with respect to which the manufacturer pays a Medicaid rebate, or units that are packaged into the payment amount for an item or service and are not separately payable. Discarded units of Part B rebatable drugs are not detailed in the exclusions from the total number of units under section 1847A(i)(3)(B)(ii) of the Act. Moreover, Medicare payment is made to providers for discarded units of drugs. As CMS stated in section III.I.2.d.iv. of this final rule, including units where Medicare payment was allowed would ensure that billing units for which Medicare and some beneficiaries have financial liability would be counted in the total number of units.

Comment: A couple of commenters noted that excluding billing units subject to discarded drug refunds during the Part B annual reconciliation process will not capture the discarded units ''updated refund quarters'' for which reports are sent after the Part B inflation rebate reconciliation process. A couple of commenters recommended that CMS establish a second reconciliation process for the Medicare Part B Drug Inflation Rebate Program to account for updated refund reports under Discarded Drug Refund Program.

Response: We thank these commenters for the input. However, while the provisions in section 1847A(i) of the Act do not expressly provide for reconciliation in the Medicare Part B Drug Inflation Rebate Program, we have determined that a process for reconciling the rebate amount for updated information is necessary and appropriate to promote the accuracy of the rebate amount for each drug for each applicable calendar quarter.

While we considered a longer period until a revision is completed, such as the 36-month period provided by the MDRP for AMP restatements at § 447.510(d)(3), we believe that a 12-month reconciliation period is appropriate for the Part B rebate program because of requirements to submit timely and accurate ASP data (specified at § 414.806(b)), and it provides sufficient time to capture the majority of updates to the data specified at § 427.301 while closing out (except for the proposed circumstances at § 427.501(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting) the calculation of the rebate amount for a Part B rebatable drug for an applicable calendar quarter within a reasonable time period after the Rebate Report is issued. While we proposed a 12- and 36-month reconciliation period in the Medicare Part D Drug Inflation Rebate Program, due largely to the 36-month restatement period provided for MDRP AMP restatements (specified at § 447.510(d)(3)), we do not believe a second or longer restatement process is needed for Part B rebatable drugs because, as described previously, the ASP and claims run out periods correspond with sufficient claims run out and ASP restatement timing for Part B (particularly when considering penalties associated with failure to submit timely and accurate ASP data (specified at § 414.806(b)).

Under the timeline for processing discarded drug refunds, annual reports to determine which billing units of discarded drugs are subject to discarded drug refunds generally will not be available until after CMS issues the Rebate Report to the manufacturer. Due to these data limitations, we proposed to use data available during the reconciliation process to exclude billing units of discarded drugs that are subject to discarded drug refunds from the calculation of the rebate amount.

The Discarded Drug Refund Program includes lagged claims data in annual reports, subsequent to initial reports. Although this lagged data will generally not be available when we conduct reconciliation in the Medicare Part B Drug Inflation Rebate Program, in the CY 2024 PFS final rule (88 FR 79047 through 79049) we stated that CMS estimates that over 99 percent of claims will be final when a given quarter is first included in a discarded drug refund report. Therefore, CMS anticipates that there will not be significant revisions to the calculation of the rebate amount based on the determination of which billing units of discarded drugs are subject to discarded drug refunds after we conduct reconciliation in the Medicare Part B Drug Inflation Rebate Program. We intend to monitor the lagged claims data included in updated refund quarters on the annual discarded drug refund reports and to consider potential changes to the timing of reconciliation in the Medicare Part B Drug Inflation Rebate Program in the future if necessary.

Comment: A couple of commenters recommended CMS consider excluding a quarterly estimated amount of billing units subject to discarded drug refunds from the calculation of rebate amounts for the Preliminary Rebate Report and Rebate Report. One commenter noted that applying an estimated amount would help streamline manufacturer refund payment obligations and reduce manufacturer refund overpayments. One commenter recommended that CMS then reconcile, if needed, the quarterly estimated amount of billing units subject to discarded drug refunds with the actual amount of billing units subject to discarded drug refunds during

the reconciliation process. One commenter recommended CMS provide details to manufacturers on exclusion determinations on claims for billing units subject to discarded drug refunds.

Response: We thank these commenters for the input and recommendations. Data to determine which billing units of discarded drugs are subject to discarded drug refunds generally will not be available until after CMS issues the Rebate Report to the manufacturer and none of the data available at the time of this report offer a reliable basis to estimate the amount of billing units that will be subject to discarded drug refunds. Due to this data limitation, CMS will include all discarded billing units, including units of a refundable drug subject to the discarded drug refund (as defined at § 414.940), in the calculation of billing units for the Preliminary Rebate Report and the Rebate Report. CMS will use data available during the reconciliation process to exclude billing units of discarded drugs that are subject to discarded drug refunds from the calculation of the rebate amount. CMS will use information from discarded drug refund reports to determine the billing units of discarded drugs that are subject to discarded drug refunds and should be excluded from Part B inflation rebates. Information on how discarded drug refunds will be calculated is specified in regulation at § 414.940 (87 FR 69731).

After consideration of public comments, we are finalizing the policy proposed at § 427.303(b)(5) with a modification to align the policy described at § 427.303(b)(5) with the policy as described in the CY 2025 PFS proposed rule (89 FR 61950). CMS will exclude billing units of a refundable drug for which a refund is owed, rather than for which a refund has been paid, from the calculation of Part B inflation rebate amounts during the reconciliation process, except for calendar quarters in calendar year 2023.

v. Adjustments for Changes to Billing and Payment Codes

Changes to billing and payment codes, including new code assignments and dose description changes, may occur. When a new billing and payment code is assigned for a Part B rebatable drug and the code dose description, which determines that amount of drug in each billing unit, remains the same, we proposed to codify at § 427.304(b) the existing policy set forth in revised Medicare Part B Drug Inflation Rebate Guidance to use the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount. For example, a single source drug or biological product may be assigned a new billing and payment code if it was initially assigned to a billing and payment code with other products and then later assigned a unique billing and payment code. In this situation, a multiple source drug marketed under an NDA may become a single source drug if all its other therapeutically equivalent drugs are discontinued and the now-single source drug marketed under an NDA is later shifted into a separately payable code.

When a Part B rebatable drug's code dose description changes, we proposed to codify at § 427.304(a) policies established in section 50.9 of the revised Medicare Part B Drug Inflation Rebate Guidance and apply a conversion factor within the rebate calculation, when applicable. For example, a billing and payment code dose description that determines the amount of drug in each billing unit could be changed from 10mg to 5mg. If a billing and payment code dose description changes from 10mg to 5mg, the payment amount in the payment amount benchmark quarter for such drug was $200 based on 10mg, and the rebate period payment amount is based on 5mg, then CMS would apply a conversion factor of 0.5 to the payment amount in the payment amount benchmark quarter (yielding $100). In this example, the conversion factor would be based on the ratio of the current billing unit description to the prior billing unit description (5mg/10mg = 0.5). In addition, to ensure consistency in how CMS is calculating a rebate when a billing and payment code's dose description changes, we proposed to apply a conversion factor before applying the percentage by which the rebate period CPI–U for the calendar quarter exceeds the benchmark period CPI–U to determine the inflation-adjusted payment amount.

In situations where a new billing and payment code is assigned for a Part B rebatable drug and the code dose description changes, we will apply a conversion factor, as appropriate, and use the benchmark quarter's payment amount, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount—consistent with the policy in revised guidance that we proposed to codify at § 427.304(a) and (b).

To apply the provisions in section 1847A(i) of the Act appropriately, we also proposed at § 427.304(c) to codify existing policy to maintain a crosswalk between such changes or codes.

We solicited comments on these proposals.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 427.304.

e. Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption (§§ 427.400 Through 427.402)

Section 1847A(i)(3)(G) of the Act requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part B rebatable drug with respect to a calendar quarter in two cases: (1) when a Part B rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; and (2) when CMS determines there is a severe supply chain disruption during the applicable quarter for a Part B rebatable biosimilar biological product, such as a disruption caused by a natural disaster or other unique or unexpected event. The statute does not describe how CMS should reduce or waive inflation rebates in each of these cases.

To implement the statutory requirement under section 1847A(i)(3)(G) of the Act, we proposed to codify in subpart E of part 427 existing policies described in sections 50.10, 50.11, and 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance to reduce the total rebate amount owed by a manufacturer in each of these cases, as summarized in Table 56 and discussed later in this section.

TABLE 56: Determination of Rebate Reduction Amount for Part B Rebatable Drugs

	Drug Shortage		Severe Supply Chain Disruption
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		Four calendar quarters; manufacturer may request an extension for four additional quarters for up to eight calendar quarters total
Percent Reduction	Part B rebatable drug other than a plasma-derived product	Part B rebatable plasma-derived product	Part B rebatable biosimilar biological product
First four consecutive calendar quarters	25%	75%	75%
Second four consecutive calendar quarters	10%	50%	75%
Subsequent calendar quarters	2%	25%	Not applicable

In the CY 2025 PFS proposed rule (89 FR 61951), we described that the rebate amount owed will not be fully waived in either of the cases previously described. We stated in the proposed rule that we believe the proposed rebate reduction policies balance providing appropriate financial relief for manufacturers in certain circumstances, including when there is a severe supply chain disruption resulting from exogenous circumstances outside of a manufacturer's control, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption to avoid an obligation to pay rebates. Additionally, we stated in the CY 2025 PFS proposed rule (89 FR 61951) that we will continue to evaluate these policies and may update them in future years. We noted that most shortages involve multiple source generic drugs,[668] which are not Part B rebatable drugs and thus are not subject to Part B drug inflation rebates.

We solicited comments on these proposals. The following is a summary of the comments we received and our responses. We note that the comments and responses below generally apply to both the Medicare Part B and Part D Drug Inflation Rebate Programs, as commenters made their recommendations with respect to both programs.

Comment: Some commenters recommended CMS fully waive the inflation rebate for drugs currently in shortage and generic drugs and biosimilar biological products experiencing severe supply chain disruptions. One commenter recommended CMS implement a waiver process for a subset of drugs in currently in shortage, such as out-of-stock drugs entirely unavailable to the market. A couple of commenters stated that shortages and severe supply chain disruptions can cause swings in the ASP of a Part B rebatable drug or the AMP of a Part D rebatable drug that are beyond a manufacturer's control, and manufacturers should not be penalized by an inflation rebate in such a situation. A few commenters noted that by failing to waive the rebate amount, CMS risks jeopardizing patient access by taking away manufacturer resources that could be otherwise used to address the cause of a shortage or severe supply chain disruption. One commenter supported CMS' policy to reduce rather than waive rebate amounts but recommended that CMS consider providing a waiver in situations where shortages are caused by factors outside of a manufacturer's control.

Response: We thank these commenters for their input. Consistent with our response on page 35 of the revised Medicare Part B Drug Inflation Rebate Guidance and page 23 of the revised Medicare Part D Drug Inflation Rebate Guidance,[669] CMS will not provide a full waiver of the rebate amount for any Part B or Part D rebatable drugs that are described as ''currently in shortage'' or when CMS determines there is a severe supply chain disruption, as providing a full waiver of the rebate amount could incentivize manufacturers to delay taking appropriate steps to resolve a shortage or severe supply chain disruption to avoid an obligation to pay rebates for an extended period. As set forth in §§ 427.401 and 428.301, CMS will provide a variable reduction in the rebate amount based on the length of time a Part B or Part D rebatable drug is ''currently in shortage,'' with the reduction decreasing over time. As set forth in §§ 427.402 and 428.302, when CMS determines there is a severe supply chain disruption during the applicable calendar quarter or applicable period, such as that caused by a natural disaster or other unique or unexpected event, CMS will provide a time-limited standard reduction in the rebate amount of 75 percent. As set forth in § 428.303, when CMS determines a generic Part D rebatable drug is likely to be in shortage, CMS will provide a time-limited standard reduction in the rebate amount of 75 percent.

As described later in this final rule, CMS will provide the same reduction in the rebate amount for Part B and Part D rebatable drugs that are currently in shortage regardless of the cause of the shortage. CMS understands that some drugs may face supply chain disruptions due to exogenous factors such as a natural disaster or other unique or unexpected event, and manufacturers of such drugs may temporarily increase the price of such drugs to account for increased costs associated with resolving a severe supply chain disruption. To provide financial relief to manufacturers in such situations, CMS will provide a standard time-limited reduction of 75 percent in the rebate amount for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply

[668] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

[669] See: *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf* and *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.*

chain disruption during an applicable calendar quarter or applicable period, such as that caused by a natural disaster or other unique or unexpected event.

We understand commenters' concerns regarding the effect of supply chain disruptions on ASP and AMP and consistent with the statute, will provide a reduction of the rebate amount (if any) when a Part B or Part D rebatable drug is ''currently in shortage'' or when CMS determines there is a severe supply chain disruption during an applicable calendar quarter or applicable period.

i. Definitions

We proposed at § 427.400 to define the following terms applicable to proposed subpart E (§§ 427.400 through 427.402)—

- ''Drug shortage'' or ''shortage''.
- ''Plasma-derived product''.

We also proposed at § 427.400 to codify definitions established in the revised Medicare Part B Drug Inflation Rebate Guidance for the following terms:

- ''Currently in shortage''.
- ''Natural disaster''.
- ''Other unique or unexpected event''.
- ''Severe supply chain disruption''.

The following is a summary of the comments we received on the definitions and our responses.

Comment: One commenter stated CMS does not define what constitutes a severe supply chain disruption, natural disaster, or unique or unexpected event, leaving these terms open to interpretation. This commenter recommended CMS define these terms, such as through illustrative examples.

Response: We disagree with the commenter that CMS has not defined these terms. We refer the reader to section 50.12 of the revised Medicare Part B Drug Inflation Rebate guidance and section 40.5.2 of the revised Medicare Part D Drug Inflation Rebate guidance where we defined the terms ''severe supply chain disruption,'' ''natural disaster,'' and ''other unique or unexpected events.'' We also refer the commenter to the CY 2025 PFS proposed rule (89 FR 62237, 62245) in which CMS proposed to codify these definitions and included examples of events that would meet the definition of a natural disaster or unique or unexpected event.

After consideration of the comments received, we are finalizing these definitions as proposed at §§ 427.400 and 428.300.

ii. Reducing the Rebate Amount for Part B Rebatable Drugs Currently in Shortage

At § 427.401, we proposed to codify the policy established in section 50.11 of the revised Medicare Part B Drug Inflation Rebate Guidance whereby CMS will reduce the total rebate amount for a Part B rebatable drug that is currently in shortage based on the length of time the drug is in shortage during a calendar quarter and decrease the amount of the reduction over time. We stated in the CY 2025 PFS proposed rule (89 FR 61952) that CMS will use the shortage lists maintained by the FDA Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to determine whether a Part B rebatable drug is currently in shortage [670] during a calendar quarter. We also stated that CMS will not consider an NDC–10 in the status of ''to be discontinued,'' ''discontinued,'' or ''resolved'' to be ''currently in shortage'' and that CMS would provide the same reduction in the rebate amount for Part B rebatable drugs currently in shortage regardless of the cause of the shortage.

We proposed that CMS will not provide a full waiver of the rebate amount for drugs currently in shortage, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps that may resolve a shortage more expeditiously simply to maintain having the drug listed on FDA's drug shortage list to avoid an obligation to pay rebates for an extended period. Further, as explained in the CY 2025 PFS proposed rule (89 FR 61952), in a report analyzing the root causes of drug shortages between 2013 and 2017, FDA found that more than 60 percent of drug shortages were the result of manufacturing or product quality issues, and providing a full waiver of the rebate amount in situations that may be within a manufacturer's control could be perceived as rewarding manufacturers for poor quality management.[671]

We stated in the CY 2025 PFS proposed rule (89 FR 61952) that CMS will be responsible for monitoring the status of a Part B rebatable drug on an FDA shortage list, and manufacturers would not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part B rebatable drug that is currently in shortage.

To calculate the reduced total rebate amount for a Part B rebatable drug, at § 427.401(b), we proposed the following formula:

Reduced *Total* Rebate Amount = total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the calendar quarter) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the calendar quarter)

For the purpose of this formula, for a Part B rebatable drug that is a plasma-derived product, at § 427.401(b)(2)(i), we proposed an applicable percent reduction of 75 percent for the first 4 consecutive calendar quarters such Part B rebatable drug is currently in shortage, 50 percent for the second 4 consecutive calendar quarters, and 25 percent for each subsequent calendar quarter. For a Part B rebatable drug (including a biosimilar biological product) that is not a plasma-derived product, at § 427.401(b)(2)(ii), we proposed an applicable percent reduction of 25 percent for the first 4 consecutive calendar quarters such Part B rebatable drug is currently in shortage, 10 percent for the second 4 consecutive calendar quarters, and 2 percent for each subsequent calendar quarter.

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC–10 level, and Part B drug inflation rebates are calculated at the HCPCS level, we proposed at § 427.401(c) that if any NDC–10 assigned to the HCPCS code(s) is currently in shortage, we will apply the rebate reduction to all of the NDCs under the relevant HCPCS code(s). CMS will closely monitor market data for the Part B rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy.

We proposed to provide a reduction in the rebate amount for as long as a Part B rebatable drug is currently in shortage. We stated in the CY 2025 PFS proposed rule (89 FR 61952) that we believe the rebate reduction should be proportional to the time the drug is currently in shortage and decrease over time to balance providing financial relief to manufacturers experiencing a drug shortage while not incentivizing manufacturers to delay taking appropriate steps to resolve a shortage simply to maintain having the drug listed on an FDA shortage list to avoid an obligation to pay rebates for an extended period.

To determine the percentage of time a Part B rebatable drug was currently in shortage during the calendar quarter, as

[670] For the purposes of this final rule, we use the term ''currently in shortage'' to refer to Part B rebatable drugs that are in the status of ''currently in shortage'' on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

[671] See: *https://www.fda.gov/media/131130/download?attachment#page=33.*

proposed at § 427.401(b)(3), we proposed to determine the number of days such drug is currently in shortage in a calendar quarter and divide by the total number of days in that calendar quarter.

At § 427.401(b)(2), we proposed to codify the policy set forth in section 50.11 of the revised Medicare Part B Drug Inflation Rebate Guidance to apply a greater applicable percent reduction for plasma-derived products than non-plasma derived products because the former rely on a variable supply of donated blood plasma that can impact downstream production and therefore hamper the ability to promptly resolve a shortage.

When the status of a Part B rebatable drug changes from currently in shortage to resolved during a calendar quarter and then changes to currently in shortage during one or more of the subsequent 3 calendar quarters, we stated in the CY 2025 PFS proposed rule (89 FR 61952) that CMS would apply the shortage reduction as if there was a continuous shortage beginning with the quarter in which the drug has re-entered a shortage and move to the percent reduction applicable for the second 4 consecutive quarters. (In this scenario, once this drug enters its fifth quarter of shortage from the first quarter in which it was listed as currently in shortage, the applicable percent reduction would be 50 percent for the fifth through eighth calendar quarters for a Part B rebatable drug that is a plasma-derived product and 10 percent for a Part B rebatable drug that is not a plasma-derived product.) When the status of a Part B rebatable drug changes from currently in shortage to resolved and either remains in the status of resolved or is removed from the list for at least 4 full consecutive calendar quarters and then subsequently reemerges on a shortage list, we proposed to treat the subsequent shortage as a new shortage and would apply the applicable percent reduction for the first 4 consecutive calendar quarters.

We received public comments on our proposal to not provide a waiver of the rebate amount for drugs currently in shortage. We refer readers to section III.I.2.e. of this final rule for a summary of these comments and our responses.

After consideration of the comments received, we are finalizing this policy as proposed with an additional provision at § 427.401(b)(2)(iii) to clarify the starting point for application of the rebate reduction. CMS adopted this provision to clarify CMS' intended policy, as highlighted by examples in the CY 2025 PFS proposed rule, that while CMS will generally apply the shortage reduction starting with the first applicable calendar quarter that a Part B drug or biological product is described as currently in shortage, CMS acknowledges that for a Part B drug or biological that has been granted a rebate reduction for a severe supply chain disruption, it would be appropriate to delay the start of the applicable percent reduction for being in shortage until after the conclusion of the severe supply chain disruption reduction if the shortage continues. The section below discusses this clarification in detail. Specifically, and as shown in Table 58, we are clarifying in this final rule that CMS will apply the greatest rebate reduction to the first applicable calendar quarter that a drug or biological product is described as currently in shortage regardless of whether the drug meets the definition of a Part B rebatable drug or whether a rebate amount is owed for that applicable period, starting with the calendar quarter that begins January 1, 2023. For example, if a plasma-derived product was currently in shortage from October 15, 2022 through December 15, 2024, CMS would apply an applicable percent reduction of 75 percent for the applicable calendar quarters beginning January 1, 2023, April 1, 2023, July 1, 2023, and October 1, 2023, followed by a 50 percent reduction for the applicable calendar quarters beginning January 1, 2024, April 1, 2024, July 1, 2024, and October 1, 2024, even if such drug did not meet the definition of a Part B rebatable drug or there was no rebate amount owed to which to apply the reduction for those applicable calendar quarters. Similarly, for a drug that is not a plasma-derived product, in this example, CMS would apply an applicable percent reduction of 25 percent for the applicable calendar quarters beginning January 1, 2023, April 1, 2023, July 1, 2023, and October 1, 2023, followed by a 10 percent reduction for the applicable calendar quarters beginning January 1, 2024, April 1, 2024, July 1, 2024, and October 1, 2024, even if such drug did not meet the definition of a Part B rebatable drug or there was no rebate amount owed to which to apply the reduction.

TABLE 57: Application of Shortage Reduction

	4Q2022	1Q2023	2Q2023	3Q2023	4Q2023	1Q2024	2Q2024	3Q2024	4Q2024
In shortage on FDA shortage list	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Meets definition of Part B rebatable drug	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Owes a >$0 rebate	No	No	No	Yes	Yes	No	No	Yes	Yes
Applicable percent reduction applied for a Part B rebatable drug other than a plasma-derived product	0%	25%	25%	25%	25%	10%	10%	10%	10%
Applicable percent reduction for a Part B rebatable plasma-derived product	0%	75%	75%	75%	75%	50%	50%	50%	50%

Note: CMS would "start the clock" for rebate reductions with 1Q2023. The highest percent reduction would thus apply beginning with 1Q2023, regardless of how many days the Part B rebatable drug is in shortage during the calendar quarter. In this example, the 25 percent reduction (for a non-plasma derived product) or 75 percent reduction (for a plasma-derived product) would apply to 1Q2023-4Q2023, even though there would be no rebate amount in 1Q2023 and 2Q2023 to which it applies.

We believe this clarification helps ensure clarity on CMS' policy in applying rebate reductions, which is intended to provide appropriate financial relief for drugs currently in shortage while limiting opportunities for manufacturers to manipulate a shortage start date to align with future price increases that coincide with the application of the reduction, as well as to decrease the amount of the rebate reduction the longer a drug is in shortage as set forth in the CY 2025 PFS proposed rule (89 FR 61974).

iii. Reducing the Rebate Amount for Part B Rebatable Biosimilar Biological Products When There Is a Severe Supply Chain Disruption

At § 427.402, we proposed to codify the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance for rebate reductions when CMS determines there is a severe supply chain disruption during a calendar quarter. We proposed at § 427.402(b)(1) to provide a time-limited standard reduction of 75 percent in the total rebate amount for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event. We proposed that to receive a rebate reduction in accordance with § 427.402(b)(1), the manufacturer will have to submit to CMS a rebate reduction request that meets the eligibility requirements at § 427.402(c). A rebate reduction request should specify each NDC–11 and HCPCS code to which the request applies and if CMS grants a manufacturer's request for an NDC–11, we proposed at § 427.402(b)(3) that the rebate reduction will apply to all the NDC–11s under the relevant HCPCS code(s). We refer manufacturers to the approved collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction requests.

We proposed at § 427.402(c)(4) to grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating that (1) a severe supply chain disruption has occurred during the calendar quarter, (2) the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer,[672] or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product, and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.[673] We proposed at § 427.402(c)(2), for a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order for CMS to consider a rebate reduction.

In the CY 2025 PFS proposed rule (89 FR 61953), we stated that severe supply chain disruptions generally take time to resolve and proposed at § 427.402(a) to codify the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance whereby a determination that a severe supply chain disruption has occurred would be deemed to disrupt the supply chain for the quarter in which the event occurred and the 3 subsequent calendar quarters. We proposed that if a manufacturer makes a timely request that includes all the supporting documentation and CMS

[672] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See ''Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry,'' November 2016: *https://www.fda.gov/media/86193/download*.

[673] Consistent with the collection of information approved under OMB control number 0938–1474, for a natural disaster or other unique or unexpected event that occurred or began on or after January 1, 2023 but before August 2, 2024 that the manufacturer believes caused a severe supply chain disruption, the manufacturer must have submitted the rebate reduction request no later than 11:59 p.m. PT on October 1, 2024 for CMS to consider a rebate reduction for the Part B rebatable biosimilar biological product.

determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS will reduce the total rebate amount owed by a manufacturer by 75 percent for the calendar quarter in which the event that caused the severe supply chain disruption occurred or began, or the following calendar quarter if the request is submitted less than 60 calendar days before the end of a calendar quarter, and the three calendar quarters thereafter.

We proposed at § 427.402(c)(5) that if the manufacturer believes a severe supply chain disruption continues into a fifth consecutive calendar quarter after the start of the natural disaster or other unique or unexpected event, the manufacturer may request a reduction of the rebate amount for the fifth through eighth calendar quarters by submitting a rebate reduction extension request to CMS along with any new supporting documentation. We refer manufacturers to the approved collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction extension requests. At § 427.402(c)(5)(ii), we proposed that a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of the fifth calendar quarter in order for CMS to consider a rebate reduction extension.

We further proposed that if a manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount would be reduced by 75 percent for the fifth through eighth calendar quarters for that manufacturer's Part B rebatable biosimilar biological product, in accordance with § 427.402(b)(2).

Consistent with the policy established in section 50.12 of the revised Medicare Part B Drug Inflation Rebate Guidance, we proposed at § 427.402(c)(5) that a manufacturer may receive only one extension of the rebate reduction per Part B rebatable biosimilar biological product per CMS determination of a severe supply chain disruption. Said differently, the severe supply chain disruption rebate reduction would be limited to 8 consecutive calendar quarters total per Part B rebatable biosimilar biological product per CMS determination of a severe supply chain disruption.

At § 427.402(b)(4)(i), we proposed that if the manufacturer believes there are multiple events causing severe supply chain disruptions during the same 4 calendar quarters for the same Part B rebatable biosimilar biological product and submits multiple rebate reduction requests for the same product, CMS will grant no more than one rebate reduction for that Part B rebatable biosimilar biological product for those 4 consecutive calendar quarters. For example, if the manufacturer of a Part B rebatable biosimilar biological product is granted a severe supply chain disruption rebate reduction request for its product due to a natural disaster that occurred in January 2025 and then experiences a second severe supply chain disruption caused by a second, distinct natural disaster in July 2025, CMS will not grant the second rebate reduction request. That is, the manufacturer will receive the 75 percent reduction for 4 calendar quarters for the severe supply chain disruption caused by the first natural disaster but will not receive a reduction for the second natural disaster. However, if the second natural disaster exacerbated the severe supply chain disruption caused by the first natural disaster, the manufacturer may reflect such circumstances in its request for an extension of the rebate reduction for the fifth through eighth calendar quarters.

At § 427.402(b)(4)(ii), we proposed that if CMS grants a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product, and the product appears as currently in shortage during one of the same 4 calendar quarter(s) as for which the severe supply chain disruption reduction was granted, CMS will apply the 75 percent reduction to the four calendar quarters for which the severe supply chain disruption request was granted and would not grant any additional reduction for the shortage status during those quarters. For any subsequent calendar quarters that the Part B rebatable biosimilar biological product appears as currently in shortage, CMS will reduce the rebate amount in accordance with the drug shortage reduction proposed at § 427.401, starting with the highest reduction (that is, 75 percent for a plasma-derived product and 25 percent for a Part B rebatable drug that is not a plasma-derived product). We provided as an example in the CY 2025 PFS proposed rule (89 FR 61953) the following: if CMS grants a severe supply chain disruption request for a Part B rebatable biosimilar biological product that was submitted on February 15, 2024, and that product is currently in shortage from December 15, 2024 until May 15, 2025, CMS would apply a 75 percent reduction in the total rebate amount to all 4 calendar quarters in 2024,[674] and then would apply the shortage reduction as proposed in § 427.401, beginning with a reduction of 25 percent for a Part B rebatable biosimilar biological product or 75 percent in the case of a plasma-derived product that is a Part B rebatable biosimilar biological product for the first 2 calendar quarters of 2025.At § 427.402(b)(4)(iii), we proposed that if a Part B rebatable biosimilar biological product that is currently in shortage experiences a severe supply chain disruption, the manufacturer may submit a request for a severe supply chain disruption rebate reduction. If CMS grants the rebate reduction request, the rebate amount will be reduced by 75 percent for the duration of 4 consecutive calendar quarters (that is, the calendar quarter in which the event that caused the severe supply chain disruption occurred and the 3 calendar quarters thereafter), and CMS will not grant any additional reduction under § 427.401 for the currently in shortage status during those 4 calendar quarters. If CMS receives the request and all supporting documentation describing the natural disaster or other unique or unexpected event causing the severe supply chain disruption less than 60 days before the end of a calendar quarter, CMS will apply the 75 percent rebate reduction to the next calendar quarter and to the three subsequent calendar quarters thereafter. We refer readers to the CY 2025 PFS proposed rule (89 FR 61953) for an example of how CMS would apply the rebate reduction in this scenario.

At § 427.402(c)(6), we proposed to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the calendar quarter that begins on October 1, 2024. If a manufacturer's rebate reduction request does not meet the criteria in proposed § 427.402(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements at § 427.402(c), we proposed that CMS will deny the request. We also proposed that if a manufacturer's rebate reduction extension request does not meet the criteria at § 427.402(c)(5), is incomplete

[674] We have provided a correction to this example later in this final rule. Specifically, because in this example the rebate reduction request was submitted less than 60 days before the end of the calendar quarter, the severe supply chain disruption rebate reduction would apply to the next calendar quarter (that is, the calendar quarter beginning April 1, 2024) and the 3 subsequent calendar quarters rather than the calendar quarter in which the event occurred (that is, the calendar quarter beginning January 1, 2024) and the 3 subsequent calendar quarters.

or untimely based on the requirements at § 427.402(c)(5), or if a reduction under proposed § 427.402(b)(1) was not provided for such Part B rebatable biosimilar biological product, CMS will deny the rebate reduction extension request. At § 427.402(c)(6)(iii), we proposed that CMS' decision to deny a request will be final and not be subject to an appeals process.

As proposed at § 427.402(c)(7), we will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. We proposed that information provided as part of a severe supply chain disruption rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. We will protect confidential and proprietary information as required by applicable law.

The following is a summary of the comments we received on rebate reduction requests and our responses. Some of the comments received were not specific to rebate reduction requests for Part B rebatable drugs or Part D rebatable drugs. Other comments received addressed both Part B rebatable drugs and Part D rebatable drugs. We addressed these comments in the following summary of comments and do not repeat this summary of comments and our responses further below in the discussion of Part D drug inflation rebate policies.

Comment: One commenter stated that requiring manufacturers to submit a request to CMS to receive consideration for a rebate reduction is duplicative of the FDA's existing processes for addressing drug shortages and increases administrative burden on manufacturers. This commenter recommended CMS leverage existing tools such as the FDA shortage database rather than establishing new reporting requirements. One commenter recommended CMS coordinate with the FDA to ensure accuracy of the drug shortages lists.

Response: We appreciate commenters sharing their concerns about the reporting requirements and recommendations regarding existing resources that CMS may use for determining rebate reductions.

Consistent with our response in the information collection request approved under OMB control number 0938–1474, the FDA Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) each maintain publicly available drug shortages lists via web pages for drugs and biological products within their respective jurisdictions. We believe these FDA shortage lists can readily be used to determine whether a drug is currently in shortage. In accordance with sections 1847A(i)(3)(G)(i) and 1860D–14B(b)(1)(C) of the Act, CMS will use the FDA drug shortage lists to determine whether to grant a rebate reduction for a Part B or Part D rebatable drug described as ''currently in shortage.'' As described elsewhere in this final rule, CMS will monitor the status of Part B and Part D rebatable drugs on an FDA shortage list, and manufacturers do not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part B or Part D rebatable drug described as ''currently in shortage.''

However, the IRA also instructs CMS to grant a rebate reduction or waiver when CMS determines there is a severe supply chain disruption for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. The statute does not instruct CMS to use FDA's drug shortages lists in making determinations regarding severe supply chain disruptions. As such, we consider severe supply chain disruptions to be generally distinct from current drug shortages identified on FDA's drug shortage lists for purposes of providing a rebate reduction for an eligible biosimilar biological product.

We understand that manufacturers must report to FDA certain information related to drug and biological product discontinuances and manufacturing interruptions under section 506C of the FD&C Act (''506C notification''). We understand that manufacturers are also encouraged to voluntarily notify FDA of other circumstances that are likely to lead to a meaningful disruption in supply of certain finished drugs or biological products, although such notifications are not expressly required by section 506C of the FD&C Act. However, the criteria for determining whether a request qualifies for a rebate reduction differ from the requirements for submission of a 506C notification to FDA, and manufacturers requesting a rebate reduction may not have submitted a voluntary notification to FDA. We believe that the information required in a 506C notification submitted to FDA would not be sufficient to make a rebate reduction determination because while 506C notifications must include information related to permanent discontinuances or manufacturing interruptions of a drug, they are not required to include information about other changes in production or distribution that may be relevant for CMS' determination of whether a severe supply chain disruption has occurred. In addition, 506C notifications and voluntary shortage notifications submitted to FDA by manufacturers are not made public, so even if such notifications included sufficient information for CMS to determine whether a severe supply chain disruption occurred, CMS would not have access in the ordinary course to the information in such notifications. For these reasons, we are requiring that a manufacturer submit a request to CMS to receive consideration for a rebate reduction when the manufacturer believes there is a severe supply chain disruption.

We appreciate commenters' feedback that it should partner with FDA to obtain the information CMS needs to review rebate reductions requests. As indicated in the revised Medicare Part B Drug Inflation Rebate Guidance, the revised Medicare Part D Drug Inflation Rebate Guidance, and this final rule, CMS may consult with FDA for technical assistance in implementing the severe supply chain disruption and likely shortages provisions, as needed. However, for the reasons stated above, we maintain that there is a distinct informational need associated with severe supply chain disruptions and that manufacturers are well positioned to provide CMS with the information needed to review rebate reduction requests associated with severe supply chain disruptions.

Comment: One commenter stated CMS does not specify the evaluation criteria it will use to determine rebate reductions, how CMS will ensure requests are timely, complete, and accurate, or whether CMS will conduct any audits or investigations to verify the information. This same commenter recommended that CMS require manufacturers to demonstrate efforts taken to resolve or mitigate a drug shortage and establish consequences for manufacturers submitting false or misleading statements or documentation.

Response: We disagree with the commenter that CMS has not specified evaluation criteria for rebate reduction requests. In the CY 2025 PFS proposed rule (89 FR 62238, 62247, and 62248) and this final rule, we have described

the criteria that must be satisfied for CMS to grant a rebate reduction request. For example, as set forth in §§ 427.402(c)(4) and 428.302(c)(4), CMS will grant a severe supply chain disruption rebate reduction request if a manufacturer submits to CMS a request in writing for an eligible drug demonstrating that: (1) a severe supply chain disruption has occurred during the applicable calendar quarter or applicable period; (2) the severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar; and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event. CMS further describes the required elements of a rebate reduction request at §§ 427.402(c)(3) and 428.302(c)(3), and specifies the timing for submission of a rebate reduction request at §§ 427.402(c)(2) and 428.302(c)(2). Similarly, for likely to be in shortage rebate reduction requests, CMS specifies the evaluation criteria at § 428.303(c)(4), including a demonstration that the manufacturer is taking actions to avoid the potential drug shortage, as well as the elements of a rebate reduction § 428.303(c)(3), including information and supporting documentation regarding actions the manufacturer is taking to avoid the potential drug shortage. CMS also specifies the timing for submission for likely to be in shortage rebate reduction requests at § 428.303(c)(2).

As specified in the approved collection of information approved under OMB control number 0938–1474, a manufacturer submitting a rebate reduction request form must describe and provide any relevant supporting documentation regarding actions the manufacturer has taken to resolve or mitigate a severe supply chain disruption or to avoid the potential shortage and explain why those actions may not be sufficient. If CMS determines that the rebate reduction request does not meet the criteria stated above or is incomplete or untimely, CMS will deny the request. CMS reiterates that decisions to deny a request are final and will not be subject to an appeals process. CMS expects manufacturers to ensure the information they submit to the government is complete and accurate. Submitting false information may result in liability, including without limitation under the False Claims Act.

Comment: One commenter recommended CMS provide greater transparency by detailing what information CMS will share with stakeholders pertaining to rebate reduction requests and potential severe supply chain disruptions.

Response: We thank this commenter for their recommendation. As described in the CY 2025 PFS proposed rule (89 FR 62238, 62247) and as we are finalizing at § 427.402(c)(7) and § 428.302(c)(7), CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a severe supply chain disruption rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. We will protect confidential and proprietary information as required by applicable law.

After consideration of comments received, we are finalizing this provision as proposed, with a modification. For alignment with language in the preamble of the CY 2025 PFS proposed rule (89 FR 61954), we clarified at § 427.402(b)(1) that CMS will apply a severe supply chain disruption rebate reduction to the applicable calendar quarter in which the event occurred or began, or the following applicable calendar quarter if the request is submitted less than 60 calendar days before the end of an applicable calendar quarter, and the 3 subsequent applicable calendar quarters. This application of a rebate reduction (initial or extension) applies regardless of whether a biosimilar biological product meets the definition of a Part B rebatable drug during that applicable calendar quarter or whether a rebate amount is owed for such biosimilar biological product for that applicable calendar quarter. That is, regardless of whether the biosimilar biological product meets the definition of a Part B rebatable drug or whether a rebate amount is owed for such biosimilar biological product for that applicable calendar quarter, CMS will apply the 75 percent reduction in the total rebate amount as set forth in § 427.402(b)(1), even if there is no rebate amount owed to reduce. For example, as shown in Table 59, if CMS grants a severe supply chain disruption rebate reduction request for a Part B biosimilar biological product for 4 calendar quarters, CMS will apply the rebate reduction beginning with the first applicable calendar quarter for which the reduction request was granted, regardless of whether the biosimilar biological product meets the definition of a Part B rebatable drug or is subject to a rebate amount in that calendar quarter.

TABLE 58: Application of Severe Supply Chain Disruption Reduction

	Applicable calendar quarter 1	Applicable calendar quarter 2	Applicable calendar quarter 3	Applicable calendar quarter 4	Applicable calendar quarter 5
Meets definition of Part B rebatable drug	No	Yes	Yes	Yes	Yes
Owes a > $0 rebate	No	No	Yes	Yes	Yes
Applicable percent reduction applied	75%	75%	75%	75%	0%

Note: CMS would "start the clock" with applicable calendar quarter 1 if the request was granted for applicable calendar quarters1 through 4. In this example, the 75 percent reduction would apply to applicable calendar quarters 1-4, even though there would be no rebate amount in applicable calendar quarters 1 and 2 to which the reduction applies.

We believe this clarification helps ensure clarity on CMS' policy in applying rebate reductions, which is intended to provide appropriate financial relief to a manufacturer experiencing a severe supply chain disruption while limiting opportunities for manufacturers to plan future price increases to coincide with the application of the reduction. If the reduction is applied to 4 applicable calendar quarters in which there is no rebate amount to reduce, the manufacturer could still apply for an extension of the reduction, which would apply to the fifth through eighth applicable calendar quarters.

In this final rule, we are also providing further clarification to the policy in the CY 2025 PFS proposed rule intended to address situations in which CMS grants a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product, and the product appears as currently in shortage during one of the same 4 calendar quarters as the period the severe supply chain disruption rebate reduction was granted. In the CY 2025 PFS proposed rule (89 FR 61953), we included an example in which CMS receives a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product on February 15, 2024, and that product is currently in shortage from December 15, 2024 until May 15, 2025. We stated that in this example, CMS would apply a 75 percent reduction in the total rebate amount to all 4 calendar quarters in 2024, and then would apply the shortage reduction at § 427.401, beginning with a reduction of 25 percent for a non-plasma-derived Part B rebatable biosimilar biological product or 75 percent in the case of a plasma-derived product that is a Part B rebatable biosimilar biological product for the first two calendar quarters of 2025. First, we are correcting this example to clarify that the severe supply chain disruption rebate reduction would apply for the calendar quarter beginning April 1, 2024 and the 3 subsequent calendar quarters (rather than all 4 calendar quarters of 2024), followed by the shortage reduction set forth in § 427.401, illustrated as ''Example 1'' in Table 60. For purposes of applying the shortage reduction, the highest reduction (25 percent for a non-plasma-derived Part B rebatable biosimilar biological product or 75 percent in the case of a plasma-derived product that is a Part B rebatable biosimilar biological product) would apply to the second calendar quarter in 2025. We made this correction because, in the example given, the severe supply chain disruption rebate reduction 60 calendar days before the end of the calendar quarter, and thus the reduction would apply to the next calendar quarter (and the 3 subsequent calendar quarters) rather than the calendar quarter in which the severe supply chain disruption-causing event occurred (and the 3 subsequent calendar quarters). The shortage reduction would begin to apply once the severe supply chain disruption rebate reduction ends and for as long as the Part B rebatable biosimilar biological product is currently in shortage (that is, until May 15, 2025 in this example), gradually decreasing over time. We believe this gradually decreasing rebate reduction would provide appropriate financial relief to manufacturers to mitigate the severity of a shortage or recover from a shortage following a severe supply chain disruption, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption to avoid an obligation to pay rebates.

Second, we are also providing a second, modified version of this example to reflect a situation in which the severe supply chain disruption rebate reduction is granted for the same calendar quarter as the Part B rebatable biosimilar biological product is currently in shortage, and the application of the shortage reduction precedes application of the severe supply chain disruption reduction due to the timing of the shortage and submission of the rebate reduction request, illustrated as ''Example 2'' in the table. For example, if CMS receives a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product on February 15, 2024, and the product is currently in shortage beginning March 15, 2024 instead of December 15, 2024, through May 15, 2025 (as in the first example), CMS would apply a 25 percent reduction for the first calendar quarter in 2024 for a non-plasma-derived Part B rebatable biosimilar biological product or 75 percent for a plasma-derived product, which would be prorated based on the numbers of the days the drugs is currently in shortage in that calendar quarter. CMS would then apply the severe supply chain disruption rebate reduction of 75 percent for the calendar quarter beginning April 1, 2024 and the 3 subsequent calendar quarters, followed by a shortage reduction of 10 percent for the second calendar quarter in 2025 for a non-plasma-derived Part B rebatable biosimilar biological product or 50 percent for a plasma-derived product.

Finally, we are providing a third example, which, similar to the second example above, reflects a situation in which the severe supply chain disruption rebate reduction is granted for the same calendar quarter as the Part B rebatable biosimilar biological product is currently in shortage, but the application of the severe supply chain disruption reduction precedes the application of the shortage reduction due to the timing of the submission of the rebate reduction request, illustrated as ''Example 3'' in the table. For example, if CMS receives a severe supply chain disruption rebate reduction request for a Part B rebatable biosimilar biological product on January 15, 2024 instead of February 15, 2024 such that the reduction applies to the calendar quarter that begins on January 1, 2024 and the 3 subsequent calendar quarters, and the product is currently in shortage beginning March 15, 2024 until May 15, 2025 (consistent with the second example above), CMS would apply the reduction of 75 percent under the severe supply chain disruption policy for all 4 calendar quarters in 2024, followed by a 25 percent shortage reduction for the first calendar quarter in 2025 for a non-plasma-derived Part B rebatable biosimilar biological product or a 75 percent shortage reduction for a plasma-derived product.

In all of these examples, regardless of whether the timing of the shortage and submission of the rebate reduction request results in the severe supply chain disruption rebate reduction preceding or following the shortage reduction, CMS intends to continue the shortage reduction clock once it starts for as long as a drug is currently in shortage. In each of these examples, the shortage reduction clock would start (that is, the calendar quarter would be the first of the four *consecutive* applicable calendar quarters as set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of § 427.401) with the applicable calendar quarter to which the shortage reduction first applies, as set forth in § 427.401(b)(4)(iii), unless the shortage reduction clock would start in a calendar quarter subject to a severe supply chain disruption reduction, in which case the shortage reduction clock will instead start with the applicable calendar quarter subsequent to the fourth quarter (or eighth quarter, if extended) of the severe supply chain disruption reduction. We have revised the regulation text to reflect this clarification by adding paragraph (b)(4)(iv) at § 427.401.

TABLE 59: Application of Severe Supply Chain Disruption Reduction for a Part B Rebatable Biosimilar Biological Product other than a Plasma-Derived Product that is Currently in Shortage on an FDA Shortage List

	Example 1	Example 2	Example 3
1Q2024	Not applicable	25% (shortage reduction)	75% (severe supply chain disruption reduction)
2Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
3Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
4Q2024	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)
1Q2025	75% (severe supply chain disruption reduction)	75% (severe supply chain disruption reduction)	25% (shortage reduction)
2Q2025	25% (shortage reduction)	10% (shortage reduction)	25% (shortage reduction)

Note: This table illustrates the application of the initial severe supply chain disruption reduction. A manufacturer may still apply for a rebate reduction extension request. Example 1 illustrates the application of the rebate reduction when a severe supply chain disruption precedes a shortage, and the severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of a calendar quarter. Example 2 illustrates the application of the rebate reduction when a severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of a calendar quarter for a non-plasma-derived Part B rebatable biosimilar biological product that is currently in shortage during the same calendar quarter. Example 3 illustrates the application of the rebate reduction when a severe supply chain disruption rebate reduction request is submitted at least 60 days before the end of a calendar quarter for a non-plasma-derived Part B rebatable biosimilar biological product that is currently in shortage during the same calendar quarter.

We believe this clarification is consistent with the policy set forth in §§ 427.402(b)(4) whereby CMS will not apply multiple rebate reductions for the same Part B rebatable drug and applicable calendar quarter. We believe this clarification is also consistent with the policy articulated in the CY 2025 PFS proposed rule and throughout this final rule to continue the shortage reduction clock once it begins in other scenarios such as for drugs that fluctuate on and off the shortage list within a timespan less than four full calendar quarters. Further, we believe this clarification is consistent with CMS' policy goals of providing a time-limited standard reduction of 75 percent in the rebate amount when there is a severe supply chain disruption, which supersedes the reduction under the shortage policy to mitigate the likelihood or severity of a shortage, and providing gradually decreasing financial relief to manufacturers of a drug currently in shortage. We believe transitioning the manufacturer from the severe supply chain disruption reduction to the shortage reduction, by beginning the shortage reduction clock as set forth in § 427.401(b)(2)(i)(A) or (b)(2)(ii)(A) after the severe supply chain disruption reduction no longer applies, and gradually declining the rebate reduction over time could help prevent exacerbation of the shortage. Because the timing of the application of a severe supply chain disruption rebate reduction depends on the timing of

submission of the rebate reduction request, the highest reduction under the shortages policy may be applied for an applicable calendar quarter that precedes or follows the severe supply chain disruption reduction. As stated above, CMS will not start the shortage reduction clock during a quarter subject to a severe supply chain disruption reduction as set forth in § 427.401(b)(2)(iv), but intends to continue the shortage reduction clock once it starts for as long as a drug is currently in shortage, regardless of whether a severe supply chain disruption follows or precedes a shortage.

f. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 427.500 Through 427.505)

Section 1847A(i)(1)(A) of the Act requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug with the following information not later than 6 months after the end of an applicable calendar quarter: (1) the total number of billing units for each Part B rebatable drug; (2) the amount, if any, of the excess average sales price increase (the amount by which the specified amount exceeds the inflation-adjusted payment amount as calculated at § 427.301(g)) for an applicable calendar quarter; and (3) the rebate amount for the Part B rebatable drug. In compliance with section 1847A(i)(1)(B) of the Act, manufacturers of a Part B rebatable drug must provide a rebate for each Part B rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1847A(i)(1)(A) of the Act.

To fulfill this statutory requirement, we proposed to provide a Preliminary Rebate Report followed by a Rebate Report, as set forth in § 427.501(b) and (c), to all manufacturers of a Part B rebatable drug, even if the amount due is $0; all rebate amounts will be subject to reconciliation as determined under § 427.501(d). As proposed at § 427.501(d)(4), we will not perform a reconciliation for manufacturers of drugs that are not considered rebatable as set forth in § 427.20.

Additionally, to address the completeness and accuracy of the rebate amount, we proposed to conduct one regular reconciliation to determine whether the rebate amount will be adjusted due to updated claims and payment data used in the calculation of such rebate amount (determined under § 427.501(c)(1)) to occur 12 months after the issuance of the Rebate Report. The reporting process for reconciliation will be the same process described for the original Rebate Report, with payment due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount. In addition to regular reconciliation, we proposed a process to conduct reconciliation of the rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a rebate amount was inaccurate due to manufacturer misreporting.

We believe conducting a reconciliation for the Part B Rebate Program is important to ensure the accuracy of the rebate amount and for programmatic alignment with the Part D Rebate Program.

We solicited comments on these proposed policies. Some of the comments received addressed both the Medicare Part B and Part D Drug Inflation Rebate Programs. We addressed these comments in the relevant sections and do not repeat these summaries of comments and our responses in the discussion of Part D drug inflation rebate policies.

i. Definitions

At § 427.500, we proposed the following term applicable to proposed subpart F (§§ 427.500 through 427.505):

- ''Date of receipt'' is the calendar day following the day on which a report of a rebate amount (as set forth in §§ 427.501(b) through (d) and 427.502 (b) and (c)) is made available to the manufacturer of a Part B rebatable drug by CMS.

For example, if CMS issues a Rebate Report through the method and process set forth in § 427.504 on June 30, 2026, then July 1, 2026, will be the date of receipt and day one of the 30-calendar-day payment period.

We did not receive comment on this proposed provision and, we are finalizing as proposed as set forth in § 427.500.

ii. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance involving preliminary and final reports, we proposed to codify a multi-step process to provide a manufacturer as set forth in § 427.20 with the rebate information specified in section 1847A(i)(1)(A) of the Act. As stated in the CY 2025 PFS proposed rule (89 FR 61955), we considered the following factors in determining a method and process for providing the rebate information: meeting statutorily provided deadlines in section 1847A(i) of the Act (for example, dates by which to provide the rebate amount to the manufacturer); the operational time to acquire the relevant information specified in part 427; the operational time to calculate the rebate amount specified in subpart D of part 427; clarity of the information provided as well as potential burden on manufacturers; and how to ensure accuracy of the rebate amount.

We proposed at § 427.501 the use of an initial Preliminary Rebate Report and a subsequent Rebate Report, with an opportunity for manufacturers to identify certain mathematical errors (see § 427.503 and discussed in further detail later in this section) and one regular reconciliation of the rebate amount to account for data revisions 12 months after the Rebate Report is provided. We proposed at § 427.501(d)(1), to conduct a reconciliation 12 months after issuance of the subsequent Rebate Report as set forth in § 427.501(c) to include restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the rebate calculation specified in subpart D of the part.

We proposed at § 427.501 that the multi-step reporting process for providing rebate information to a manufacturer would include: (1) an initial report, which we proposed to entitle the ''Preliminary Rebate Report'' as set forth in § 427.501(b) and (2) a second report, which we proposed to entitle the ''Rebate Report'' as set forth in § 427.501(c). The Rebate Report serves as the invoice for the rebate amount due, if any, for each NDC that has been assigned to a billing and payment code for a product determined to be a Part B rebatable drug for the applicable calendar quarter, as set forth in § 427.101. We stated in the CY 2025 PFS proposed rule (89 FR 61955) that manufacturers of Part B rebatable drugs will receive a Rebate Report for their rebatable drugs even if the amount due is $0. We proposed at § 427.501(d)(1) a regular reconciliation of the rebate amount to occur 12 months after issuance of the subsequent Rebate Report as set forth in § 427.501(c).

As the first step in the reporting process, as set forth in § 427.501(b) and consistent with section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, we will provide the manufacturer of a Part B rebatable drug with the preliminary rebate amount through a Preliminary Rebate Report that is provided to each manufacturer of a Part B rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in § 427.501(c) for an applicable calendar quarter (that is, not more than 5 months after the end of the

applicable calendar quarter). To facilitate manufacturer understanding of the Preliminary Rebate Report, we proposed at § 427.501(b)(1) that the Preliminary Rebate Report will include the following information: the NDC(s) and billing and payment code for the Part B rebatable drug as set forth in § 427.20, the total number of billing units as determined under § 427.303; the payment amount in the payment amount benchmark quarter as set forth in § 427.302(d); the applicable calendar quarter specified amount as set forth in § 427.302(b); the applicable benchmark period and rebate period CPI-Us as set forth in § 427.302(e) and (f); the inflation-adjusted payment amount as determined under § 427.302(g); the amount, if any, by which the specified amount as set forth in § 427.302(b) exceeds the inflation-adjusted payment amount as determined under § 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as determined under § 427.302; any applied reduction as determined under §§ 427.401 and 427.402; and the rebate amount due as set forth in § 427.301(a).

In the CY 2025 PFS proposed rule (89 FR 61955), we stated that when determining what information should be included on rebate reports, we considered the statutory requirements outlined in section 1847A(i)(1)(A) of the Act to determine which data elements are necessary to review the Preliminary Rebate Report for error (described later in this section) and to protect proprietary information. In response to comments on the initial Medicare Part B Drug Inflation Rebate Guidance, we proposed to disclose data elements as suggested by interested parties that are not enumerated in the statute, such as the applicable benchmark period and rebate period CPI–Us. We acknowledged requests from interested parties to provide additional data elements such as claim-level data at the NDC–11 level, that are not included in this proposal. We considered these requests in development of the CY 2025 PFS proposed rule, but we do not believe it necessary to provide further information to fulfill CMS' statutory obligation and believe that the potential benefit to manufacturers of additional data is outweighed by the administrative burdens additional reporting will impose to the agency. We also stated that the elements listed previously provide sufficient information for a manufacturer to review the Preliminary Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide. We believe the elements as set forth in § 427.501(b)(1) satisfy these considerations.

As explained in the CY 2025 PFS proposed rule (89 FR 61955), by structuring the Rebate Report process to include a Preliminary Rebate Report before the Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary Rebate Report before the rebate amount is invoiced via the Rebate Report. While CMS is not required to provide a preliminary report, we stated in the CY 2025 PFS proposed rule that we seek to facilitate manufacturer understanding of the report and believe it would be beneficial for manufacturers to review the report for mathematical errors that can be corrected before invoicing via the Rebate Report. Further, a Preliminary Rebate Report would provide additional notice to manufacturers regarding whether they may owe a rebate amount.

As set forth in § 427.503, we proposed a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary Rebate Report. For example, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error. In this example, Suggestions of Error would be due by 11:59 p.m. PT on June 10, 2026. We reviewed comments on the 10-day Suggestion of Error period submitted in response to the initial Medicare Part B Drug Inflation Rebate Guidance, many of which suggested that manufacturers receive at least 30 days to review the Preliminary Rebate Report. We considered a 10-day, 15-day, and 30-day Suggestion of Error period and we believe the 10-calendar-day period as set forth in § 427.503(c) is sufficient after considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as a Suggestion of Error, and the operational time necessary for CMS to provide a Rebate Report within 6 months of the end of the applicable calendar quarter as required under section 1847A(i)(1)(A) of the Act. However, we proposed at § 427.502(c)(1)(ii) to expand the Suggestion of Error period to 30 calendar days for the Preliminary Rebate Report for CY 2023 and CY 2024. As explained in the CY 2025 PFS proposed rule (89 FR 61955), this extended Suggestion of Error period will provide additional time and flexibility during the first invoicing cycle of the Part B Rebate Program.

Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount as determined under § 427.503(a)(1). Therefore, we stated in the CY 2025 PFS proposed rule at 89 FR 61955 that the Suggestion of Error process will be limited to mathematical steps involved in determining the rebate amount and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Additionally, we stated in the CY 2025 PFS proposed rule that we will not provide an administrative dispute resolution process. We intend to consider all in-scope submissions under the Suggestion of Error process as set forth in § 427.503(a) (for example, suggestions regarding a mathematical error). We do not intend to review suggestions of error that are out-of-scope or submissions for a rebatable drug with an amount due of $0.

As the second step in the reporting process, we proposed at § 427.501(c) to provide the rebate amount to the manufacturer through the Rebate Report no later than 6 months after the end of the applicable calendar quarter. As proposed at § 427.501(c)(1), the Rebate Report will include the same data elements as the Preliminary Rebate Report (as set forth in § 427.501(b)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error as determined under § 427.503, or any CMS-determined recalculations as determined under § 427.501(d)(2), if applicable. Manufacturers must pay the rebate amount within 30 calendar days from the date of receipt of the Rebate Report (as set forth in § 427.505(a)). For example, if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.

As set forth in §§ 427.504 and 427.505, we proposed to establish a standard method and process to issue Rebate Reports and accept manufacturer rebate payments. This method and process may include an online portal administered by a CMS contractor which will provide manufacturers with access to their Rebate Reports, submit Suggestions of Error, and pay a rebate amount due. We intend to provide technical instructions separate from this rulemaking to manufacturers of Part B

rebatable drugs regarding how to access Rebate Reports and how to receive notifications alerting the manufacturer when information is available. We stated in the CY 2025 PFS proposed rule (89 FR 61956) that CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments. As set forth in § 427.504(a), the manufacturer that may access Rebate Reports and make applicable rebate amount payments is the manufacturer responsible for paying a rebate, and as stated above, we proposed to identify the manufacturer that is responsible for paying a rebate using the same approach used for reporting ASP and Medicaid Drug Rebate Program data.

We solicited comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We note that the comments and responses below generally apply to both the Medicare Part B and Part D Drug Inflation Rebate Programs, as commenters made their recommendations with respect to both programs.

Comment: A couple of commenters requested that we provide a predictable date during each rebate cycle for when the preliminary report will be provided to help manufacturers ensure timely review of Preliminary Rebate Reports.

Response: We appreciate commenters' request for specific dates for the release of Preliminary Rebate Reports and how this may assist manufacturers in preparing for report review. We intend to publish a regular release schedule or calendar of release dates in future years of the rebate program, as we indicated on page 78 of the revised Medicare Part B Drug Inflation Rebate Guidance and page 66 of the revised Medicare Part D Drug Inflation Rebate Guidance. We also note that for the first two Part B Rebate Reports, which will include calendar quarters in calendar years 2023 and 2024, and the first two Part D Rebate Reports, which will include Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, we are finalizing the proposal to extend the Suggestion of Error review period to 30 days as set forth in § 427.503 for the Medicare Part B Inflation Rebate Program and § 428.403 for the Medicare Part D Inflation Rebate Program. Our aim in extending this review period for the first reports issued is to provide additional time for manufacturers to become familiar with the rebate process and develop internal review procedures.

Comment: A few commenters suggested that claim-level data be provided for each period for review. Specifically, one commenter stated that data should include the percent increase in inflation calculated by CMS and a detailed description of the types of data included in each Preliminary Rebate Report. Another commenter urged CMS to include in the preliminary reports all information, calculations, and supporting documentation necessary for a manufacturer to be able to make an informed determination as to whether the intended invoicing is correct or incorrect.

Response: We appreciate the comments to provide claim-level data for review. As stated in the revised guidance, we considered the statutory requirements outlined in section 1847(i)(1)(A) of the Act for Part B rebatable drugs and section 1860D–14B(a)(1) of the Act for Part D rebatable drugs to determine what data elements are necessary to review the Preliminary Rebate Report for a Suggestion of Error. Upon consideration of these comments and review of proposed §§ 427.501 and 428.401, we believe that the data listed to be provided in the Part B and Part D Preliminary Rebate Reports are sufficient for manufacturers to review the Preliminary Rebate Report for a Suggestion of Error. In addition to being sufficient for manufacturer review, we believe including additional data elements would not be feasible from an operational perspective given statutory timelines and the need for sufficient claims run-out.

Comment: A couple of commenters asked that CMS consider more than just mathematical errors in the suggestion of error process. A couple of commenters requested that CMS accept feedback from the manufacturer and supporting documentation regarding the data. A couple of commenters also asked CMS to establish an administrative dispute resolution process to consider feedback and errors in the data elements provided to manufacturers. These commenters stated that the statutory preclusions to administrative review at section 1847A(i)(8) of the Act do not prevent CMS from establishing an informal review process.

Response: Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part B rebatable drug, and the calculation of the rebate amount (as determined under § 427.503(a)(1)). Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount (see subparts B and C of part 428). We do not believe additional review is necessary and therefore, we are finalizing our proposal as set forth in §§ 427.503 and 428.403 for Part B and Part D, respectively, to provide an opportunity for manufacturers to informally review and provide feedback to CMS of manufacturer-identified mathematical errors.

Comment: Some commenters requested that we extend the Suggestion of Error period because commenters do not believe 10 calendar days is a sufficient amount of time for manufacturers to review the Preliminary Rebate Report and the preliminary report of the revised rebate amount. Among these commenters, a few suggested we provide at least 30 days for manufacturers to review and submit a Suggestion of Error; a couple of commenters suggested extending the review period to 45 days. One commenter requested a 45-day period for manufacturers to submit a Suggestion of Error rather than the proposed 10 calendar days.

Response: We appreciate commenters' feedback on the Suggestion of Error process. As we discussed on page 41 of the revised Medicare Part B Inflation Rebate Guidance and page 29 of the revised Medicare Part D Drug Inflation Rebate Guidance, in setting the review period of 10 calendar days we considered the volume of the data to be provided to manufacturers, the narrow set of items that may be identified as a Suggestion of Error, and the operational time period necessary for CMS to complete the process to publish a Rebate Report and the revised rebate amount, if applicable. Given these factors, we believe that a review period of 10 calendar days is sufficient.

Comment: One commenter requested that CMS clarify that manufacturers are not required to submit payment on disputed claims until the disputes are resolved.

Response: As set forth in proposed § 427.501 for Part B and § 428.401 for Part D, manufacturers will receive a Preliminary Rebate Report to include a preliminary rebate amount. Manufacturers will have 10 days to review the Preliminary Rebate Report and submit a Suggestion of Error, if applicable, as set forth in in proposed §§ 427.503 and 428.403. The Suggestion of Error process will be completed prior to issuance of the Rebate Report or a reconciled Rebate Report and therefore will include any revisions resulting from CMS' review of a Suggestion of Error in the rebate amount. Subsequently, payment is required within 30 days after the date of receipt of the Rebate Report as set forth in

§ 427.501(c) (and a reconciled Rebate Report as set forth in § 427.501(d)(1) and (2)) for a Part B rebate amount and within 30 days after the date of receipt of the Rebate Report set forth in § 428.401(c) (and a reconciliation of the Rebate Report as determined under § 428.401(d)(1) and (2)) for a Part D rebate amount.

Comment: One commenter requested that CMS provide an electronic payment system.

Response: We thank the commenters for the suggestions. CMS will establish a standard method and process for the payment of rebate amount owed (as set forth in §§ 427.505 and 428.405 which provide the deadline and process for payment of a rebate amount), and CMS is planning to provide an electronic payment mechanism similar to other existing systems used in the Medicare program.

After consideration of public comments, we are finalizing §§ 427.500 through 427.505 regarding Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments as proposed.

iii. Reconciliation of a Rebate Amount

As discussed in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, we considered options for establishing a standardized method and process at regular intervals to determinate any appropriate adjustments to the rebate amount for a Part B rebatable drug for an applicable calendar quarter to account for revised information as well as options for recalculation based on CMS identifying an agency error or determining manufacturer data was misreported. While the provisions in section 1847A(i) of the Act do not expressly provide for reconciliation in the Medicare Part B Drug Inflation Rebate Program, as explained in the CY 2025 PFS proposed rule (89 FR 61956), we have determined that a process for reconciling the rebate amount for updated information is necessary and appropriate to promote the accuracy of the rebate amount for each drug for each applicable calendar quarter. We proposed policies for reconciliation, including with respect to enforcement of payment of any reconciled rebate amount, consistent with both the statutory framework for the Medicare Part B Drug Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Prescription Drug Inflation Rebate Program.

As we proposed at § 427.501(d) and noted in the CY 2025 PFS proposed rule (89 FR 61956), we believe it is necessary and appropriate for CMS to recalculate the rebate amount for an applicable calendar quarter at a regular interval to include updated information about key data elements included in the calculation of the rebate amount. These data elements as set forth in § 427.501(d)(1)(i) include: total units; the payment amount in the payment amount quarter; and any applied reductions as determined under §§ 427.401 and 427.402. Updating these calculation inputs at a regular reconciliation interval will result in a rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of claims in the claims processing system. Because the information accessed represents the claims' status in the claims processing system at that moment in time, additional claims run-out may yield different information, either because more claims with dates of service during the applicable calendar quarter were finalized and added to the claims processing system or because the status of the existing claims changed. CMS refers to ''X months of run-out'' as the period between the end of the applicable calendar quarter and the date when CMS accesses information about the claims; for example, ''3 months of run-out'' means that claims data are accessed for claims with service dates during an applicable calendar quarter 3 months after the end of such applicable calendar quarter. Conducting a reconciliation of the rebate amount with additional claims run-out will improve the accuracy of the rebate amount. Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of payment amounts in other CMS programs (such as the Coverage Gap Discount Program) that provide for a reconciliation period.

As noted in the CY 2025 PFS proposed rule (89 FR 61956), the reconciliation of a rebate amount, whether the regular reconciliation as set forth in § 427.501(d)(1) or a discretionary reconciliation as set forth in § 427.501(d)(2) discussed further below, will not create a separately payable and distinct rebate amount. Rather, reconciliation updates the prior rebate amount owed to CMS, if any, by a manufacturer of a Part B rebatable drug so that the rebate amount ultimately reflects a more precise calculation of the rebate amount, as required by section 1847A(i) of the Act, to account for shifts in the underlying data following additional time for claims run-out after the Rebate Report is issued as well as subsequently identified data integrity issues. Moreover, because the reconciled rebate amount is an adjustment to the prior rebate amount, we proposed at § 427.501(d)(1)(i)(F) for the report of a reconciled rebate amount to also identify the difference between the rebate amount due as specified on the Rebate Report set forth in § 427.501(c) and the reconciled rebate amount. We noted in the CY 2025 PFS proposed rule (89 FR 61957) that we will only collect the net rebate amount due, if any, upon reconciliation, to prevent any duplicate payments. We also proposed to refund any overpayment made by a manufacturer, as determined during reconciliation, as set forth in § 427.505(c).

Additionally, as suggested in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, we considered multiple options for establishing a standardized method and process to occur at regular intervals to determine any appropriate adjustment to the rebate amount for a Part B rebatable drug for an applicable calendar quarter to account for revised information prior to proposing the policy described here for a 12-month reconciliation of the Part B inflation rebate amount. We considered the length of time needed to capture relevant changes to data inputs for recalculation, whether the timing should align with the reconciliation of Part D rebate amounts, and manufacturer burden. Specifically, we considered the average time span needed to ensure submission of the majority of revisions from claims run-out periods for Part B,[675] and how such unit revisions compare to the Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act. We also considered the average time span needed to ensure the majority of Part B claims submitted would already be adjudicated and determined to be final action claims, CMS' policies related to the frequency of ASP restatements, the reporting timeline for refunds on discarded drug units, and reporting timelines for 340B claims and claims for beneficiaries dually eligible for Medicare and Medicaid. Without a reconciliation process, the Part B rebate amount will include units of discarded drugs on which manufacturers potentially owe a refund, thereby potentially requiring manufacturers to pay both a discarded drug refund and a

[675] See the CCW White Paper: Medicare Claims Maturity, *https://www2.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf.*

rebate amount on certain units of a Part B rebatable drug due to the timing of revisions to discarded drug units discussed in further detail in section II.I.2.d.iv. of this final rule.

We noted in the CY 2025 PFS proposed rule (89 FR 61957) that we believe a longer period of claims run-out (at least 12 months of run-out time in the proposed approach) will ensure that CMS more fully accounts for capturing of revised units. We considered that penalties associated with failure to submit timely and accurate ASP data (specified at § 414.806(b)) encourage timely submission of ASP data with the submission timeline in accordance with § 414.804(a)(5) when considering the completeness of 12 months of claims run-out. While we considered a longer period until a revision is completed, such as the 36-month period provided by the MDRP for AMP restatements as set forth in § 447.510(d)(3), we believe that a 12-month reconciliation period is appropriate for the Part B rebate program because of requirements to submit timely and accurate ASP data (specified at § 414.806(b)), and it provides sufficient time to capture the majority of updates to the data as set forth in § 427.301 while closing out (except for the proposed circumstances as set forth in § 427.501(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting) the calculation of the rebate amount for a Part B rebatable drug for an applicable calendar quarter within a reasonable time period after the Rebate Report is issued. While we proposed a 12- and 36-month reconciliation period in the Medicare Part D Drug Inflation Rebate Program, due largely to the 36-month restatement period provided for MDRP AMP restatements (specified at § 447.510(d)(3)), we explained in the CY 2025 PFS proposed rule that we do not believe a second or longer restatement process is needed for Part B rebatable drugs because, as described previously, the ASP and claims run-out periods correspond with sufficient claims run-out and ASP restatement timing for Part B (particularly when considering penalties associated with failure to submit timely and accurate ASP data (specified at § 414.806(b)).

Further, as discussed in the CY 2025 PFS proposed rule (89 FR 61957), in considering whether consistency across CMS programs is critical, we believe that consideration for the completeness of data, as discussed above, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the rebate amount, we prioritized, to the extent feasible, completeness and accuracy of the data elements contributing to the calculation of the rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. Finally, we noted in the CY 2025 PFS proposed rule (89 CFR 61981) that we believe that a restatement of each data element set forth in § 427.501(d) to reconcile the rebate amount provided in the Rebate Report as set forth in § 427.501(c) and drugs acquired through the 340B Program as set forth in § 427.303(b)(1)(i) is appropriate to capture an updated rebate amount and is in line with other CMS programs that provide for a reconciliation period, including ASP restatements (see § 414.806). While some data points may not change, we proposed to review the data to determine if there are any updates in the data and use the updated data in the reconciliation to provide a reconciled rebate amount to the manufacturer.

Based on these considerations, similar to the multi-step process for the Rebate Report as set forth in § 427.501(b) and (c), in summary, we proposed a multi-step process to provide each manufacturer of a Part B rebatable drug with a reconciled rebate amount on a regular basis. At the 12-month reconciliation, we proposed a reconciliation process will include: (1) a preliminary reconciliation of the rebate amount, which we will provide to manufacturers of Part B rebatable drugs as set forth in proposed § 427.501(d)(1) and (2) a reconciled rebate amount, which we will provide to manufacturers of a Part B rebatable drug as determined under proposed § 427.501(d)(1)(ii). We also proposed to apply the Suggestion of Error process as set forth in § 427.503 to the preliminary reconciliation.

In detail, first, as set forth in § 427.501(d)(1) and similar to the Preliminary Rebate Report process as set forth in proposed § 427.501(b), we proposed to provide the manufacturer with information about the preliminary reconciliation of the rebate amount at least 1 month prior to the issuance of the reconciled rebate amount (as set forth in § 427.501(d)(1)) to each manufacturer of a Part B rebatable drug for an applicable calendar quarter. We proposed at § 427.501(d)(1) that the preliminary reconciliation will include, at a minimum, the same information outlined for the Rebate Report and the following updated information, if applicable: updated total number of rebatable units as specified at § 427.303; the payment amount in the payment amount benchmark quarter, if any inputs are restated within the reconciliation run-out period, as set forth in § 427.302(d); applicable calendar quarter specified amount (as set forth in § 427.302(b)), if any inputs are restated within the reconciliation run-out period; the excess amount by which the specified amount exceeds the inflation-adjusted payment amount, if any inputs are restated within the reconciliation run-out period, as determined under § 427.302; the reconciled total rebate amount calculated as set forth in § 427.301; and the difference between the total rebate amount due as specified on the Rebate Report set forth in § 427.501(d)(1)(i)).

As set forth in § 427.503(a), similar to the Suggestion of Error process proposed for the Preliminary Rebate Report at § 427.501(a), within 10 calendar days after date of receipt of the information about the preliminary reconciliation of the rebate amount, we proposed that a manufacturer may suggest to CMS that the manufacturer believes the preliminary reconciled rebate amount contains a mathematical error. As stated in the CY 2025 PFS proposed rule (89 FR 61958), we believe a 10-calendar-day period is sufficient due to the same considerations of data volume, the narrow set of reviewable items, and the operational time period necessary for CMS to complete the process to publish the reconciled rebate amount. The preclusions in section 1847A(i)(8) of the Act on administrative and judicial review apply to the reconciliation process.

Second, in detail, we proposed at § 427.501(d) to provide the reconciled rebate amount to the manufacturer 12 months after the Rebate Report was issued for an applicable calendar quarter. As set forth in § 427.501(d)(1)(i), the information in the report for the reconciled rebate amount would include the same data elements as provided in the information provided to the manufacturer of a Part B rebatable drug regarding the preliminary reconciliation of a rebate amount (set forth in § 427.501(d)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from § 427.503. A reconciliation of the rebate amount may result in an increase, decrease, or no change to the rebate amount, compared to the Rebate Report for an applicable calendar quarter (as determined under § 427.501(d)(3)) or amount described in a previous reconciliation (as determined under § 427.501(d)(2)).

Additionally, as we suggested in section 60 of the revised Medicare Part B Drug Inflation Rebate Guidance, CMS considered options for establishing circumstances where a recalculation of

the rebate amount may be appropriate for an applicable calendar quarter after issuing the Rebate Report and/or a reconciled rebate amount based on CMS identifying an error or CMS determining that the information used to calculate a rebate amount was inaccurate due to false reporting or similar fault by the manufacturer (for example, manufacturer pricing or product data under section 1927(b)(3) of the Act). We also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

As explained in the CY 2025 PFS proposed rule (89 FR 61958), based on these considerations, we believe that, to capture an accurate rebate amount and consistent with reconciliations of pricing data otherwise submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances may merit a recalculation of the rebate amount separate from the 12-month reconciliation set forth in § 427.501(d)(1). Specifically, we proposed at § 427.501(d)(2) that CMS may recalculate a rebate amount, when CMS identifies either: (1) an agency error such as a mathematical error or an error in the information specified in a Rebate Report set forth in § 427.501(c) or report of a reconciled rebate amount set forth in § 427.501(d)(1) including reporting system or coding errors, or (2) CMS determining that information used to calculate the rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly assigning a billing or payment code or incorrectly calculating the billing units per package, or the mechanism that provides a Rebate Report to the manufacturer or the Rebate Report incorrectly displays a rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate ASP data as specified at § 414.806). This does not include standard restatements to ASP or other data outside of the standard process of issuing the reconciled rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS Office of Inspector General, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12-month reconciliation of the rebate amount as set forth in proposed § 427.501(d)(1), CMS may choose to include a correction based on the circumstances proposed at § 427.501(d)(2) concurrently with the 12-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, we proposed that the agency would limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the Rebate Report (as set forth in § 427.501(c)) or the report of the reconciled rebate amount (as set forth in § 427.501(d)(1)) unless the correction directly impacts additional data fields. For example, we believe corrections to an ASP quarterly file may not change the specified amount for the applicable calendar quarter.

In addition, as noted in the CY 2025 PFS proposed rule (89 FR 61958), because reconciling a rebate amount imposes substantial administrative burden on CMS to reprocess the rebate amount, retest the reporting system, and reissue a rebate report, we proposed at § 427.501(d)(2) that CMS may exercise discretion not to initiate a recalculation of the rebate amount in these situations which are outside of the regular reconciliation process set forth in § 427.501(d)(1).

We proposed that for a recalculation due to agency error, the error must be identified within 3 years of the date of receipt of the reconciled rebate amount for the applicable calendar quarter (set forth in § 427.501(d)(2)(i)). Identification means that CMS has knowledge of the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the rebate amount within the 3-year period. CMS will timely complete these steps and determine, when the reconciliation does impact the rebate amount, whether the reconciliation must be included in a discretionary revision or within an upcoming reconciled rebate amount for an applicable calendar quarter. We stated in the CY 2025 PFS proposed rule that we believe a 3-year period dating from the issuance of a reconciliation aligns broadly with the timeframe in which most manufacturers provide Part B ASP restatements.

We proposed at § 427.501(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, we will not be bound by the 3-year time limit for revision of the rebate amount. For example, if a determination is made that a manufacturer misreported ASP data, then CMS may recalculate the rebate amount owed for a Part B rebatable drug. We solicited comments on the proposals related to manufacturer misreporting.

We proposed at § 427.505(a)(1) that upon receipt of the reconciled rebate amount manufacturers must pay the rebate within 30 calendar days from the date of receipt of the reconciled rebate amount. A 30-day payment deadline aligns with the payment period set forth in statute at section 1847A(i)(1)(B) of the Act. As set forth in § 427.504, we will use the same method and process for issuing Rebate Reports and submission of payments for reports with a reconciled rebate amount. We stated that we will provide notice to manufacturers when a report with a reconciled rebate amount, which will include the information set forth at § 427.501(d), is available for the manufacturer's Part B rebatable drugs. We proposed at § 427.505(c) that if a refund is owed to a manufacturer based on a reconciled rebate amount, we will initiate the process to issue such a refund within 60 days from the date of receipt of the reconciled rebate amount (set forth at § 427.501(d)). CMS will issue additional information on this method and process through additional program communications.

We received public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: One commenter asked CMS to establish a minimum threshold amount it will use in determining if a reconciled rebate amount is owed, and to clarify that amount to manufacturers in the final rule. The commenter provided an example wherein a manufacturer could owe a rebate amount of 1 cent but did not suggest a specific minimum threshold.

Response: We thank the commenter for their suggestion. Section 1847A(i)(1)(A) of the Act requires the Secretary to provide a report to each manufacturer of a Part B rebatable drug with the following information not later than 6 months after the end of an applicable calendar quarter: (1) the total number of billing units for each Part B rebatable drug; (2) the amount, if any, of the excess average sales price increase (the amount by which the specified amount exceeds the inflation-adjusted payment amount as determined under § 427.301(g)) for an applicable calendar quarter; and (3) the rebate amount for

the Part B rebatable drug. The goal of the reconciliation process is to ensure the rebate amount is complete and accurate. The statute does not direct CMS to only collect rebate amounts above a specific threshold. As such, we decline to provide a minimum threshold for a rebate amount owed for a reconciled rebate amount in the report as set forth in § 427.501(d)(1).

Comment: One commenter expressed support for the proposed 12-month reconciliation process. One commenter suggested that CMS finalize the reconciliation period of one year in order to appropriately capture restatements of ASP. Another commenter urged CMS to provide reconciliation for up to 3 years as ASP restatements can occur after the 1-year mark. The commenter also suggested that CMS establish a clear and consistent process for manufacturers to notify the agency of ASP restatements that occur after initial rebate invoices are issued, and for those ASP restatements to be fully accounted for in the Part B inflation rebate reconciliation.

Response: We thank these commenters for their feedback. As part of the 12-month reconciliation, we will incorporate updates to the data as set forth in §§ 427.501(b)(1) and 427.501(d)(1). This will include updates to ASP data that have been processed by CMS prior to the 12-month reconciliation. Section 414.806(b) requires timely and accurate reporting of ASP data,[676] including a requirement that manufacturers submit corrections to ASP data by the correction deadline, which is the 10th day of the month preceding the effective date of the payment limits. Further, CMS may issue restatements for up to four previous quarters; manufacturers have until the 30th day of the month after the end of the previous quarter to submit corrected data. In the Medicare Part B Inflation Rebate Program, the Rebate Report will be issued no later than 6 months after the end of each calendar quarter, followed by reconciliation which will occur 12 months after the Rebate Report is issued. This is after the timeframe in which ASP is restated.

We also noted previously that the Discarded Drug Refund Program includes lagged claims data in annual reports, subsequent to the initial report. Although this lagged data will generally not be available when we conduct reconciliation in the Medicare Part B Drug Inflation Rebate Program, CMS has estimated that over 99 percent of claims will be final when a given quarter is first included in a discarded drug refund report.[677] Therefore, CMS anticipates that there will not be significant revisions to the number of units of discarded drugs subject to refunds for rebatable drugs after we conduct reconciliation in the Medicare Part B Drug Inflation Rebate Program. As such, we believe that as a general matter the reconciliation 12 months after the Report is issued, as set forth in § 427.501(d)(1), also enables CMS to majority of updates to the data specified set forth in § 427.301. Reconciliation 12 months after the Rebate Report is issued, after the Rebate Report as set forth in § 427.501(d)(1), also enables CMS to close out the calculation of the rebate amount for a Part B rebatable drug for an applicable calendar quarter within a reasonable time period after the Rebate Report is issued. We believe the reconciliation set forth in § 427.501(d)(2) regarding manufacturer misreporting is sufficient to account for ASP restatements that occur after 12 months. We do not believe a second or longer restatement process is needed for Part B rebatable drugs to account for ASP restatements in the ordinary course, because, as described previously, the reconciliation timing as set forth at § 427.501(d)(1) would allow sufficient time for ASP restatement and claims run-out before the reconciliation as set forth in § 427.501(d)(1) would occur. We will monitor the data specified at § 427.301 and consider changing the timing of reconciliation in the Medicare Part B Drug Inflation Rebate Program in the future if necessary.

Comment: A couple of commenters requested that CMS clarify the definition of ''manufacturer misreporting.'' These commenters suggested that CMS limit the application to situations of manufacturer fraud or similar fault.

Response: We thank the commenters for their feedback. We provided examples of manufacturer misreporting within the CY 2025 PFS proposed rule to illustrate the scope of the proposal. These examples are instances in which the manufacturer has made a correction to previously submitted data, as well as instances in which the individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate ASP data as specified at § 414.806). We decline to apply these instances of reconciliation only to circumstances where fraud has been identified as this approach would remove reconciliation when manufacturer misreporting due to a manufacturer correction occurred. Additionally, we decline to further define manufacturer misreporting. We believe that a prescriptive definition may not fully capture the range of circumstances within the Medicare Part B or Medicare Part D Drug Inflation Rebate Programs in which we may conclude the information a manufacturer reported was inaccurate or misleading.

Comment: A couple of commenters suggested that CMS provide limited time parameters to a reconciliation due to manufacturer misreporting, as set forth in proposed § 427.501(d)(2). Specifically, these commenters suggested that CMS use an end date of 3 or 4 years and mirror the standards provided at 42 CFR 405.980(b) regarding revisions to Medicare contractor determinations of Part A and Part B benefit eligibility.

Response: We thank commenters for their feedback. We have considered other Medicare and Medicaid program parameters regarding reconciliation of program data, and we are finalizing our proposal as proposed because we believe it consistent with other CMS programs that do not include time parameters on certain revisions (for example, the Medicaid Drug Rebate Program obligations for reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices are not limited to 12 quarters in instances in which the change is to address an internal, Office of Inspector General, or Department of Justice investigation as specified at § 447.510(b)(1)(v)). We believe this approach appropriately accounts for the significant periods of time that may be necessary to accomplish fact finding and investigations that may be present in some instances of manufacturer misreporting. Additionally, we recognize that other authorities may include statutory timing limitations that overlay § 427.501(d)(2), as applicable.

In response to some commenters that suggested a 3- or 4-year end date for reconciliation in order to align our policy with the claim reopening rules at 42 CFR 405.980(b), we note our polices for reconciliation are more consistent with the reopening rules than the commenters' recommendation. Our policy for recalculation in the context of manufacturer misreporting is consistent with 42 CFR 405.980(b) which allows for exceptions to the otherwise applicable end date for recalculation in

[676] The CMS ''Average Sales Price (ASP) Restatement Policy Overview'' is available at: *https://www.cms.gov/files/document/average-sales-price-asp-restatement-policy-overview.pdf.*

[677] *https://www.federalregister.gov/d/2023-24184/p-2172.*

certain instances that could include misreporting (see 42 CFR 405.980(b)(3)). Additionally, we note that the Medicare Part B Drug Inflation Rebate Program does provide end dates for reconciliation of restated data for any reason, within the reconciliation set forth at § 427.501(c), and for reconciliation related to CMS technical errors, within the reconciliation specified at § 427.501(d)(1), which are substantially similar to the reopening policies stated in 42 CFR 405.980(b)(1) and (2).

Comment: One commenter suggested that we employ a preliminary report process for reconciled rebate amounts, aligned with the process proposed for Rebate Reports. The commenter recommended preliminary reconciled reports include data that manufacturers will need for a meaningful review of the report.

Response: It is unclear from the comment whether the commenter was referring to the reconciliation as set forth at § 427.501(d)(1) and/or at § 457.501(d)(2). We proposed to provide a preliminary report for a reconciled rebate amount set forth at § 427.501(d)(1). We decline to provide a preliminary report for a reconciled amount due to CMS identification of error or manufacturer misreporting set forth at § 427.501(d)(2) because the circumstances captured for these ad hoc reconciliations will likely be specific to a manufacturer and communication will reflect the facts and circumstances of the data revision.

After consideration of public comments, we are finalizing our proposal as proposed at § 427.501, with modification. In this final rule, we are revising § 427.501(b)(iii) and § 427.501(d)(i)(B) to reflect that the Rebate Report will include the payment amount benchmark quarter, in addition to the payment amount in the payment amount benchmark quarter, the corresponding cross-reference at § 427.302(c) to identify both the benchmark period and the price in the benchmark period within the report information. Additionally, we are including technical edits to § 427.501(d)(1) to clarify that a reconciliation will include any changes incorporated in the Rebate Report specified at § 427.501(c)(1).

iv. Rebate Report for Applicable Calendar Quarters in CY 2023 and CY 2024

Section 1847A(i)(1)(C) of the Act provides CMS with the option to delay sending the information required by section 1847A(i)(1)(A) of the Act for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025. At § 427.502, consistent with section 60.2 of the revised Medicare Part B Drug Inflation Rebate Guidance, we proposed consolidating the Preliminary Rebate Reports and Rebate Reports for CYs 2023 and 2024 into two reports: one report for the 4 applicable calendar quarters in CY 2023 and one report for the 4 applicable calendar quarters in CY 2024. This approach allows for at least 12 months of claims run-out for each applicable calendar quarter in CY 2023 and at least 3 months of claims run-out for each applicable calendar quarter in CY 2024. For these combined reports, we proposed at § 427.502 to provide an extended 30 calendar day Suggestion of Error period for the Preliminary Rebate Report.

In the CY 2025 PFS proposed rule (89 FR 61959), we proposed to send a reconciled rebate amount for the four applicable calendar quarters in CY 2024 9 months after the Rebate Report, to allow for 12 months of claims run-out for each applicable calendar quarter; in proposed § 427.502(b) we noted that we do not intend to conduct reconciliation for the 4 applicable calendar quarters in CY 2023 since the Rebate Report would already reflect 12 months of claims run-out. We stated in the CY 2025 PFS proposed rule that this approach aligns claims and payment data run-out with the run-out used during a regular reconciliation cycle. The Suggestion of Error period for the report containing the reconciled rebate amount for applicable calendar quarters in CY 2024 will be 10 calendar days.

As noted in the CY 2025 PFS proposed rule (89 FR 61959), this approach also minimizes the number of reports issued to manufacturers as a result of the delay in reporting and simplifies payment procedures, thereby minimizing manufacturer burden. Starting with the first applicable calendar quarter of CY 2025, reporting will begin a standard cadence and follow the procedures otherwise proposed in subpart F of this part 427.

We received public comment on this proposal. The following is a summary of the comment we received and our response.

Comment: One commenter suggested that CMS provide a 45-day suggestion of error review period in CY 2023 and CY 2024 instead of a 30-day review period, given that these are the first two periods that review will be effective.

Response: We appreciate this commenter's feedback. Similar to our response in suggestion of error review period for the Preliminary Rebate Report, in setting the review period of 30 calendar days, we considered the volume of the data to be provided to manufacturers, the narrow set of items that may be identified as a Suggestion of Error, and the operational time period necessary for CMS to complete the process to publish the CY 2023 and CY 2024 Rebate Reports. Given these factors, we believe that a review period of 30 calendar days is sufficient.

After consideration of public comment on this proposed provision, we are finalizing as proposed at § 427.502(c).

We proposed that manufacturers that do not pay the Medicare Part B inflation rebate amount owed for a Part B rebatable drug within 30 calendar days of receiving a Rebate Report, including reports containing a reconciled rebate amount, may be subject to a civil money penalty of 125 percent of the rebate amount, as applicable, for such drug for the applicable calendar quarter. We noted that the civil money penalty is in addition to the rebate amount.

g. Enforcement of Manufacturer Payment of Rebate Amounts (§ 427.600)

Section 1847A(i)(7) of the Act gives CMS the authority to impose a civil money penalty equal to at least 125 percent of the rebate amount for each drug for each applicable calendar quarter on a manufacturer that fails to pay the rebate amount for each rebatable Part B drug. In the CY 2025 PFS proposed rule (89 FR 61959) we stated that subpart G would implement this section of the Act and establish the procedures for determining and collecting a civil money penalty.

In accordance with section 1847A(i)(1)(B) of the Act and as set forth in § 427.505(a), manufacturers must provide to CMS a rebate amount owed within 30 calendar days of receipt of the Rebate Report containing the rebate amount due. As set forth in § 427.600(a), we proposed that CMS may impose a civil money penalty when a manufacturer fails to pay the rebate amount in full by the payment deadlines proposed at § 427.505(a). This means a manufacturer may be subject to a civil money penalty if the manufacturer fails to pay the full rebate amount as invoiced in the Rebate Report or any reconciled rebate amount that is greater than the amount invoiced in the Rebate Report. More specifically, as described in the CY 2025 PFS proposed rule (89 FR 61959), a manufacturer could be subject to a civil money penalty when a manufacturer fails to pay a rebate amount due by any payment deadline proposed at § 427.505(a)(1) and (2) for: (1) a Rebate Report as set forth at § 427.501(c); (2) a

reconciled rebate amount greater than the rebate amount reflected in the Rebate Report as set forth at § 427.501(d); or (3) a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable calendar quarters in calendar years 2023 and 2024 as set forth at § 427.502. We noted that the reconciled rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled rebate amount is an update to the rebate amount owed to CMS by a manufacturer of a Part B rebatable drug.

As stated in the CY 2025 PFS proposed rule (89 FR 61959), we explained that civil money penalties are a point-in-time penalty tied to the rebate amount due at the applicable payment deadline, which occurs 30 days after the date of receipt of a Rebate Report. At § 427.600(b), we proposed to establish the methodology for determining the amount of the civil money penalty as equal to 125 percent of the rebate amount for such drug for such applicable calendar quarter, and that this penalty would be due in addition to the rebate amount due. That is, a manufacturer will be responsible for paying the full rebate amount due in addition to any civil money penalty imposed because of late payment. While CMS has the statutory authority to impose a civil money penalty greater than 125 percent of the rebate amount in the Medicare Part B Drug Inflation Rebate Program under section 1847(A)(i)(7) of the Act, we proposed a penalty amount of 125 percent of the rebate amount to align with the penalty amount in the Medicare Part D Drug Inflation Rebate Program. We proposed this approach to civil money penalties based on section 1847A(i)(1)(B) of the Act, which establishes a requirement by the manufacturer to provide CMS with a rebate not later than 30 days after receipt from CMS of the report on the amount of the excess average sales price increase. As noted in the proposed rule, we believe that the ability to assess civil money penalties is necessary in all circumstances where a payment is due for a rebate amount to CMS to ensure compliance with the rebate program's requirements. The civil money penalty would be calculated based on the outstanding rebate amount due at the payment deadline, which is defined at § 427.505(a) as 30 calendar days after the date of receipt of a Rebate Report containing any rebate amount due; once a civil money penalty is assessed due to a late payment, the penalty would remain in effect even if the manufacturer pays the outstanding amount as the penalty is initiated due to a missed payment deadline. Because the payment deadline is clearly defined in section 1847A(i)(1)(B) of the Act, any late payments of a rebate amount due, including late payment of any reconciled rebate amounts greater than the amount reflected in the Rebate Report, would be considered a violation potentially subject to a civil money penalty. Any civil money penalty will be assessed before the next reconciliation process.

We proposed at § 427.600(b) that civil money penalties may be calculated at several points in time associated with missing a payment deadline for the rebate amount due reflected in the Rebate Report or missing a payment deadline associated with any rebate amount determined after a reconciliation to be greater than the amount invoiced in the Rebate Report. As these separate events can result in distinct assessments of civil money penalties, this means that CMS will not modify a civil money penalty from a prior missed payment deadline based on changes to the rebate amount due following reconciliation, including scenarios where the rebate amount is reduced following reconciliation. However, in the event that the rebate amount due on a Rebate Report was not paid and a civil money penalty was issued for violation of the payment deadline, CMS will not issue a second civil money penalty on a reconciled rebate amount if reconciliation decreased the rebate amount stated on the Rebate Report. As stated in the CY 2025 PFS proposed rule (89 FR 61959), we believe that enforcing this requirement after each payment deadline, regardless of what rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the program and consistency of the implementation of the program. Further, we proposed this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

As an example of this approach in practice, in the CY 2025 PFS proposed rule (89 FR 61960), we presented a scenario where the rebate amount due on the Rebate Report is $100. Following reconciliation 12 months after the Rebate Report was issued, CMS calculates a reconciled rebate amount for the applicable calendar quarter of $120 (an increase of $20 from the rebate amount identified in the Rebate Report due to updated claims run-out and payment data). Under this scenario, in the event the manufacturer does not pay the $100 rebate amount owed within the 30-day deadline following receipt of the Rebate Report, a civil money penalty for $125 ($100 × 1.25) could be assessed against the manufacturer due to their failure to meet the payment deadline. If the manufacturer pays the $100 before the reconciliation is completed, and then timely pays the $20 due within the 30-day payment deadline following the reconciliation 12 months after the Rebate Report or does not pay the $100 before the reconciliation is completed but timely pays the $120 due within the 30-day payment deadline following reconciliation 12 months after the Rebate Report, no further civil money penalty would be assessed.

Alternatively, in the event the manufacturer pays the $100 rebate amount due within the 30-day deadline following receipt of the Rebate Report but fails to meet the payment deadline for the net $20 rebate amount due following reconciliation, a civil money penalty of $25 ($20 × 1.25) could be assessed against the manufacturer due to their failure to meet the payment deadline for the updated rebate amount due following reconciliation. Finally, under this scenario in the event the manufacturer fails to meet any payment deadline throughout the full reconciliation cycle of this rebate amount; that is, the deadline is missed for the $100 amount due stated in the Rebate Report, and the $20 net rebate amount due following reconciliation, we may assess a separate civil money penalty on the rebate amount due at each of these missed deadlines. In this example, violations of each of these payment deadlines would result in a penalty of $125 ($100 × 1.25), followed by a penalty of $25 ($20 × 1.25), each of which would be assessed following the manufacturer's failure to meet the related payment deadline for the outstanding rebate amount due.

In an alternative possible scenario, consider the following. The rebate amount due on the Rebate Report is $100. Following reconciliation 12 months after the Rebate Report was issued, CMS calculates a reconciled rebate amount owed for the applicable period of $80 (a decrease of $20 from the rebate amount identified in the Rebate Report). In this scenario, if a manufacturer does not pay the $100 by the payment deadline for the rebate amount due in the Rebate Report, a civil money penalty for $125 ($100 × 1.25) may be assessed against the manufacturer due to its failure to meet the payment deadline for the rebate amount due identified in the Rebate Report. This civil money penalty is not affected if the manufacturer pays the rebate amount once it is past the

deadline, nor is it impacted by the reconciled rebate amount, because at the payment deadline missed by the manufacturer, the manufacturer owed a rebate of $100 to CMS and that rebate amount was not paid timely. As noted previously, under this scenario, given that there is no additional rebate amount due upon reconciliation compared to the rebate amount stated on the Rebate Report, there would not be a civil money penalty assessed on the reconciled rebate amount.

Further, we noted in the CY 2025 PFS proposed rule that payment of any civil money penalty does not obviate the requirement for the manufacturer to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Therefore, paying a civil money penalty does not satisfy the obligation to pay the underlying rebate amount on which the civil money penalty is calculated. In addition, CMS will evaluate all available options to ensure manufacturers' timely compliance with their rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

At § 427.600(c), we proposed that if CMS makes a determination to impose a civil money penalty on a manufacturer for violation of a payment deadline, we will send a written notice of the decision to impose a civil money penalty that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, we proposed applying existing appeal procedures for civil money penalties in 42 CFR 423, subpart T of this title to manufacturers appealing a civil money penalty imposed under the Medicare Part B Drug Inflation Rebate Program. We have utilized this appeals process for many years for civil money penalty determinations affecting MA organizations and Part D sponsors. Therefore, we proposed to use this well-established process for civil money penalty appeals from manufacturers that do not make inflation rebate payments by the payment deadline. We also proposed at § 427.600(e)(1) that the scope of appeals is limited to: (1) CMS determinations relating to whether the rebate payment was made by the payment deadline; and (2) the calculation of the penalty amount. Section 1847A(i)(8) of the Act precludes judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Section 1847A(i)(7) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A(a) of the Act. We proposed to codify this requirement at § 427.600(f). In alignment with the procedure outlined in section 1128A of the Act, we proposed at § 427.600(d) that collection of the civil money penalty will follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the civil money penalty is upheld, we will initiate collection of the civil money penalty once the administrative decision is final. We solicited comment on proposals related to the violations of payment deadlines and issuance of a civil money penalty.

We proposed at § 427.600(g) that in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer.

We received public comment on these proposals. The following is a summary of the comment we received and our response. Some of the comments received addressed both Part B rebatable drugs and Part D rebatable drugs. We addressed these comments below and do not repeat these summaries of comments and our responses in the discussion of Part D drug inflation rebate policies.

Comment: A few commenters stated that CMS does not have the statutory authority to issue CMPs for reconciled amounts in the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. One of these commenters stated that sections 1847A(i)(7) and 1860D–14B(e) of the Act only mention CMPs related to late payments of the rebate amount and no language in the IRA provides CMS with the authority to issue a CMP for reconciled amounts.

Response: We thank the commenters for their input but disagree with their assessment of the agency's CMP authority under the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program.

In the Part B Inflation Rebate Program, section 1847A(i)(7) of the Act provides that ''[i]f a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to . . . a civil money penalty equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. Section 1847A(i)(1)(B) of the Act establishes that the manufacturer of a Part B rebatable drug is required to provide to CMS a rebate for such drug for the calendar quarter ''not later than 30 days after the date of receipt from the Secretary of the information described in [section 1847A(i)(1)(A)].'' Section 1847A(i)(1)(A) of the Act in turn establishes the information CMS must report to the manufacturer of the Part B rebatable drug to trigger the payment obligation, including the rebate amount and other data specified in section 1847A(i)(3) of the Act. Section 1847A(i)(1)(A) of the Act also reflects a date by which CMS shall provide information to the manufacturer for each calendar quarter.

Consistent with the strong support from commenters, CMS is implementing section 1847A(i)(1)(A) of the Act with a reporting process that complies with this date and also incorporates a reconciliation process to ensure the agency's provision of information to each manufacturer of a Part B rebatable drug and the manufacturers' requirements to provide rebates are in accordance with section 1847A(i)(3) of the Act. Specifically, as set forth in §§ 427.500 through 427.505, CMS will provide the information described in section 1847A(i)(1)(A) of the Act through a Rebate Report as well as through subsequent reports in a reconciliation process to ensure this information, including the rebate amount, are in accordance with section 1847A(i)(3) of the Act. The reconciled rebate amount provided to the manufacturer in the report of reconciliation is not a separately payable and distinct rebate amount. Rather, the reconciled rebate amount is an update to the rebate amount owed to CMS by a manufacturer of a Part B rebatable drug. However, the report with

the reconciled rebate amount is a separate provision of the information described in section 1847A(i)(1)(A) of the Act and the provision of the information described in section 1847A(i)(1)(A) of the Act triggers the timely payment requirements in section 1847A(i)(1)(B) of the Act. Section 1847A(i)(7) of the Act gives CMS the authority to impose a civil money penalty on a manufacturer of a part B rebatable drug that fails to comply with the requirements under section 1847A(i)(1)(B) of the Act. In this rulemaking, CMS is simply affirming that § 427.600(a), which restates the express authority to impose CMPs if a manufacturer of a Part B rebatable drug fails to comply with the requirement to timely pay rebates, applies with an appropriate CMP amount when the requirements under section 1847A(i)(1)(B) of the Act are triggered by the receipt of reconciled information.

Similarly, in the Part D Inflation Rebate Program, section 1860D–14A(e) of the Act provides that ''[i]f a manufacturer of a part D rebatable drug has failed to comply with the requirements under paragraph (a)(2) with respect to such drug for an applicable period, the manufacturer shall be subject to a civil money penalty in an amount equal to 125 percent of the amount specified in subsection (b) for such drug for such period.'' Section 1860D–14B(a)(2) of the Act establishes the manufacturer requirement to provide a rebate within 30 calendar days of receipt from CMS of ''the information described in [section 1860D–14B(a)(1)]'' for the Part D rebatable drug for the applicable period. Section 1860D–14B(a)(1) of the Act establishes the information CMS must report to the manufacturer of the Part D rebatable drug to trigger the payment obligation, including the rebate amount and other data specified in section 1860D–14B(b) of the Act. Section 1860D–14B(a)(1) of the Act also reflects a date by which CMS shall provide information to the manufacturer for each applicable period. In this rulemaking, §§ 428.400 through 428.405 implements section 1860D–14B(a)(1) of the Act with a reconciliation process that reflects the reconciliation described in section 1860D–14B(b)(6) of the Act and otherwise ensures that the agency's provision of information to each manufacturer of a Part D rebatable drug and the manufacturers' requirements to provide rebates are in accordance with section 1860D–14B(b) of the Act. Section 1860D–14B(e) of the Act gives CMS the authority to impose a civil money penalty on a manufacturer of a Part D rebatable drug that fails to comply with the requirements under section1860D–14B(a)(2) of the Act. In this rulemaking, CMS is simply affirming that § 428.500(a), which restates the express authority to impose CMPs if a manufacturer of a Part D rebatable drug fails to comply with the requirement to timely pay rebates, applies with an appropriate CMP amount when the requirements under section 1860D–14B(a)(2) of the Act are triggered by the receipt of reconciled information.

In sum, the regulations describing the agency's CMP authority in §§ 427.600 and 428.500 are fully consistent with the express authority granted to CMS by statute to impose a civil money penalty when a manufacturer fails to meet statutory requirements to timely pay the rebate owed following the receipt from CMS of information from the agency regarding the rebate amount, including requirements triggered by the receipt of reconciled information.

The regulations are also fully consistent with the purpose of granting the agency CMP authority. If CMS did not have the ability to impose CMPs when a manufacturer does not meet requirements triggered based on the receipt of reconciled information, the CMPs would not accurately reflect extent to which a manufacturer had failed to timely pay the rebate amount owed. Congress directed CMS to reconcile inflation rebate amounts to account for revised information. See, for example, section 1860D–14B(b)(6) of the Act. It would frustrate the purpose of the statute if CMS did not have the ability to hold manufacturers accountable for providing a rebate in instances in which the reconciliation identifies a manufacturer underpayment. The imposition of CMPs on manufacturers that do not pay reconciled rebate amounts appropriately incentivizes manufacturers to comply with CMS requirements.

Comment: One commenter supports the CMP structure and recommended that CMS establish an ''escalating'' CMP structure for failing to timely pay the rebate amount.

Response: We appreciate this comment. We assume the commenter means that an ''escalating'' CMP structure would provide for increasing CMP amounts due as more time passes CMS is retaining its policy as proposed to assess CMPs for a late rebate payment in a fixed amount equal to 125 percent of the rebate amount for both the Medicare Part B and Part D Drug Inflation Rebate Programs. CMS believes this approach is best to create consistency across the two programs; and that a fixed CMP amount resulting from a simple, clear calculation is more effective than escalating CMPs to put manufacturers on notice of the potential penalty that will be assessed if a rebate payment is not made by the payment deadline. CMS will monitor the effectiveness of this CMP approach on manufacturer compliance as the program is implemented, and reconsider the CMP structure if necessary in the future.

Comment: One commenter stated that there is not enough time allowed to review and contest the rebate amount before payment is due. The commenter suggested that CMS establish a grace period wherein, if a manufacturer timely submits a Suggestion of Error and does not pay the rebate amount then CMS would not assess a CMP on that rebate amount until after the reconciliation process, at which time CMS would make a final determination on the Suggestion of Error. The commenter suggested that after reconciliation, if CMS determines that the manufacturer is liable for all or part of the rebate amount, the manufacturer would then be liable for the rebate amount plus interest; the commenter recommended that interest be ''a reasonable rate, such as the yield rates of 13-Week Treasury bills.''

Response: We reiterate that sections 1847A(i)(1)(B) and 1860D–14B(a)(2) of the Act dictate the payment due date for the rebate amount is 30 days after the date of receipt of the information included in a Rebate Report, as described in proposed §§ 427.505(a) and 428.405(a)(1). CMS notes that the Suggestion of Error process established in these regulations allows for enough time for manufacturers to review the preliminary rebate amount and voice concerns about the calculation before the rebate amount is due. We also note that, should a CMP be assessed for failure to meet an applicable payment deadline, the Primary Manufacturer has 60 days to appeal the CMP as described in proposed § 427.600(e) for Part B Drug Inflation Rebates and § 428.500(e) for Part D Drug Inflation Rebates. CMS further notes that at this time, we do not plan to assess interest on either overdue rebate amounts or CMP payments.

Comment: One commenter stated that CMS should establish a policy for manufacturers to contest a rebate amount. Under the commenter's proposal, during the time of the dispute the CMP will not be imposed but if the manufacturer is found liable, they will have a late payment interest at a reasonable rate.

Response: We appreciate this comment. CMS believes the Suggestion

of Error process established in these regulations provides manufacturers a means to voice concerns about the calculation of the rebate amount before it is finalized. We reiterate that sections 1847A(i)(8) and 1860D–14B(f) of the Act preclude administrative and judicial review of CMS determination of the rebate amount. CMS further notes that at this time, we do not plan to assess interest on either overdue rebate amounts or CMP payments.

After consideration of public comments, we are finalizing this policy as proposed at §§ 427.600 and 428.500.

h. Severability (§ 427.10)

At § 427.10, we proposed that were any provision of part 427 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from the other provisions in part 427, and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. As stated in the CY 2025 PFS proposed rule (89 FR 61961), while the provisions in part 427 are intended to present a comprehensive approach to implementing the Medicare Part B Drug Inflation Rebate Program, we intend that each of them is a distinct, severable provision. We also stated our intent that a finding that a provision of part 427 is invalid or unenforceable would not affect similar provisions in the Medicare Part D Drug Inflation Rebate Program.

As discussed in the CY 2025 PFS proposed rule, the Part B drug inflation rebate proposals are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, we stated that we intended the proposed policies related to reducing the rebate amount for Part B rebatable drugs currently in shortage and when there is a severe supply chain disruption (§§ 427.401 and 427.402) to be distinct and severable from the proposals related to the determination of Part B rebatable drugs subject to rebates (§ 427.101). As another example, we stated our intent that the proposed policy for using the payment limit for purposes of calculating the beneficiary coinsurance adjustment (§ 427.201(b)) would be distinct and severable from the proposals to use the specified amount for purposes of the Part B rebate calculation (§ 427.301). Even where one provision refers to a second provision, the preamble and the regulatory text clarify the intent of the agency that the two provisions would be severable if one provision were to be invalidated in whole or in part. For example, we would still be able to calculate drugs and biological products with average total allowed charges below the applicable threshold as described at § 427.101(c)(1), for exclusion from inflation rebate calculations, even if the provision to apply the applicable threshold at the billing and payment code level were deemed invalid (§ 427.101(c)(3)).

We received public comments on our proposed severability policy. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters disagreed with CMS' proposal that each regulatory provisions in part 427 is severable and distinct. One of these commenters stated that the preamble seeks to dictate to the courts how each regulatory provision should be evaluated for the purposes of severability. This commenter recommended CMS indicate an intent for severability but delete preamble or regulatory language related to the courts' evaluation of the issue. One of these commenters wrote that courts have rejected similar severability clauses, particularly in instances where a regulation's provisions were too intertwined to sever. This commenter also noted that CMS does not provide a legal or policy rationale for how it believes the Part B inflation rebates regulations can operate independently from one another. As a result, the commenter writes, a court would likely find the Part B inflation rebate regulations should be treated as a ''single, integrated proposal.''

Response: We appreciate these commenters sharing their feedback. We disagree with the commenters' contention that the policies in this final rule are not individual and severable. Under the Administrative Procedure Act (APA), an ''agency action'' may be either ''the whole or a part of an agency rule.'' 5 U.S.C. § 551(13). Thus, the APA permits a court to sever a rule by setting aside only the portion of the rule found invalid.[678] Courts have stated that in determining if an agency action is severable, they look at the agency intent,[679] and if parts of the action are ''intertwined'' or if ''they operate entirely independently of one another.'' [680] Even if a court were to strike down some provision of this final rule, CMS' intent is that other portions of this rule would remain in effect. CMS' intent is evidenced by § 427.10, which states that were any provision of part 427 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from part 427 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. CMS believes severability applies to each provision of the Part B drug inflation rebate regulation, because deeming any particular provision to be invalid or illegal would not result in a material change to the Medicare Part B Drug Inflation Rebate Program so as to cause all of the requirements that compose the program to be invalid.

Contrary to the commenter's assertion, CMS did explain how the Part B inflation rebate regulations can operate independently from one another. As noted above, CMS provided two examples that are illustrative of how the provisions of part 427 will operate independently from one another: (1) the proposed policies related to reducing the rebate amount for Part B rebatable drugs currently in shortage and when there is a severe supply chain disruption (§§ 427.401 and 427.402) are distinct and severable from the proposals related to the determination of Part B rebatable drugs subject to rebates (§ 427.101), and (2) the proposed policy for using the payment limit for purposes of calculating the beneficiary coinsurance adjustment (§ 427.201(b)) is distinct and severable from the proposals to use the specified amount for purposes of the Part B rebate calculation.

After consideration of public comments, CMS is finalizing this policy as proposed at § 427.10.

3. Medicare Part D Drug Rebates for Drugs, Biologicals, and Sole Source Generic Drugs with Prices that Increase Faster than the Rate of Inflation

a. Definitions (§ 428.20)

At § 428.20, we proposed to codify definitions of terms with meanings given in section 1860D–14B of the Act and established in the revised Medicare Part D Drug Inflation Rebate Guidance, as well as new definitions based on policies detailed in the CY 2025 PFS proposed rule.

We proposed that the following terms in section 1860D–14B of the Act be defined:

[678] *Carlson* v. *Postal Regulatory Comm'n,* 938 F.3d 337 (D.C. Cir. 2019).

[679] *Davis Cnty. Solid Waste Mgmt.* v. *U.S. E.P.A.,* 108 F.3d 1454, 1459 (D.C. Cir. 1997).

[680] *Wilmina Shipping AS* v. *United States Dep't of Homeland Sec.,* 75 F. Supp. 3d 163, 171 (D.D.C. 2014).

- ''Annual manufacturer price (AnMP)''.
- ''Applicable period''.
- ''Applicable period Consumer Price Index for All Urban Consumers (CPI–U)''.
- ''Benchmark period CPI–U''.
- ''Part D rebatable drug''.
- ''Payment amount benchmark period''.
- ''Unit''.

Further, we proposed to codify at § 428.20 definitions established in the revised Medicare Part D Drug Inflation Rebate Guidance and new definitions based on policies detailed in this final rule for the following terms:

- ''Applicable threshold''.
- ''Average manufacturer price (AMP)''.
- ''Benchmark period manufacturer price''.
- ''Covered Part D drug''.
- ''CPI–U''.[681]
- ''First marketed date''.
- ''Inflation-adjusted payment amount''.
- ''Manufacturer''. We proposed that manufacturer identification in the Medicare Prescription Drug Inflation Rebate Program, inclusive of communications and rebate liability, will be consistent with the policies and practices adopted at § 447.502 for purposes of manufacturer obligations under the Medicaid Drug Rebate Program. We stated we believe this approach will provide clarity and allow for consistency in the agency's treatment of financial transactions, including in the contexts of debt collection, bankruptcy, and changes in ownership. We solicited feedback on this proposed approach and whether there are alternative approaches that may better achieve the agency's goals for application of rebate liability and collection of rebate amount, including whether additional policies and/or a Medicare Prescription Drug Inflation Rebate Program agreement are needed to clarify financial accountability for rebate amounts in situations where there are changes in ownership of a manufacturer or of a rebatable drug.
- ''National Drug Code (NDC)''.
- ''Subsequently approved drug''.

We solicited comments on these definitions. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended CMS provide greater clarity on the proposed definition of manufacturer. Specifically, these commenters noted that CMS did not indicate in the CY 2025 PFS proposed rule whether it would adopt potential revisions to the Medicaid definition of manufacturer for purposes of the Medicare Part D Drug Inflation Rebate Program. If CMS is considering incorporating Medicaid proposals into the Medicare Part D Drug Inflation Rebate Program, these commenters suggested CMS should clearly forecast this possibility to commenters.

Response: We appreciate the commenters sharing this feedback. Because CMS operationalizes the Medicare Part D Drug Inflation Rebate Program based on data reported under the MDRP, certain policies adopted under the MDRP may affect manufacturer obligations under the Medicare Part D Drug Inflation Rebate Program. We note that in the final Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program rule released on September 20, 2024, CMS did not finalize the agency's proposed revisions to the Medicaid Drug Rebate Program definition of manufacturer.[682] As such, the commenter's suggestion is moot.

Comment: One commenter asserted that CMS' request for comments on a potential agreement for purposes of the Medicare Part B and Part D Drug Inflation Rebate Programs is inconsistent with the statute. This commenter stated that the Act is silent on agreements between manufacturers and CMS for the Medicare Part B and Part D Drug Inflation Rebate Programs, in contrast to other sections of the Act that establish agreements for other CMS programs, and thus does not authorize CMS to require manufacturer agreements for these programs.

Response: We appreciate the commenter sharing these concerns. CMS has determined not to require manufacturers to enter into agreements with CMS for purposes of the Medicare Part B or Part D Drug Inflation Rebate Programs at this time.

After consideration of public comments, we are finalizing these definitions as proposed at § 428.20, with modification to the definition of National Drug Code (NDC). Because the provisions of the Medicare Part D Drug Inflation Rebate program apply at the NDC–9 level unless otherwise specified, CMS omitted reference to the package size and type in the definition of NDC for purposes of the Medicare Part D Drug Inflation Rebate Program.

b. Determination of Part D Rebatable Drugs (§§ 428.100 through 428.101)

i. Definitions

At § 428.100, we proposed to define the following terms applicable to subpart B (§§ 428.100 through 428.101):

- ''Individual who uses such a drug or biological''.
- ''Gross covered prescription drug costs''.

We did not receive public comments on these proposed definitions, and we are finalizing as proposed at § 428.100.

ii. Identification of Part D Rebatable Drugs

Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' in part, as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act. A drug or biological set forth in section 1860D–14B(g)(1)(C) of the Act means a drug or biological that, as of the first day of the applicable period involved, is: (1) a drug approved under an NDA under section 505(c) of the FD&C Act (that is, a brand name drug); (2) a drug approved under an ANDA under section 505(j) of the FD&C Act that meets the criteria in section 1860D–14B(g)(1)(C)(ii) (that is, a generic drug that meets certain sole source criteria); or (3) a biological licensed under section 351 of the PHS Act (that is, a biological product, including a biosimilar).

At § 428.101(a), we proposed to identify a Part D rebatable drug[683] for each applicable period by determining which covered Part D drugs, as defined in section 1860D–2(e) of the Act, meet the requirements in section 1860D–14B(g)(1)(C) of the Act (that is, are brand name drugs approved under an NDA, biologicals licensed under a biologics license application (BLA), or generic drugs approved under an ANDA). As noted, a Part D rebatable drug must meet the requirements in section 1860D–14B(g)(1)(C) of the Act as of the first day of the applicable period.

To evaluate whether a generic drug approved under an ANDA meets all the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act, we proposed at § 428.101(a)(3) to codify the policy established in section 30 of the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would use

[681] These data are referenced to 1982–84 = 100—that is, the average of pricing data for the 36 months from 1982 through 1984 serve as the basis for the index and are assigned a value of 100. These data are not seasonally adjusted.

[682] See *https://www.federalregister.gov/documents/2024/09/26/2024-21254/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates.*

[683] For purposes of this final rule, we use the term ''Part D rebatable drug'' to refer to the dosage form and strength with respect to such drug for which Part D drug inflation rebates are calculated.

specified FDA resources such as the ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) [684] and NDC Directory [685] to determine whether a generic drug meets the definition of a Part D rebatable drug. At § 428.101(a)(3)(i) and (ii), we proposed to clarify the policy established in revised Medicare Part D Drug Inflation Rebate Guidance by adding that, for purposes of § 428.101, we consider historical information from NDC Directory files, such as discontinued, delisted, and expired listings, provided by FDA to CMS or published by FDA on its website to be included in the NDC Directory. As proposed at § 428.101(a)(3)(iii), to determine whether the manufacturer of the generic drug is a first applicant during the 180-day exclusivity period, or whether the manufacturer of the generic drug is a first approved applicant for a competitive generic drug therapy, CMS would refer to FDA website resources such as the Orange Book and may consult with FDA for technical assistance as needed. We proposed that CMS will determine whether a generic drug that is a covered Part D drug meets the definition of a Part D rebatable drug based on the status of the drug on the first day of the applicable period.

While generic drugs that do not meet the sole source criteria in section 1860D–14B(g)(1)(C)(ii) of the Act (that is, multiple source generic drugs) are excluded from the definition of a Part D rebatable drug, we understand that a generic drug may meet the definition of a Part D rebatable drug on the first day of an applicable period and then cease to meet such definition later in the applicable period if, for example, the FDA approves another therapeutically equivalent generic drug under a 505(j) ANDA and that drug is marketed during such applicable period. As described later in this final rule, CMS proposed at § 428.203(b)(1) to exclude from the rebate calculation any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug.

We did not receive public comments on these proposed provisions, and we are finalizing as proposed at § 428.101(a).

[684] FDA Orange Book: *https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeuticequivalence-evaluations-orange-book.*

[685] National Drug Code Directory: *https://dps.fda.gov/ndc.*

iii. Drugs and Biologicals with Average Annual Total Cost Under Part D Below the Applicable Threshold

Under section 1860D–14B(g)(1)(B) of the Act, a drug or biological is excluded from the definition of a Part D rebatable drug if the ''average annual total cost'' under Part D for such period per individual who uses such a drug or biological product is less than $100 per year, as determined by the Secretary using the most recent data available, or, if data are not available, as estimated by the Secretary. The statute provides that the $100 annual amount for the applicable period beginning October 1, 2022, is to be increased by percentage changes in the CPI–U for subsequent applicable periods. At § 428.101(b), we proposed to codify the policy established in section 30.2 of the revised Medicare Part D Drug Inflation Rebate Guidance for determining the applicable threshold and excluding from the definition of a Part D rebatable drug, and thus Part D drug inflation rebates, drugs and biologicals for which the average annual total cost under Part D for such applicable period per individual who uses such drug or biological product is below that applicable threshold.

Consistent with the approach described in the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed to calculate the average annual total cost based on gross covered drug costs for the Part D rebatable drug at the NDC–9 level. We proposed CMS would divide the gross covered drug costs for the drug by the number of unique Part D beneficiaries that were dispensed the drug in that applicable period. For this calculation, CMS proposed to use Prescription Drug Event (PDE) data with gross covered drug costs greater than zero that are available for the drug with dates of service during that applicable period. Drugs that are determined to have average annual total costs under Part D of less than $100 per individual using such drug per year, adjusted by changes in the CPI–U, will be excluded from Part D drug inflation rebate calculations for the applicable period in question.

Comment: One commenter expressed concern that implementation of the Medicare Part D Drug Inflation Rebate Program could impose new administrative or financial burdens on community pharmacies. This commenter requested that CMS clarify that any provisions related to the reporting of PDE data would not require additional reporting by community pharmacies for tracking and calculating drugs or biologicals below the applicable threshold, or any additional reporting or change to existing claim submission by community pharmacies for tracking and calculating Part D rebatable drugs.

Response: We thank the commenter for sharing these concerns. Consistent with CMS' response on page 10 of the revised Medicare Part D Drug Inflation Rebate Guidance, we affirm that § 428.101(b) does not impose additional reporting requirements on pharmacies related to the exclusion of drugs where the average annual total cost under Part D is less than $100 per individual per year. CMS will calculate and determine which Part D rebatable drugs fall below, meet, or exceed the $100 per individual per year threshold based on PDE data. We also affirm that this final rule does not impose additional reporting requirements on pharmacies related to tracking Part D rebatable drugs and calculating Part D drug inflation rebates.

After consideration of comments received, we are finalizing as proposed at § 428.101(b) with a modification at § 428.101(b)(1). Specifically, we note below that, for operational reasons at this time, we are finalizing at § 428.203(b)(3) that CMS will exclude from the total number of units dispensed of a Part D rebatable drug when those units are associated with a Part D rebatable drug that has been billed as compounded. For alignment, we are finalizing at § 428.101(b)(1) that, when calculating the gross covered prescription drug costs for the drug or biological, CMS will exclude PDE records indicating the drug or biological was billed as a compound.

c. Determination of the Rebate Amount for Part D Rebatable Drugs (§§ 428.200 through 428.204)

i. Definitions

At § 428.200, we proposed to define the following terms applicable to subpart C (§§ 428.200 through 428.204):

- ''340B Program''.
- ''Line extension''.
- ''New formulation''.
- ''Oral solid dosage form''.

We received public comment on these proposed definitions. The following is a summary of the comment we received and our response.

Comment: One commenter argued that the MDRP regulatory definitions of ''line extension'' and ''new formulation'' are inconsistent with the Medicaid rebate statute, exceed CMS' authority, and would cause significant harm to pharmaceutical innovation by undermining the incentives to produce innovative new drugs. For these reasons, the commenter argued that

CMS should not extend the MDRP ''line extension'' and ''new formulation'' regulatory definitions to the Medicare Part D Drug Inflation Rebate Program regulations.

Response: CMS appreciates the commenter's perspective. As we stated below and in revised Medicare Part D Drug Inflation Rebate Guidance on page 20, section 1860D–14B(b)(5)(B)(ii) of the Act defines the term ''line extension'' as ''a new formulation of the drug, such as extended-release formulation, but does not include abuse-deterrent formulations of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended-release formulation.'' Because section 1927(c)(2)(C) of the Act uses identical language to define the term ''line extension'' for purposes of the MDRP, CMS believes that, for the purposes of identifying new formulations of Part D rebatable drugs in the Medicare Part D Drug Inflation Rebate Program, it is appropriate to use the regulatory definitions of ''line extension'' and ''new formulation'' that were adopted through rulemaking [686] for the MDRP, which can be found at § 447.502.

After consideration of public comments, we are finalizing these definitions as proposed at § 428.200.

ii. Calculation of the Total Rebate Amount To Be Paid by Manufacturers

Under section 1860D–14B(b)(1) of the Act, the Part D drug inflation rebate for each Part D rebatable drug and applicable period, subject to certain considerations, is the estimated amount that is equal to the product of: (1) the amount, if any, by which the annual manufacturer price (AnMP) for such Part D rebatable drug for the applicable period exceeds the inflation-adjusted payment amount for the Part D rebatable drug for the applicable period, and (2) the total number of units of the Part D rebatable drug dispensed under Part D and covered and paid by Part D plan sponsors during the applicable period. To calculate the Part D drug inflation rebate consistent with section 1860D–14B(b)(1) of the Act, we proposed at § 428.201(a)(1) to codify the calculation methodology described in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance, which provides that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount, as determined under § 428.202(a), multiplied by the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors, as determined in accordance with § 428.203. We proposed at § 428.201(a)(2) that the total Part D drug inflation rebate amount for a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form is equal to the amount specified at § 428.204. We further proposed the Part D drug inflation rebate amount calculated in accordance with this subpart is subject to adjustment based on any reductions in accordance with subpart D of this part or any reconciliations in accordance with subpart E of this part.

At § 428.201(b), we proposed to exclude from the calculation performed under subpart C drugs and biologicals that meet the definition of a Part D rebatable drug, but which are missing AMP data for the entire duration of the applicable period because, for the reasons specified below, there were no quarters during that period in which their manufacturers were required to report AMP data under section 1927(b)(3) of the Act. We noted in the CY 2025 PFS proposed rule (89 FR 61963) that the calculations for the rebate amount set forth in section 1860D–14B(b) of the Act contemplate use of AMP and unit data reported by manufacturers under section 1927 of the Act. Similarly, section 1860D–14B(d) of the Act indicates CMS should use, for purposes of carrying out the Medicare Part D Drug Inflation Rebate Program, information submitted by manufacturers under section 1927(b)(3) of the Act. Section 1927 requires manufacturers that participate in the Medicaid Drug Rebate Program (MDRP) to enter into agreements with the HHS Secretary and submit price and drug product information to CMS for each covered outpatient drug (COD), as defined in sections 1927(k)(2)–(4) of the Act and at § 447.502 of this title. Not every drug that satisfies the definition of a Part D rebatable drug may be marketed by a manufacturer that has an MDRP agreement in effect with the Secretary during the applicable period. Similarly, there may be limited instances in which a drug or biological satisfies the definition of a Part D rebatable drug but is not a COD under the MDRP. As a result, information may not be reported under section 1927(b)(3) of the Act for all Part D rebatable drugs, and thus may not be available to CMS for purposes of calculating Part D drug inflation rebates under section 1860D–14B of the Act. Said differently, in limited cases where a Part D rebatable drug is marketed by a manufacturer that does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act for the reasons noted, the manufacturer does not currently report information needed for CMS to be able to calculate Part D drug inflation rebates.

Due to this operational issue, we proposed at § 428.201(b) to codify the policy established in section 30.1 of the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would exclude from Part D drug inflation rebate calculations drugs and biologicals that meet the definition of a Part D rebatable drug but for which the manufacturer does not have an MDRP agreement in effect with the HHS Secretary under section 1927 of the Act at any point during the applicable period, or the Part D rebatable drug is one that does not meet the definition of a COD. We noted this would effectively exclude from rebate calculations Part D rebatable drugs for which there is missing AMP data for the entire duration of the applicable period for the sole reason that there were no quarters during that period in which the manufacturer was required to report AMP data for the drug or biological under section 1927(b)(3) of the Act. In either of these situations, we noted a manufacturer does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act and thus the information required to calculate Part D drug inflation rebates for these drugs is not available to CMS. If there were no quarters for which the manufacturer was required to report AMP under section 1927(b)(3) of the Act in the applicable period for a drug or biological that meets the definition of a Part D rebatable drug, we proposed CMS would exclude such drug or biological from Part D drug inflation rebate calculations. We also clarified that the proposed exclusion at § 428.201(b) relates only to the calculation of the rebate amount and does not affect the determination of whether a drug or biological meets the definition of a Part D rebatable drug. When performing the reconciliation described at § 428.401(d), we proposed that CMS would reexamine whether the manufacturer was required to report AMP for any part of the applicable period for the Part D rebatable drug; if at reconciliation the manufacturer was required to report AMP for any part of the applicable period, CMS would calculate a Part D rebate amount for this Part D rebatable drug. We stated in the CY 2025 PFS

[686] Medicaid Program Final Rule (0938–AU96), 85 FR 87,000, 87,039 (Dec. 31, 2020): *https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf.*

proposed rule (89 FR 61963) that CMS intends to monitor how these exclusions from the Part D drug inflation rebate calculation may impact manufacturer behavior and may revisit this exclusion in the future.

In the initial Medicare Part D Drug Inflation Rebate Guidance, we solicited comments on the proposed approach and alternative approaches. We stated in the proposed rule that we continued to be interested in comments on this topic and thus welcomed additional comments on this approach and alternative approaches—specifically, how CMS should address the situations in which the manufacturer of a Part D rebatable drug does not have an MDRP agreement in effect for any part of the applicable period or when a Part D rebatable drug may be excluded from the definition of a COD and manufacturers may not be required to report pricing and drug product information under section 1927(b)(3) of the Act.

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for the exclusion of drugs for which the manufacturer does not have an MDRP agreement in effect, including vaccines.

Response: We thank the commenter for their support.

Comment: One commenter recommended CMS consider a waiver process to exclude from Part D inflation rebate calculations a drug or biological that is essential to public health or that would cause economic hardship to the manufacturer, similar to the provisions included in the Prescription Drug User Fee Act.

Response: We thank the commenter for this recommendation and refer the commenter to the policies set forth in §§ 428.301, 428.302, and 428.303 and discussed later in this final rule regarding rebate reductions for certain Part D rebatable drugs currently in shortage, likely to be in shortage, or experiencing a severe supply chain disruption, as authorized under section 1860D–14B of the Act. In contrast to the Prescription Drug User Fee Act, which instructs FDA to waive or reduce certain user fees if, for example, such waiver or reduction is necessary to protect the public health or if the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,[687] section 1860D–14B of the Act does not expressly authorize CMS to waive or reduce inflation rebates in such circumstances.

After consideration of public comments, CMS is finalizing this policy as proposed at § 428.201(b).

iii. Calculation of the Per Unit Part D Drug Rebate Amount

To calculate the total rebate amount in accordance with § 428.201(a), we stated in the CY 2025 PFS proposed rule that CMS will first calculate the per unit Part D drug rebate amount as described at § 428.202. Consistent with the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed at § 428.202(a) that CMS will calculate the per unit Part D drug inflation rebate amount by determining the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount for such drug for the applicable period. We stated that to determine the per unit Part D inflation rebate amount for a Part D rebatable drug, CMS must calculate the AnMP for the drug, identify the payment amount benchmark period and calculate the benchmark period manufacturer price for the drug, identify the benchmark period CPI–U, and calculate the inflation-adjusted payment amount for the drug.

(1) Calculation of the AnMP for the Applicable Period

To determine the AnMP for a Part D rebatable drug and applicable period, we proposed at § 428.202(b) to codify the policy described in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would use the AMP reported by a manufacturer to the Medicaid Drug Programs system under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the applicable period, as well as the units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of the applicable period. The manufacturer-reported AMP units represent the total units of a drug sold by the manufacturer each month to retail community pharmacy and wholesaler purchasers as described under section 1927(k)(1)(A) of the Act. Manufacturers may include under certain circumstances non-retail community pharmacy sales units in the calculation of their AMPs for 5i drugs.[688]

As specified in section 1860D–14B(b)(2) of the Act, the AnMP for a Part D rebatable drug for an applicable period is equal to the sum of the products for each calendar quarter of the applicable period of: (1) the AMP for the Part D rebatable drug reported for the calendar quarter and (2) the total units of the Part D rebatable drug reported for the corresponding calendar quarter divided by the total units of the Part D rebatable drug reported for the 4 calendar quarters in the applicable period. We proposed the following formula to illustrate how CMS would calculate the AnMP for a Part D rebatable drug as at § 428.202(b):

(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly units for October calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly units for January calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly units for April calendar quarter *divided by* total units for 12-month applicable period) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly units for July calendar quarter *divided by* total units for 12-month applicable period)

At § 428.202(b)(2), we proposed that the first applicable period for a Part D rebatable drug will be the earliest applicable period that follows the payment amount benchmark period identified at § 428.202(c)(1) through (4). For a Part D rebatable drug first approved or licensed on or before October 1, 2021, with a payment amount benchmark period identified at § 428.202(c)(1), we proposed that the first applicable period will begin on October 1, 2022 and end on September 30, 2023. For a Part D rebatable drug first approved or licensed on or before October 1, 2021 with a payment amount benchmark period identified at § 428.202(c)(3), or a subsequently approved drug with a payment amount benchmark period identified at § 428.202(c)(2) or (4), we proposed that the first applicable period will begin on October 1 of the year following the payment amount benchmark period identified at § 428.202(c)(2) through (4). In the case of a Part D rebatable drug that was previously a selected drug as described at § 428.202(c)(5) for which the payment amount benchmark period is reset as the last calendar year of the price applicability period for such drug,

[687] FD&C Act Section 736(d).

[688] 5i drugs are CODs that are inhaled, infused, instilled, implanted, or injected. Manufacturers are instructed to calculate the AMP for 5i drugs that are not generally dispensed through a retail community pharmacy using the methodology described at § 447.504(d) and (e). Section 447.507(b)(1) provides that a 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC–9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

we proposed that the earliest applicable period that follows the reset payment amount benchmark period will begin on October 1 of the year following the payment amount benchmark period identified at § 428.202(c)(5). We stated in the CY 2025 PFS proposed rule that the date that CMS will use to determine when a drug is first approved or licensed is the FDA approval date that the manufacturer reports to the Medicaid Drug Programs system under section 1927(b)(3)(A)(v) of the Act.

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses:

Comment: One commenter agreed with CMS' proposal to define the first applicable period for subsequently approved drugs as ''the earliest applicable period that follows the payment amount benchmark period identified in proposed § 428.202(c)(1) through (4).'' This commenter stated this proposal aligns with the statute and recommended CMS finalize this policy as proposed.

Response: We thank this commenter for their support.

Comment: Two commenters opposed CMS calculating inflation rebates using AMP, noting that AMP may fluctuate even when list prices do not increase. One commenter stated that rebate calculations should be based on WAC rather than AMP. Another commenter suggested CMS should consider comparing changes in WAC with corresponding AMP changes to confirm the list prices did not increase prior to calculating a Part D drug rebate amount to help more accurately determine when a rebate should be assessed.

Response: We thank the commenters for expressing their concerns. Consistent with CMS' response on page 15 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS recognizes that there are certain circumstances in which AMP can fluctuate for reasons that that may be, at least to some degree, outside of the control of a manufacturer. Sections 1860D–14B(b)(2) and (4) of the Act specify that CMS shall use AMP data and units reported under section 1927 of the Act for the purpose of calculating the AnMP and benchmark period manufacturer price, respectively. Section 1860D–14B(d)(1) of the Act also requires that CMS use information submitted by manufacturers under section 1927(b)(3) of the Act. CMS is implementing these statutory criteria.

After consideration of comments received, we are finalizing this policy as proposed at § 428.202(b).

(2) Identification of the Payment Amount Benchmark Period

Consistent with section 1860D–14B(g)(3) of the Act and as described in sections 40.2.2 and 40.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed at § 428.202(c)(1) that for a drug first approved or licensed by the FDA on or before October 1, 2021, the payment amount benchmark period is the period beginning on January 1, 2021 and ending on September 30, 2021. For a subsequently approved drug, we proposed at § 428.202(c)(2) that the payment amount benchmark period would be the first calendar year beginning after the drug's first marketed date, as specified under section 1860D–14B(b)(5)(A) of the Act. To identify the payment amount benchmark period for a Part D rebatable drug, we proposed that CMS will use the FDA approval date or the first marketed date reported under section 1927(b)(3)(A)(v) of the Act, as applicable. As described below, we solicited comments on proposed and alternative policies for determining the payment amount benchmark period in certain instances where an NDC is missing reported AMP.

(a) Establish a Payment Amount Benchmark Period in Certain Instances of Missing AMP

As discussed in the CY 2025 PFS proposed rule, section 1860D–14B of the Act does not expressly address how CMS should calculate the benchmark period manufacturer price for a Part D rebatable drug when a manufacturer has not reported AMP during the payment amount benchmark period identified by statute. For example, as described in the revised Medicare Part D Drug Inflation Rebate Guidance, while section 1860D–14B(g)(3) of the Act contemplates that drugs first approved or licensed by the FDA on or before October 1, 2021, would have a payment amount benchmark period of January 1, 2021, through September 30, 2021, the statute does not address circumstances in which such drugs are not marketed until after October 1, 2021, and thus lack reported AMP from January 1, 2021, through September 30, 2021, to calculate the benchmark period manufacturer price. In response to comments, we stated in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance that Part D rebatable drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date and thus did not have AMP in the statutorily defined payment amount benchmark period (that is, January 1, 2021, through September 30, 2021) would be treated in the same manner as subsequently approved drugs for purposes of establishing the payment amount benchmark period, benchmark period CPI–U, first applicable period, and first applicable period CPI–U. In the revised guidance, we also stated that we intended to address this policy in future rulemaking and would solicit comments on this policy at that time.

As stated in the CY 2025 PFS proposed rule (89 FR 61964), based on further review, we observed that a number of NDC–9s of Part D rebatable drugs approved on or before October 1, 2021, do not have AMP reported in the period of January 1, 2021, through September 30, 2021, and a number of NDC–9s of subsequently approved drugs do not have AMP reported in the first calendar year beginning after the drug's first marketed date. To enable CMS to calculate the benchmark period manufacturer price and inflation rebate amounts for these NDC–9s, we proposed at § 428.202(c)(3) that for a Part D rebatable drug first approved or licensed on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act, we would identify the payment amount benchmark period as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP reported. Said differently, to identify the payment amount benchmark period for the purpose of calculating the benchmark period manufacturer price for a Part D rebatable drug first approved or licensed on or before October 1, 2021, CMS would first look to the period from January 1, 2021, to September 30, 2021 and if no AMP was reported under the MDRP for that 3-quarter period, CMS would then identify the payment amount benchmark period as the first calendar year no earlier than calendar year 2021 in which such drug has at least 1 quarter of AMP reported. Similarly, at § 428.202(c)(4), we proposed that for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act, the payment amount benchmark period would be the first calendar year in which such drug has at least 1 quarter of AMP reported. To identify the payment amount benchmark period for the purpose of calculating the benchmark period manufacturer price

for a subsequently approved drug, we would look to the first calendar year beginning after the drug's first marketed date and if no AMP was reported under the MDRP for such NDC–9 for that 4-quarter period, we would then identify the payment amount benchmark period as the first calendar year in which such drug has at least 1 quarter of AMP reported. We stated in the CY 2025 PFS proposed rule (89 FR 61965) that this approach (or the alternative approaches described below), if finalized, would replace the policy in the revised Medicare Part D Drug Inflation Rebate Guidance to treat Part D rebatable drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date in the same manner as subsequently approved drugs. At § 428.202(b)(2), we proposed the first applicable period for such drug would begin on October 1 of the year following the payment amount benchmark period identified under § 428.202(c)(3) or (4). We stated in the CY 2025 PFS proposed rule (89 FR 61965) that this policy would apply to Part D rebatable drugs first approved or licensed on or before October 1, 2021, drugs first approved or licensed on or before October 1, 2021, but not marketed until after that date, as well as subsequently approved drugs.

As an example of how CMS proposed to identify the payment amount benchmark period at § 428.202(c)(3), if a Part D rebatable drug that was first approved or licensed by the FDA on July 7, 2021 and has a first marketed date of September 15, 2021 does not have AMP reported in the period beginning January 1, 2021 and ending September 30, 2021, but does have AMP reported for the second calendar quarter of 2022, CMS would identify the payment amount benchmark period for such drug as calendar year 2022 (that is, January 1, 2022, through December 31, 2022). In this example, the benchmark period CPI–U would be the CPI–U for January 2022, the first applicable period would be the applicable period beginning October 1, 2023, and ending September 30, 2024, and the applicable period CPI–U would be the CPI–U for October 2023. Similarly, as an example of how CMS would identify the payment amount benchmark period as proposed at § 428.202(c)(4), if a subsequently approved drug with a first marketed date of December 15, 2021 does not have AMP reported for any quarters in calendar year 2022 (that is, the first calendar year after the drug's first marketed date) but does have AMP reported for the first calendar quarter of 2023, CMS would identify the payment amount benchmark period as calendar year 2023 (that is, January 1, 2023, through December 31, 2023). In this example, the benchmark period CPI–U would be the CPI–U for January 2023, the first applicable period for this drug would be the applicable period beginning October 1, 2024, and ending September 30, 2025, and the applicable period CPI–U would be the CPI–U for October 2024.

We solicited comments on this approach, as well as alternative approaches, as described below.

(b) Comment Solicitation on Alternatives Considered for Calculating the Benchmark Period Manufacturer Price When AMP Is Missing

As stated in the CY 2025 PFS proposed rule (89 FR 61965), CMS is aware that one reason why a manufacturer may not report AMP for any quarters of a payment amount benchmark period described at § 428.202(c)(1) or (2), as applicable, is that a manufacturer may acquire a Part D rebatable drug from another manufacturer and, due to that acquisition and the use of a new labeler code, obtain a new NDC–9 for that Part D rebatable drug. In this instance, the NDC–9 of the selling manufacturer and the NDC–9 of the buying manufacturer belong to the same dosage form and strength and therefore the same Part D rebatable drug. Although the buying manufacturer may not have AMP for the new NDC–9 to report to the Medicaid Drug Programs system for the Part D rebatable drug's payment amount benchmark period described at § 428.202(c)(1) or (2), the buying manufacturer is required under the MDRP to report for the new NDC–9 the base date AMP associated with the dosage form and strength to which the new NDC–9 belongs. This base date AMP is equal to the quarterly AMP that a manufacturer reports as described at § 447.509(a)(7)(ii)(B). There also may be instances outside of the acquisition context in which a new NDC–9 for an existing dosage form and strength is reported under the MDRP. To prevent a manufacturer from resetting the payment amount benchmark period and therefore the benchmark period manufacturer price by obtaining a new NDC–9 for the Part D rebatable drug, CMS stated in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance that it will use the benchmark period manufacturer price of the earliest NDC–9 of the Part D rebatable drug.

As explained in the CY 2025 PFS proposed rule (89 FR 61965), after further consideration of this policy and the data that are available to CMS in the Medicaid Drug Programs system, we do not believe that calculating the benchmark period manufacturer price using the 3 or 4 quarters, as applicable, of AMP reported in the payment amount benchmark period described at § 428.202(c)(1) or (2) of the earliest NDC–9 of the Part D rebatable drug is operationally feasible at this time. Although the buying manufacturer is required under the MDRP to report for the new NDC–9 the base date AMP associated with the earliest NDC–9 of the dosage form and strength, and to report the first marketed date associated with the earliest NDC–9 of the dosage form and strength as the first marketed date for the new NDC–9, the buying manufacturer is not required to report which NDC–9 was used to determine the base date AMP and first marketed date. We may therefore lack the information necessary to identify the earliest NDC–9 of the Part D rebatable drug for purposes of determining the benchmark period manufacturer price to be used in calculating the inflation rebate amount.

We stated in the CY 2025 PFS proposed rule (89 FR 61965) that we understand that statutory provisions at section 1860D–14B of the Act require that CMS establish the payment amount benchmark period at the dosage form and strength level, and that allowing manufacturers to reset the payment amount benchmark period for a new NDC–9 of an existing Part D rebatable drug may not fully align with this directive. Simultaneously, and as described in the CY 2025 PFS proposed rule (89 FR 61965–61967), we understand there may be a gap in the AMP data available to calculate the benchmark period manufacturer price at the dosage form and strength level for certain drugs. To enable CMS to calculate the benchmark period manufacturer price when a new NDC–9 of an existing Part D rebatable drug is reported under the MDRP and that NDC–9 lacks AMP data for the time period described at § 428.202(c)(1) or (2), we solicited comments on alternative policy options that are described in more detail below.

First, we solicited comments on a modified version of the policy described in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance. Under this modified policy, we proposed that if a new NDC–9 of an existing Part D rebatable drug is reported under the MDRP, CMS would calculate the benchmark period manufacturer price for such NDC–9 using the base date AMP reported by a manufacturer under section 1927(b)(3) of the Act for such Part D rebatable

drug, if such base date AMP was reported for a calendar quarter that overlaps with the time period described at § 428.202(c)(1) or (2), as applicable for that Part D rebatable drug. We believed this modified policy would be operationally feasible because CMS could calculate the benchmark period manufacturer price using the base date AMP that is reported with the new NDC–9; therefore, CMS would not need to identify the earliest NDC–9 of the Part D rebatable drug. Under this proposed policy, we stated CMS could only use the base date AMP to calculate the benchmark period manufacturer price if the base date AMP was associated with a calendar quarter that overlapped with the time period described at § 428.202(c)(1) or (2), as applicable for that Part D rebatable drug. We stated in the CY 2025 PFS proposed rule (89 FR 61966) that if we were to adopt this alternative approach, we would expect to operationalize it through conforming changes to proposed § 428.202(c) and other applicable proposed regulatory text. We also noted that if we were to finalize this alternative approach, CMS would be unable to use this approach to calculate the benchmark period manufacturer price in the case of a new NDC–9 of an existing Part D rebatable drug with base date AMP that does not overlap with the time period described at § 428.202(c)(1) or (2). In such instances, CMS would have to either establish a future payment amount benchmark period using an approach similar to that described at § 428.202(c)(3) and (4) or apply one of the other proposed alternative policies.

The second alternative we considered was to require manufacturers of Part D rebatable drugs to submit to CMS AMP data for the time period identified at § 428.202(c)(1) or (2) in cases where the manufacturer did not report AMP under section 1927(b)(3) of the Act for such period but AMP data are available either for the NDC–9 or for another NDC–9 within the same dosage form and strength. For example, if the quarter for which a manufacturer reports base date AMP for a new NDC–9 of an existing dosage form and strength does not overlap with the time period identified at § 428.202(c)(1) or (2), but the earliest NDC–9 of the dosage form and strength that served as the basis for the base date AMP has AMP data available during any quarter of that time period, we would require manufacturers to report such AMP data. For a Part D rebatable drug with a payment amount benchmark period identified at § 428.202(c)(1), a manufacturer would be required to submit to CMS AMP data for the calendar quarters in the period beginning January 1, 2021, and ending on September 30, 2021, to the extent such drug was first marketed before September 30, 2021. For a subsequently approved drug with a payment amount benchmark period identified under § 428.202(c)(2), a manufacturer would be required to submit to CMS AMP data for the first calendar year beginning after the drug's first marketed date. In the CY 2025 PFS proposed rule (89 FR 61966), we acknowledged the intersection between a potential reporting requirement under the Medicare Part D Drug Inflation Rebate Program for manufacturers to provide AMP data and existing AMP data reporting requirements for manufacturers under the MDRP.

We stated in the CY 2025 PFS proposed rule (89 FR 61966) that should we pursue this option, we would explore using existing AMP reporting processes for the MDRP to operationalize any new AMP reporting requirement. This approach of requiring manufacturers to report such information would be consistent with CMS' understanding of the provisions of section 1860D–14B of the Act requiring CMS to establish the payment amount benchmark period at the dosage form and strength level, and with CMS' authority under sections 1102(a) and 1871(a)(1) of the Act to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. We welcomed comments on the method by which CMS could collect such information, the timing of the potential collection and deadlines, and whether information reported by manufacturers should be taken into account for purposes of compiling the Rebate Reports for a Part D rebatable drug or instead only be included in the reconciliation processes specified in at § 428.401(d) and described later in this final rule.

We also considered a third alternative policy whereby CMS would calculate the benchmark period manufacturer price for a new NDC–9 of an existing Part D rebatable drug that lacks AMP data for the time period described at § 428.202(c)(1) or (2) using a reasonable proxy metric. We asked for comments on potential proxy metrics CMS could use to calculate the benchmark period manufacturer price for a new NDC–9 of an existing dosage form and strength for which no AMP data are reported for such periods.

As stated in the CY 2025 PFS proposed rule (89 FR 61966), these alternative policy options would be intended to achieve the same goal as the policy described in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance (that is, to disincentivize a manufacturer from resetting its payment amount benchmark period by obtaining a new NDC–9 for an existing Part D rebatable drug). Finally, we solicited comments on the policy described in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would treat drugs first approved or licensed on or before October 1, 2021, that were not marketed until after that date in the same manner as subsequently approved drugs for purposes of establishing the payment amount benchmark period, benchmark period CPI–U, first applicable period, and first applicable period CPI–U. We solicited comments on these alternatives and stated in the CY 2025 PFS proposed rule that we may adopt one or more of such alternatives in the final rule based on comments received. Additionally, we solicited comments on other policies that CMS should consider to prevent manufacturers from inappropriately resetting the payment amount benchmark period by obtaining a new NDC–9 for an existing Part D rebatable drug.

As stated in the CY 2025 PFS proposed rule (89 FR 61966), under CMS' proposed policy at §§ 428.202(c)(3) and (4) to identify a payment amount benchmark period in certain instances of missing AMP and each alternative considered, CMS would consider any restatements to the AMP data used to calculate the benchmark period manufacturer price during reconciliation, as specified at § 428.401(d) and described later in this final rule. Furthermore, we stated CMS would monitor the extent to which manufacturers obtain a new NDC–9 for the same Part D rebatable drug in a manner that could result in inappropriately resetting the payment amount benchmark period or otherwise affect the calculation of the benchmark period manufacturer price. We reminded manufacturers of their reporting obligations under section 1927(b) of the Act and § 447.510 of this title and that failure to provide timely information may result in penalties as detailed in section 1927(b)(3)(C)(i) of the Act.

We proposed that CMS would apply the policies described in the CY 2025 PFS proposed rule to rebate calculations beginning with the applicable period that began on October 1, 2022. As explained in the CY 2025 PFS proposed rule (89 FR 61967), CMS determined that, consistent with the policy described in section III.I.1. of this final

rule, in order to calculate inflation rebates for Part D rebatable drugs that do not have AMP or other pricing data available under section 1927(b)(3) of the Act on which to base the benchmark period manufacturer price, CMS' policy must apply for applicable periods beginning with the applicable period that began on October 1, 2022.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for CMS' proposal to establish a new payment amount benchmark period for drugs approved on or before October 1, 2021 when no AMP is reported for the period that begins on January 1, 2021 and ends on September 30, 2021. One commenter did not express support or opposition to CMS' proposal for establishing a payment amount benchmark period in certain instances of missing AMP but stated that to the extent CMS finalizes its proposed policy, the policy should apply prospectively only. This commenter asserted that the statute does not expressly permit retroactive regulations, nor does it permit CMS to revoke final guidance after the relevant applicable periods have concluded and that revoking established policies creates uncertainty in the Medicare Prescription Drug Inflation Rebate Program. This commenter also recommended CMS clarify whether it would consider a Part D rebatable drug to have ''at least 1 quarter of AMP reported'' if AMP was not reported for each month of a quarter (for example, if AMP is reported for November and December, but not October of a quarter).

Response: In this final rule, we are finalizing our proposal to apply the policies described at §§ 428.202(c)(3) and (4) to rebate calculations beginning with the applicable period that began on October 1, 2022. We are also finalizing at § 428.202(d)(3), with modifications to §§ 428.202(c)(3) and (4), the alternative for CMS to identify the payment amount benchmark period and calculate the benchmark period manufacturer price of a new NDC–9 of a Part D rebatable drug by using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period described in §§ 428.202(c)(1) or (2). We will also apply this alternative policy to rebate calculations beginning with the applicable period that began on October 1, 2022. If these policies were not applied to rebate calculations beginning with the applicable period that began on October 1, 2022, CMS would be unable to calculate a benchmark period manufacturer price for certain new NDC–9s of Part D rebatable drugs using the policy described in the revised Medicare Part D Drug Inflation Rebate Guidance since, as explained in the CY 2025 PFS proposed rule (89 FR 61768), the policy described in the revised guidance is not operationally feasible at this time. CMS also would not be able to calculate a benchmark period manufacturer price for other NDC–9s missing AMP data in the period described at §§ 428.202(c)(1) and (2). Without a benchmark period manufacturer price, CMS could not calculate Part D drug inflation rebates for these NDC–9s. We disagree with the commenter that the statute does not permit the application of this policy to rebate calculations beginning with the applicable period that began on October 1, 2022. As of this rulemaking, CMS has not yet performed rebate calculations or determined rebate liabilities for Part D rebatable drugs for any applicable period, including the applicable periods starting October 1, 2022 and October 1, 2023. The policy described herein will be used in the agency's future rebate calculations for those applicable periods and for subsequent applicable periods. To the extent the policy described herein is considered to apply retroactively for an applicable period, consistent with CMS's authority under section 1871(e)(1)(A) of the Act, CMS has determined that such retroactive application would be both necessary to implement the requirements of the IRA and in the public interest because it ensures that the regulations address the time periods and manufacturer pricing conduct addressed in the IRA. The statute directs CMS to perform various calculations involving pricing activities from prior periods for applicable periods ''beginning with October 1, 2022'' (per the definition in section 1860D–14B(g)(7) of the Act). With respect to Part D rebatable drugs, the time periods during which prices are subject to rebates began as early as several weeks after the statute's enactment. At the same time, the IRA specifically requires CMS to use program instruction to implement the Part D inflation rebate program for 2022, 2023, and 2024, contemplating that CMS would establish policies for prior periods in time. Further, the statutory provision expressly allowing the agency to delay the issuance of rebate reports for the applicable periods beginning October 1, 2022 and October 1, 2023 until 2025 contemplates CMS performing calculations for these prior periods.

With respect to the commenter's request for clarification regarding whether CMS would consider a Part D rebatable drug to have at least 1 quarter of AMP reported if AMP was not reported for each month of a quarter, we note that under section 1927(b)(3) of the Act, AMP is reported to the Medicaid Drug Programs system as a quarterly value while AMP units are reported as a monthly value. As such, we do not believe the scenario proposed by the commenter is applicable.

Comment: A few commenters expressed support for the first alternative proposed in the CY 2025 PFS proposed rule to calculate the payment amount benchmark period for an NDC–9 using base date AMP reported for the earliest NDC–9 of the Part D rebatable drug. One commenter stated that of the three alternative options proposed, the first alternative would be most preferred and suitable for CMS to accurately calculate the benchmark period manufacturer price in cases of missing AMP data. Another commenter stated that the first alternative is a reasonable approach but noted that it would not apply to cases where a base date AMP quarter does not happen to fall within the payment amount benchmark period. One commenter opposed this proposal, asserting this approach is inconsistent with the Part D drug inflation rebate statute, which does not permit CMS to base the payment amount benchmark period off the AMP reported by a different manufacturer for a different NDC–9.

Response: We thank the commenters for their feedback. We disagree with the commenter's assertion that our proposal to calculate the benchmark period manufacturer price of a new NDC–9 using the base date AMP reported for the earliest NDC–9 of the Part D rebatable drug is inconsistent with the Part D drug inflation rebate statute. The calculations for the rebate amount set forth in section 1860D–14B(b) of the Act contemplate use of AMP and unit data reported by manufacturers under section 1927(b)(3) of the Act. Similarly, section 1860D–14B(d) of the Act indicates CMS should use, for purposes of carrying out the Medicare Part D Drug Inflation Rebate Program, information submitted by manufacturers under section 1927(b)(3) of the Act, which includes base date AMP. As described in the CY 2025 PFS proposed rule (89 FR 61965), under the MDRP, if a manufacturer acquires a drug from another manufacturer and, due to that acquisition and the use of a new labeler code, obtains a new NDC–9 for the drug,

the NDC–9 of the selling manufacturer and the NDC–9 of the buying manufacturer belong to the same dosage form and strength and therefore the same Part D rebatable drug. The buying manufacturer is required by the MDRP under section 1927(b)(3) of the Act to report for the new NDC–9 the base date AMP associated with the dosage form and strength to which the new NDC–9 belongs. Consistent with CMS' statements in the CY 2025 PFS proposed rule regarding the potential alternative of requiring manufacturers to report AMP, the use of base date AMP described herein is consistent with CMS' understanding of the provisions of section 1860D–14B of the Act requiring CMS to establish the payment amount benchmark period at the dosage form and strength level and with CMS' authority under sections 1102(a) and 1871(a)(1) of the Act to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program.

In this final rule, we are finalizing at § 428.202(d)(3), with modifications to §§ 428.202(c)(3) and (4), the alternative proposed in the CY 2025 PFS proposed rule (89 FR 61966) for CMS to calculate the benchmark period manufacturer price of a new NDC–9 of an existing Part D rebatable drug by using other information reported by a manufacturer under the MDRP for such Part D rebatable drug as available, such as base date AMP, if such base date AMP was reported for a calendar quarter that overlaps with the time period described at § 428.202(c)(1) or (2). We agree with the commenter that this approach would not apply to cases where a base date AMP quarter does not overlap with the payment amount benchmark period described at § 428.202(c)(1) or (2) and as such, we are also finalizing at §§ 428.202(c)(3) and (4) our proposal to identify the payment amount benchmark period as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP data reported. As indicated in the CY 2025 PFS proposed rule, CMS will consider any restatements to the information used to identify the payment amount benchmark period and calculate the benchmark period manufacturer price during reconciliation, as set forth in § 428.401(d) and described later in this rule.

CMS also will monitor the extent to which manufacturers obtain a new NDC–9 for the same Part D rebatable drug in a manner that could result in inappropriately resetting the payment amount benchmark period or otherwise affect the calculation of the benchmark period manufacturer price. Consistent with the alternative considered and not finalized in this rulemaking, CMS continues to explore the potential for a new AMP reporting requirement in the future. We note that if CMS were to implement new AMP reporting requirements in future policymaking, CMS would likely explore an approach that would allow the agency to recalculate the benchmark period manufacturer price if a manufacturer reported AMP data for the period described at §§ 428.202(c)(1) or (2). That is, if CMS establishes the payment amount benchmark period for a drug as described at § 428.202(c)(3) or (4), as applicable, and CMS later obtains AMP data for the period described at § 428.202(c)(1) or (2) based on new AMP reporting requirements, CMS would likely explore recalculating the benchmark period manufacturer price based on the AMP data reported for the period described at § 428.202(c)(1) or (2). We believe such an approach could prevent manufacturers from inappropriately resetting the payment amount benchmark period by obtaining a new NDC–9 for an existing Part D rebatable drug.

Comment: One commenter stated that CMS does not address how it will determine the threshold issue of whether an NDC–9 represents a new NDC–9 of a Part D rebatable drug. This commenter noted that manufacturers participating in the MDRP already determine whether their products represent the same dosage form and strength of the same drug and where this is the case for a new NDC–9, the Medicaid ''Market Date'' in the Medicaid Drug Programs system will precede the ''Package Size Intro Date.'' This commenter recommended CMS rely on these existing manufacturer-provided fields and where such MDRP data are not available, CMS should develop a process by which manufacturers that do not participate in the MDRP can voluntarily self-identify that an NDC–9 is a new NDC–9 of an existing drug for purposes of calculating the benchmark period manufacturer price.

Response: We appreciate this commenter's feedback and recommendation. CMS agrees with the commenter that manufacturers participating in the MDRP determine whether their products represent the same dosage form and strength of the same drug, and CMS will use existing information reported by manufacturers under the MDRP to determine whether an NDC–9 represents a new NDC–9 of a Part D rebatable drug, where such data are available, consistent with § 428.202(d)(3). If a manufacturer does not participate in the MDRP and does not have an obligation to report pricing and drug product data under section 1927(b)(3) of the Act, the information required to calculate Part D drug inflation rebates for these drugs is not available to CMS, and CMS will not calculate Part D drug inflation rebates for these drugs at this time, as described at § 428.201(b). If the existing information reported by manufacturers participating in the MDRP indicates that an NDC–9 does represent a new NDC–9 of a Part D rebatable drug, but there are no quarters during the period set forth in § 428.202(c)(1) or (c)(2) for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in § 428.202(d)(3), CMS will apply the payment amount benchmark period identification policies finalized at § 428.202(c)(3) or (4), as applicable, at this time. As noted above, CMS is exploring the potential for a new AMP reporting requirement in the future.

Comment: A few commenters opposed the second alternative policy considered by CMS, which would require manufacturers of Part D rebatable drugs to submit to CMS AMP data for the payment amount benchmark period in cases where the manufacturer did not report AMP under the MDRP for such period, but AMP data are available either for the NDC–9 or for another NDC–9 within the same dosage form and strength. These commenters asserted CMS does not have authority to require reporting of AMP in the manner proposed. One commenter stated that this proposal raises confidentiality concerns and that if CMS were to move forward with this proposal, CMS should confirm that the same confidentiality provisions of the Medicaid rebate statute would apply to reporting of AMP data for the Part D rebate program.

Response: We thank these commenters for sharing their concerns regarding a new AMP reporting requirement. We are not finalizing this alternative at this time. Instead, we are finalizing our proposal to apply the policies described at §§ 428.202(c)(3) and (4) to rebate calculations beginning with the applicable period that began on October 1, 2022. We are also finalizing at § 428.202(d)(3), with modifications to §§ 428.202(c)(3) and (4), the alternative proposed in the CY 2025 PFS proposed rule for CMS to calculate the benchmark period manufacturer price of a new NDC–9 of an existing Part D rebatable drug by using the base date AMP reported under the MDRP for such Part D rebatable drug and will apply this

policy to rebate calculations beginning with the applicable period that began on October 1, 2022. As indicated in the CY 2025 PFS proposed rule, and as discussed above, CMS will monitor the extent to which manufacturers obtain a new NDC–9 for the same Part D rebatable drug in a manner that could result in inappropriately resetting the payment amount benchmark period or otherwise affect the calculation of the benchmark period manufacturer price. CMS also is exploring the potential for a new AMP reporting requirement in the future, consistent with the alternative considered and not finalized in this rulemaking. We note that if CMS were to implement new AMP reporting requirements in future policymaking, CMS would likely explore an approach that would allow the agency to recalculate the benchmark period manufacturer price if a manufacturer reported AMP data for the period described at § 428.202(c)(1) or (2), as discussed above. CMS will also consider any restatements to the information used to identify the payment amount benchmark period and calculate the benchmark period manufacturer price during reconciliation, as set forth in § 428.401(d) and described later in this rule.

Comment: A few commenters stated CMS did not provide sufficient detail regarding the third alternative considered to use a reasonable proxy metric for interested parties to meaningfully comment. These commenters recommended CMS not move forward with the third alternative until CMS has put forth a specific proxy metric in rulemaking and sought public comment on a specific proposal. In response to CMS' request for potential proxy metrics that could be used for purposes of calculating the benchmark period manufacturer price, a couple of commenters recommended WAC since it is a publicly available metric. One commenter recommended that in the acquisition context, CMS use as a reasonable proxy metric the AnMP for the first full calendar year after a buyer acquires and first markets the drug under the NDC–9.

Response: We appreciate the commenters sharing this feedback. At this time, we are not moving forward with the alternative proposal to use a reasonable proxy metric for purposes of calculating the benchmark period manufacturer price.

After consideration of public comments, we are finalizing at §§ 428.202(c)(3) and (4) the proposal to identify the payment amount benchmark period for NDC–9s of Part D rebatable drugs missing reported AMP as the first calendar year, which would be no earlier than calendar year 2021, in which such NDC–9 has at least 1 quarter of AMP reported. We are also finalizing at § 428.202(d)(3), with modifications to §§ 428.202(c)(3) and (4), the first alternative policy described in the CY 2025 PFS proposed rule (89 FR 61966) to calculate the benchmark period manufacturer price for a new NDC–9 of a Part D rebatable drug using information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, including base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period described at § 428.202(c)(1) or (2). In such circumstances, the new NDC–9 would not be subject to payment amount benchmark period identification as described in § 428.202(c)(3) or (4). These policies will apply to rebate calculations beginning with the applicable period that began on October 1, 2022.

(c) Identification of the Payment Amount Benchmark Period for a Part D Rebatable Drug No Longer Considered To Be a Selected Drug

At § 428.202(c)(5), we proposed to codify policies described in section 40.2.2 of the revised Medicare Part D Drug Inflation Rebate Guidance relating to the identification of the payment amount benchmark period for a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act) in the case such Part D rebatable drug is no longer considered to be a selected drug. As stated in the CY 2025 PFS proposed rule (89 FR 61968), the Medicare Part D Drug Inflation Rebate Program applies to selected drugs notwithstanding the status of the drug as a selected drug. However, the calculation of certain components of the rebate amount formula for selected drugs depends upon whether the selected drug has reached the end of its price applicability period and is no longer considered to be a selected drug under section 1192(c) of the Act. Specifically, section 1860D–14B(b)(5)(C) of the Act specifies a different payment amount benchmark period and benchmark period CPI–U for a Part D rebatable drug in the case such drug is no longer considered to be a selected drug under section 1192(c) of the Act, for each applicable period beginning after the price applicability period with respect to such drug. Accordingly, in such a case where a Part D rebatable drug is no longer a selected drug, we proposed at § 428.202(c)(5) that the payment amount benchmark period will be reset as the last calendar year of such price applicability period for such selected drug.

We did not receive any comments on this proposed provision, and we are finalizing as proposed at § 428.202(c)(5).

(3) Calculation of the Benchmark Period Manufacturer Price

We proposed at § 428.202(d) that, subject to § 428.202(g), to determine the benchmark period manufacturer price for a Part D rebatable drug, CMS will use the AMP reported by a manufacturer to the Medicaid Drug Programs system under sections 1927(b)(3)(A)(i) and (ii) of the Act for each calendar quarter of the payment amount benchmark period, as identified in accordance with § 428.202(c), as well as the units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of such payment amount benchmark period. For a Part D rebatable drug first approved or licensed on or before October 1, 2021, section 1860D–14B(b)(4) of the Act specifies that the benchmark period manufacturer price is the sum of the products for each calendar quarter of the payment amount benchmark period (that is, January 1, 2021, through September 30, 2021) of (1) the AMP for the Part D rebatable drug reported for the calendar quarter), and (2) the total units reported for the corresponding calendar quarters divided by the total units of the Part D rebatable drug reported for the 3 calendar quarters in the payment amount benchmark period. We proposed at § 428.202(d)(1) the following formula to illustrate how CMS will calculate the benchmark period manufacturer price for a Part D rebatable drug with a payment amount benchmark period identified at § 428.202(c)(1):

(AMP for calendar quarter beginning January 2021) *multiplied by* (sum of monthly AMP units for January 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period) +
(AMP for calendar quarter beginning April 2021) *multiplied by* (sum of monthly AMP units for April 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period) +
(AMP for calendar quarter beginning July 2021) *multiplied by* (sum of monthly AMP units for July 2021 calendar quarter *divided by* sum of the units reported for the 3 quarters of the payment amount benchmark period)

For a Part D rebatable drug with a payment amount benchmark period identified at § 428.202(c)(2) through (5), we proposed the following formula at § 428.202(d)(2) to illustrate how CMS will calculate the benchmark period

manufacturer price for a Part D rebatable drug:

(AMP for calendar quarter beginning January) *multiplied by* (sum of monthly AMP units for January calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +
(AMP for calendar quarter beginning April) *multiplied by* (sum of monthly AMP units for April calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +
(AMP for calendar quarter beginning July) *multiplied by* (sum of monthly AMP units for July calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period) +
(AMP for calendar quarter beginning October) *multiplied by* (sum of monthly AMP units for October calendar quarter *divided by* sum of the monthly units reported for the 4 quarters of the payment amount benchmark period)

CMS received public comments in response to the comment solicitation in the CY 2025 PFS proposed rule on alternatives considered for calculating the benchmark period manufacturer price when AMP is missing (89 FR 61965–61967). As described earlier in this final rule, after consideration of comments received, we revised § 428.202(d) to add a paragraph (3), which provides that to the extent that a new NDC–9 of a Part D rebatable drug is reported under section 1927 of the Act and AMP has not been reported for such NDC–9 under section 1927(b)(3)(A)(i)(I) or (ii) of the Act during the period described § 428.202(c)(1) or (2), as applicable, CMS will identify the payment amount benchmark period and calculate the benchmark period manufacturer price for such NDC–9 using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period described at § 428.202(c)(1) or (2), as applicable. Base date AMP has the meaning set forth at § 447.509(a)(7)(ii)(B) of this title.

(4) Identification of the Benchmark Period CPI–U

To calculate the inflation-adjusted payment amount in accordance with section 1860D–14B(b)(3) of the Act, CMS must identify the benchmark period CPI–U. As described in the revised Medicare Part D Drug Inflation Rebate Guidance and in accordance with section 1860D–14B(g)(4) of the Act, we proposed at § 428.202(e)(1) that the benchmark period CPI–U for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, would be the CPI–U for January 2021. For a subsequently approved drug, we proposed at § 428.202(e)(2) that the benchmark period CPI–U will be the CPI–U for January of the first calendar year beginning after the drug's first marketed date, as required under section 1860D–14B(b)(5)(A) of the Act.

As stated in the CY 2025 PFS proposed rule (89 FR 61964), we have observed that a number of NDC–9s of Part D rebatable drugs approved or licensed on or before October 1, 2021, do not have AMP reported in the period beginning January 1, 2021, and ending September 30, 2021, and a number of NDC–9s of subsequently approved drugs do not have AMP reported in the first calendar year following the drug's first marketed date. To enable CMS to calculate the benchmark period manufacturer price and inflation rebate amounts for these NDC–9s, we proposed at § 428.202(c)(3) and (4) to identify the payment amount benchmark period for such NDC–9s as the first calendar year, which would be no earlier than calendar year 2021, in which such drug has at least 1 quarter of AMP data reported. As previously discussed, we solicited comments on alternative methodologies to identify the payment amount benchmark period and calculate the benchmark period manufacturer price to address certain instances in which AMP has not been reported. To identify the benchmark period CPI–U for an NDC–9 described at § 428.202(c)(3), we further proposed at § 428.202(e)(3) that for a Part D rebatable drug first approved on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under the MDRP, the benchmark period CPI–U will be the CPI–U for January of the calendar year in which such drug has at least 1 quarter of AMP reported. We proposed at § 428.202(e)(4) that for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under the MDRP, the benchmark period CPI–U is the CPI–U for January of the calendar year in which such drug has at least 1 quarter of AMP reported.

As discussed previously, the Medicare Part D Drug Inflation Rebate Program applies to selected drugs notwithstanding the status of the drug as a selected drug. However, the calculation of certain components of the applicable rebate amount formula for selected drugs depends upon whether the selected drug has reached the end of its price applicability period and is no longer considered to be a selected drug under section 1192(c) of the Act. In accordance with section 1860D–14B(b)(5)(C) of the Act, in such a case where a Part D rebatable drug is no longer a selected drug, we proposed at § 428.202(e)(5) that the benchmark period CPI–U will be the CPI–U for January of the last calendar year of such price applicability period.

While we received public comments on CMS' proposed and alternative policies, as discussed above, we did not receive comments on CMS' further proposals specific to the benchmark period CPI–U. Nevertheless, as described in more detail in section III.I.3.c.iii.2. of this final rule, we have revised § 428.202(d) to add a paragraph (3), which provides that to the extent that a new NDC–9 of a Part D rebatable drug is reported under section 1927 of the Act and AMP has not been reported for such NDC–9 under section 1927(b)(3)(A)(i)(I) or (ii) of the Act during the period described at § 428.202(c)(1) or (2), as applicable, CMS will identify the payment amount benchmark period and calculate the benchmark period manufacturer price for such NDC–9 using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period described at § 428.202(c)(1) or (2), as applicable. Therefore, in this final rule, we have modified proposed § 428.202(e)(3) and (4) to specify that a Part D rebatable drug for which no AMP has been reported under section 1927(b)(3) of the Act includes a Part D rebatable drug for which no information as described at § 428.202(d)(3) has been reported.

(5) Calculation of the Inflation-Adjusted Payment Amount

As specified in section 1860D–14B(b)(3) of the Act and described in section 40.2.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, the inflation-adjusted payment amount with respect to a Part D rebatable drug and applicable period is the benchmark period manufacturer price increased by the percentage by which the applicable period CPI–U exceeds the benchmark period CPI–U. We proposed at § 428.202(f) to calculate the inflation-adjusted payment amount for a Part D rebatable drug by dividing the applicable period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the benchmark period manufacturer price.

We proposed the following formula at § 428.202(f) to illustrate how CMS will calculate the inflation-adjusted payment amount for a Part D rebatable drug:

(Benchmark period manufacturer price) *multiplied by* (applicable period CPI–U *divided by* benchmark period CPI–U).

We proposed at § 428.202(a) that CMS will use the inflation-adjusted payment amount to calculate the per unit Part D drug inflation rebate amount by determining the amount by which the AnMP for a Part D rebatable drug exceeds the inflation-adjusted payment amount for a Part D rebatable drug for an applicable period.

We did not receive comments on this proposed provision, and we are finalizing as proposed at § 428.202(f).

(6) Situations in Which Manufacturers Do Not Report Units Under Section 1927(b)(3)(A)(iv) of the Act

Section 1860D–14B of the Act generally requires CMS to determine the per unit Part D drug inflation rebate amount using the monthly units reported by manufacturers to the Medicaid Drug Programs system under section 1927(b)(3)(A)(iv) of the Act. We understand it is possible that a manufacturer may not have sales or monthly units of a COD to report to the Medicaid Drug Programs system for a calendar quarter because, for example, there may be a temporary interruption in sales of the COD, or there may be no sales immediately after the drug is first approved or licensed by the FDA. We proposed at § 428.202(g)(1) to codify the policy described in section 40.1.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, whereby in cases where there are 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i) and (ii) of the Act, CMS would calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units. That is, quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act would be excluded from the calculation. We proposed at § 428.202(g)(2) to codify the policy described in section 40.1.2 of the revised guidance whereby if there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, but the manufacturer has reported AMP under sections 1927(b)(3)(A)(i) and (ii) of the Act for at least 1 quarter of such period, CMS would use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

We did not receive any comments on this proposed provision, and we are finalizing as proposed at § 428.202(g). Nevertheless, as described in more detail in section III.I.3.c.iii.2. of this final rule, we have revised § 428.202(d) to add a paragraph (3), which provides that to the extent that a new NDC–9 of a Part D rebatable drug is reported under section 1927 of the Act and AMP has not been reported for such NDC–9 under section 1927(b)(3)(A)(i)(I) or (ii) of the Act during the period described at § 428.202(c)(1) or (2), as applicable, CMS will identify the payment amount benchmark period and calculate the benchmark period manufacturer price for such NDC–9 using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period described at § 428.202(c)(1) or (2), as available. Therefore, in this final rule, we have modified proposed § 428.202(g)(2) to specify that if there are no quarters of the payment amount benchmark period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, and § 428.202(d)(3) applies, CMS will use the information determined under § 428.202(d)(3) to calculate the benchmark period manufacturer price.

iv. Determination of the Total Number of Units Dispensed Under Part D

At § 428.203(a), we proposed to codify the existing policy established in the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D sponsors based on information reported to CMS by Part D plan sponsors on the Part D PDE records for the 12-month applicable period. More specifically, we proposed CMS would determine the total number of units from the Quantity Dispensed field on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero. Because the PDE record does not provide the unit type used to determine Quantity Dispensed, we proposed at § 428.203(a)(2) that CMS would crosswalk the information from the PDE record to a drug database that provides the unit type for an NDC, such as Medi-Span or the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Element (NSDE) file, matching on the NDC of the Part D rebatable drug. We understand that in limited instances, the unit type obtained from such drug databases may not match the AMP unit type reported by manufacturers to the Medicaid Drug Programs system, and in these cases, CMS would convert the total units reported on the PDE record to the AMP units reported to the Medicaid Drug Program system.

As explained in the CY 2025 PFS proposed rule (89 FR 61968–61969), CMS conducts a thorough review of PDE records, which includes the identification of outliers in the quantity dispensed field of PDE records, as part of the Part D payment reconciliation process that occurs between CMS and plan sponsors each year.[689] We stated in the CY 2025 PFS proposed rule that CMS intends to rely on this payment reconciliation process, through which Part D plan sponsors have an opportunity to correct PDE records flagged by CMS as containing potential outliers, to resolve outliers that would otherwise impact the Part D drug inflation rebate amount calculated under § 428.201(a). Because PDE records are not updated to reflect the resolution of outliers identified through the Part D payment reconciliation process for a given calendar year until after CMS plans to send Rebate Reports for the applicable period (capturing data that include the first three quarters of that calendar year), the Rebate Report will not reflect the resolution of unit outliers identified through the Part D payment reconciliation process. However, because CMS intends to conduct a reconciliation of the rebate amount with additional PDE run-out (as set forth in § 428.401(d) and described later in this final rule), the reconciled rebate amounts will reflect the resolution of any unit outliers corrected by Part D plan sponsors through the Part D payment reconciliation process. As stated in the CY 2025 PFS proposed rule (89 FR 61969), we do not intend to conduct separate outlier analysis of PDE for the purposes of the Medicare Part D Drug Inflation Rebate Program, but we did consider several adjustments to reduce the effect of outliers not resolved through the Part D payment reconciliation process, including

[689] See *https://www.hhs.gov/guidance/document/pde-analysis-process-withheld-and-invoiced-outlier-pdes.*

removal of PDE records that were identified by CMS as having potential outlier quantity dispensed fields but were neither corrected nor verified by Part D plan sponsors, removal of the quantity dispensed field for certain records at or above a certain statistically derived threshold, and imputing quantity dispensed values for such records. We solicited comments on this proposed approach to rely on CMS' existing review of PDE records, as well as on the adjustments considered to reduce the effect of outliers not resolved through the Part D payment reconciliation process.

As we proposed at § 428.203(b), CMS will remove from the total number of units any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug, as well as units acquired through the 340B Program, as described in section III.I.3.c.iv.2. of this final rule.

We received public comments on this proposed provision. We also solicited comments on any additional units that should be excluded from the rebate amount calculation. The following is a summary of the comments we received on these proposals and this comment solicitation and our responses.

Comment: One commenter stated that CMS has not provided sufficient detail to meaningfully comment on CMS' process for eliminating outliers in PDE data not resolved through the Part D reconciliation process. This commenter suggested CMS publish a second proposed rule containing concrete policy proposals for comment.

Response: We appreciate the comment. To meet the invoicing timelines of the Medicare Part D Drug Inflation Rebate Program, we are finalizing the approach described in the CY 2025 PFS proposed rule (89 FR 61968–61969) whereby CMS will rely on the Part D payment reconciliation process that occurs between CMS and plan sponsors each year to resolve outliers that would otherwise impact the Part D drug inflation rebate amount calculated at § 428.201(a). At this time, CMS will not perform additional adjustments to reduce the effect of outliers not resolved through the Part D payment reconciliation process. We believe relying on the Part D payment reconciliation process that occurs between CMS and plan sponsors each year is sufficient to resolve unit outliers for purposes of the Medicare Part D Drug Inflation Rebate Program and results in consistency across the Part D program. If in the future CMS determines that outliers not resolved through the Part D payment reconciliation process should be addressed for purposes of the Medicare Part D Drug Inflation Rebate Program, CMS may consider adjustments to reduce the effect of these outliers and would solicit comments on such adjustments at that time.

Comment: One commenter recommended CMS also exclude from the rebate amount calculation units from other federal programs such as units purchased under the Federal Supply Schedule, as these units already have statutory discounts.

Response: We appreciate the comment. In response to the request that CMS exclude from the rebate calculation units from other federal programs, section 1860D–14B(b) of the Act prescribes that the total number of units is based on the number of units for each Part D rebatable drug dispensed under Part D during the applicable period, excluding units of Part D rebatable drugs with respect to which the manufacturer provides a discount under the 340B Program. In addition, CMS will exclude units when a drug is no longer a Part D rebatable drug. CMS declines to adopt the commenter's recommendation to exclude units from other federal programs, such as units purchased under the Federal Supply Schedule.

Additionally, CMS is aware that a PDE record for a Part D rebatable drug that was billed as a compound would reflect the quantity dispensed of the compounded drug product as a whole and not the Part D rebatable drug individually. To ensure that the total number of units is determined only using PDE records that accurately reflect the actual quantity dispensed of the Part D rebatable drug, we are finalizing at § 428.203(b)(3) that, for operational reasons at this time, CMS will exclude PDE records for Part D rebatable drugs that were billed as compounds when determining the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D sponsors. Specifically, to determine the total number of units of a Part D rebatable drug, CMS will only use PDE records with a compound code indicating that the PDE record is not a compound (that is, PDE records with a compound code field equal to ''1=Not a Compound''). For alignment, CMS has also finalized at § 428.101(b)(1) that, when calculating the gross covered prescription drug costs for a drug or biological for the purpose of calculating the average annual total cost for that drug or biological, CMS will exclude PDE records indicating the drug or biological was billed as a compound.

CMS is exploring operational changes to the PDE record layout that would provide CMS with visibility into data on the quantity dispensed for a Part D rebatable drug when that Part D rebatable drug is billed as part of a compound, at which point such PDE records may be used to allow for inclusion in calculating the total number of units dispensed under Part D. These operational changes may also facilitate the inclusion of PDE records for drugs or biologicals that are billed as compounds in CMS' calculation of the gross covered prescription drug costs for a drug or biological for the purpose of calculating the average annual total cost for that drug or biological.

After consideration of comments received, CMS is finalizing § 428.203(b) as proposed, with an additional provision at § 428.203(b)(3) to specify that CMS will exclude units from the total number of units dispensed of a Part D rebatable drug when those units are associated with a Part D rebatable drug that has been billed as compounded.

(1) Removal of Units When a Generic Drug Is No Longer a Part D Rebatable Drug

At § 428.203(b)(1), we proposed to codify the policy established in section 40.2.8 of the revised Medicare Part D Drug Inflation Rebate Guidance to exclude from the rebate calculation any units of a generic drug dispensed on or after the date that such generic drug no longer meets the definition of a Part D rebatable drug. To determine whether a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period ceases to meet such definition later in the applicable period, we proposed that CMS will use the most recent version of the downloadable FDA Orange Book to identify whether FDA has approved a 505(j) ANDA for a drug that is rated as therapeutically equivalent to such generic drug. If CMS determines that FDA has approved such a therapeutically equivalent drug under a 505(j) ANDA, CMS will then use the NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by FDA or published on the FDA website to determine the marketing status of such therapeutically equivalent drug and to determine whether, during the applicable period, the therapeutically equivalent drug was marketed. Similarly, we proposed CMS will use the NDC Directory to identify whether the reference listed drug, or an authorized generic of the reference listed drug was marketed during the

applicable period. CMS will exclude from the rebate calculation any units dispensed on or after the first day of the calendar month that a generic drug no longer meets the definition of a Part D rebatable drug. CMS proposed to apply this unit exclusion at the month level and would exclude all units of a generic drug that ceases to meet the definition of a Part D rebatable drug beginning with the first day of the first month when a therapeutically equivalent drug approved under a 505(j) ANDA is marketed based on the marketing start date in the NDC Directory or when the reference listed drug, or an authorized generic of the reference listed drug is marketed based on the marketing start date in the NDC Directory. We proposed to apply this exclusion each calendar month because the Orange Book downloadable data files are updated monthly.

We did not receive public comments on this proposed provision, and we are finalizing as proposed at § 428.203(b)(1).

(2) Exclusion of 340B Acquired Units From Part D Rebatable Drug Requirements

Section 1860D–14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units would only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

As we stated in the CY 2025 PFS proposed rule (89 FR 61969), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable under the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and CMS does not currently have access to this data through other means. CMS understands that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter ''covered entities'') typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, CMS is unable to identify 340B units at the claim-level at this time. For these reasons, CMS proposed to establish an estimation methodology to remove 340B units from the total number of units for a Part D rebatable drug, as described in this section. CMS also solicited comments on alternative approaches.

(a) Estimation Methodology To Remove 340B Units From Rebate Calculations

To fulfill the statutory requirement to remove 340B units from rebate calculations beginning on January 1, 2026, we proposed at § 428.203(b)(2) a new policy to remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. We proposed the percentage (hereinafter, ''estimation percentage'') to equal the total number of units purchased by covered entities under the 340B Program for an NDC–9, divided by the total units sold of that NDC–9. We proposed the following example calculation for a Part D rebatable drug for a given applicable period for illustrative purposes:

Total number of units dispensed under Part D determined at § 428.203(a), minus the units determined at § 428.203(b)(1): 1,000.

Estimation percentage:

Total number of units purchased by covered entities under the 340B Program: 5,000.

Total units sold: 50,000.

5,000 *divided by* 50,000 = 10 percent.

340B units excluded at § 428.203(b)(2): 10 percent *multiplied by* 1,000 = 100.

The proposed estimation policy is consistent with CMS' authority under sections 1860D–14B(b)(1)(B), 1102(a), and 1871(a)(1) of the Act, the latter of which provide the authority to make rules and regulations as necessary for the efficient administration of programs, including the Medicare Part D Drug Inflation Rebate Program. Because the statutory requirement to remove 340B units from rebate calculations does not begin until January 1, 2026, for the applicable year that begins on October 1, 2025, we proposed to apply the estimation percentage only to those units associated with claims with dates of service in the last 3 quarters of the applicable period (that is, January 1, 2026, through September 30, 2026).

To identify the numerator of the estimation percentage (that is, the total number of units purchased under the 340B Program for an NDC–9), we proposed to use data from HRSA's 340B Prime Vendor Program (PVP). Certain supply chain entities report 340B unit data to the PVP at the NDC–11 level, and based on the data received, we proposed to aggregate these data at the NDC–9 level [690] to identify the total number of 340B units of a Part D rebatable drug that covered entities purchased in a given time period. We proposed that CMS would work with HRSA to obtain the necessary data from the PVP. We described in the CY 2025 PFS proposed rule (89 FR 61970) that we understand that there are limitations of using the PVP data, including that some covered entities may choose not to participate in the PVP, and CMS will not have access to 340B purchases reported by supply chain entities for this share of covered entities. Further, certain 340B purchases may not be reported to the PVP if those purchases were made through alternative distribution models such as a covered entity purchasing directly from a manufacturer, certain specialty distribution channel purchases, or drugs that receive a 340B rebate under the Ryan White HIV/AIDS Program's AIDS Drug Assistance Program. We solicited comments on what other data sources may be available to calculate the numerator of the estimation percentage. We also solicited comments on how it could account for potential underreporting of 340B units if data are not available on certain 340B purchases, such as those described above, that may not be reported to the PVP.

To identify the denominator of the estimation percentage (that is, the total units sold of an NDC–9), we proposed to use existing manufacturer reporting under the Medicaid Drug Rebate Program (MDRP) of unit sales. Specifically, we proposed to use the total number of units that are used to calculate the monthly AMP and which manufacturers are required to report to CMS for each covered outpatient drug (COD) in accordance with section 1927(b)(3)(A)(iv) of the Act. We believed that using these unit data to calculate an estimation percentage would be consistent with the use of these same data to calculate the AnMP at § 428.202(b) and the benchmark period manufacturer price at § 428.202(d).

In the CY 2025 PFS proposed rule (89 FR 61970), we stated that we recognize the importance of ensuring that the numerator and denominator of the proposed estimation percentage reflect the same time period of sales for units dispensed in the same settings. We also acknowledged in the proposed rule that

[690] NDC–9 and NDC–11 numbers are identical except for two numbers in NDC–11s that indicate package size. Because of this, NDC–11 is more granular than NDC–9, and multiple NDC–11 numbers can aggregate under a single NDC–9 number.

the proposed data source for the numerator (PVP data) reflects purchases by covered entities that dispense or administer 340B-eligible drugs in retail community pharmacies and in outpatient settings. The proposed data source for the denominator (unit sales used to calculate AMP) represents, in accordance with the definition of AMP at section 1927(k)(1) of the Act, (1) manufacturer sales to wholesalers for drugs distributed to retail community pharmacies, and (2) manufacturer sales to retail community pharmacies that purchase drugs directly from the manufacturer. Therefore, the numerator of the proposed estimation percentage represents 340B units dispensed in multiple settings, whereas the denominator represents units typically dispensed only in the retail community pharmacy setting. We welcomed evidence demonstrating how 340B dispensing rates differ between the retail community pharmacy setting versus multiple settings and may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed in multiple settings (that is, retail community pharmacies and outpatient settings) and the percentage of 340B units dispensed in only the retail community pharmacy setting. We stated that the proposed regulatory text at § 428.203(b)(2) would be subject to any such adjustment factor that may be adopted.

We also recognized that the proposed estimation percentage represents the total number of 340B units dispensed as a proportion of total units dispensed, irrespective of insurance/payor type. We solicited comments on whether the agency should further adjust the percentage of 340B units dispensed to the general population to estimate the percentage of 340B units dispensed to Part D beneficiaries for claims with dates of service on or after January 1, 2026, including comments on how the percentage of 340B units dispensed to the general population compares with the percentage of 340B units dispensed to Part D beneficiaries. We welcomed evidence that demonstrates how these percentages differ. We noted that CMS would consider this information in developing its final policies and may consider adjusting the estimation percentage to reflect variation between the percentage of 340B units dispensed to Part D beneficiaries and the percentage of 340B units dispensed to the general population. We stated that the proposed regulatory text at § 428.203(b)(2) would be subject to any such adjustment factor that may be adopted. We solicited comments on whether there are other circumstances for which CMS should apply an adjustment factor to the estimation percentage.

We considered using alternative data sources to calculate the estimation percentage. To identify the total number of units purchased under the 340B Program to use in the numerator of the estimation percentage, CMS considered requiring other entities throughout the pharmaceutical supply chain, including manufacturers, to report these data to CMS. We noted that an advantage of this approach is that manufacturers could provide data directly on total 340B units sold; in other words, this data would capture the limited 340B sales that the PVP data does not capture. A disadvantage of this approach is that not all manufacturers of Part D rebatable drugs may have existing mechanisms for tracking 340B sales for Medicare Part D, which could necessitate that new tracking and reporting mechanisms be created. We did not propose this alternative because we preferred to rely on data that are already reported to the PVP, as using these data would help to minimize reporting burdens and may result in cleaner and more accurate data due to the quality checks performed on the PVP data for purposes of compliance with the 340B Program. For example, audit and price integrity checks are performed on the PVP data to ensure the distributors submit and code the data correctly.

To identify the total units sold to use in the denominator of the estimation percentage, we similarly considered establishing a new requirement for other entities throughout the pharmaceutical supply chain, including manufacturers, to report these data to CMS. We noted that an advantage of this approach is that the denominator would represent sales that are ultimately dispensed in retail community pharmacy settings and in outpatient settings (whereas, as mentioned previously, unit reporting under the MDRP represents units typically dispensed only in the retail community pharmacy setting). A disadvantage of this approach is that it could necessitate that new tracking and reporting mechanisms be created. We did not propose this alternative as we believed that relying upon existing manufacturer reporting of unit sales reported with AMP under the MDRP would be preferable to a new reporting option and would help minimize reporting burden. Further, the use of unit sales reported with AMP may provide cleaner and more accurate data than establishing a new manufacturer reporting requirement since manufacturers must certify their AMP reporting, in accordance with § 447.510(e), and are subject to civil money penalties for false or inaccurate reporting, in accordance with section 1927(b)(3)(B) of the Act. We also considered using data on unit sales available in a nationally representative and commercially available database, but one disadvantage of this option would be that CMS would be unable to audit the quality of data available through such a database.

We solicited comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters strongly objected to the proposed estimation methodology and urged CMS to not finalize this approach. Many of these commenters stated that the estimation methodology conflicts with section 1860D–14B(b)(1)(B) of the Act, which states that the Secretary ''shall exclude'' 340B units from the total number of units used to calculate the Part D drug inflation rebate amount. The commenters asserted that estimating the number of 340B units would not comply with this provision because it would be ''highly doubtful'' that the 340B units excluded via the estimation percentage would be reasonably correct and would likely underestimate the number of 340B units; the commenters stated that, in contrast, the Act requires CMS to exclude all 340B units. The commenters objected to CMS proposing to use data with known limitations when, according to the commenters, there is case law that supports the notion that the agency must use the ''most reliable'' data available. A couple of commenters asserted that the estimation methodology would offend principles of due process and basic fairness.

Conversely, many commenters agreed with CMS' approach of developing an estimation percentage because this approach would not place unreasonable burden on covered entities and would be preferable to any methodology that requires point-of-sale or retrospective identification by covered entities or pharmacies through the use of a claims-based indicator. One commenter stated that the estimation methodology would be preferable to requiring the use of a Medicare Part D claims data repository (a topic discussed later in this section).

Response: CMS thanks the commenters for their feedback. After further consideration and taking into account the comments received on the proposed estimation methodology, CMS is not finalizing the estimation methodology for the applicable period that begins on October 1, 2025. Instead,

as discussed later in this section, CMS will explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a Medicare Part D claims data repository.

Comment: CMS received many comments on the proposed data sources for the estimation percentage. Many commenters stated that the PVP data is sufficient to help CMS calculate the estimated total number of units purchased under the 340B Program but raised concerns about using a broad data set from the PVP that would include hospitals and other covered entity outpatient purchases such as clinician-administered drugs. These commenters recommended that CMS only include retail pharmacy data from the PVP data to avoid any overestimates of the estimation percentage. Another commenter also supported the use of PVP data but cautioned that this data does not include certain purchases and could therefore deflate the true number of units purchased under the 340B Program. Many commenters objected to any use of the PVP data, stating that it would undercount a Part D rebatable drug's total 340B sales because some covered entities do not participate in the PVP and alternate distribution channels are not captured in the data. Some of these commenters claimed that the PVP is opaque and not validated, and interested parties would therefore be unable to fully verify the accuracy of the data. A few commenters raised concerns that potential undercounting of 340B units will be more pronounced for HIV therapies since a significant portion of 340B utilization for HIV therapies comes from AIDS Drug Assistance Programs (ADAPs).

Some commenters also raised concerns with the use of AMP data to capture the total number of units sold. These commenters were concerned that AMP excludes 340B sales to covered entities and excludes most units not purchased by retail community pharmacies. One commenter stated that this latter exclusion could have a not insignificant impact on therapeutic classes frequently administered by clinicians, such as oncology products. A couple of commenters also asked how CMS would treat drugs with no reported AMP units but for which there is reported AMP when determining the number of units to exclude from Part D inflation rebate amounts.

Response: CMS thanks the commenters for providing their feedback. As previously stated, after further consideration and taking into account the comments received on the proposed estimation methodology, CMS is not finalizing the estimation methodology for the applicable period that begins on October 1, 2025.

Comment: Many commenters agreed with the limitations of the estimation percentage that CMS described in the CY 2025 PFS proposed rule (89 FR 61969–61971) but did not offer recommendations on how CMS could adjust the estimation percentage. In response to CMS' comment solicitation on how the 340B dispensing rate may differ in the general population versus in the Part D population, a couple of commenters stated that estimating the percentage of Part D 340B units based on the percentage of overall 340B sales may underestimate 340B Part D units because many drug units dispensed to Medicaid beneficiaries are carved out of the 340B program, whereas Medicare Part D does not have an equivalent carve-out; therefore, the percentage of Part D units that are 340B would be greater than the percentage of overall sales that includes Medicaid units in its calculation.

Although no commenters offered specific recommendations on how CMS could adjust the estimation percentage, many commenters recommended changes that CMS should make to the estimation approach. One commenter recommended that CMS should at minimum permit manufacturers to submit data on the 340B utilization of their products to inform the numerator of the estimation percentage, whereas a few commenters strongly opposed any approach that would shift the responsibility of identifying 340B units to manufacturers. A couple of commenters stated that the estimation methodology does not account for the complexity of the structure of 340B organizations and their purchasing processes. A few commenters advised that CMS validate its calculations carefully and periodically audit the estimation percentage with covered entities, as overestimating the number of 340B units could have negative downstream impacts by artificially decreasing the inflation rebate amount for a Part D rebatable drug.

Response: CMS thanks the commenters for providing their feedback. As previously stated, after further consideration and taking into account the comments received on the proposed estimation methodology, CMS is not finalizing the estimation methodology for the applicable period that begins on October 1, 2025.

After consideration of public comments, CMS is not finalizing the estimation methodology for the applicable period that begins on October 1, 2025. Instead, as discussed later in this section, CMS will explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program starting January 1, 2026, through the establishment of a Medicare Part D claims data repository.

(b) Comment Solicitation on a Medicare Part D Claims Data Repository

In the initial Medicare Part D Drug Inflation Rebate Guidance, CMS solicited comments on the best mechanism to identify 340B units dispensed under Part D.[691] CMS discussed requiring the dispensing entity to include a 340B claims indicator on the Part D drug claim to be included in PDE records. Many commenters disagreed that the PDE record was the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with both point-of-sale modifiers and retrospective 340B identifiers. In addition, a wide array of interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B claims dispensed under Part D. Interested parties urged that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors.

In response to this feedback from interested parties, in the CY 2025 PFS proposed rule (89 FR 61971–61972) we solicited comments on establishing a Medicare Part D claims data repository (hereinafter, ''repository'') in a future year of the Medicare Part D Drug Inflation Rebate Program to comply with the requirement under section 1860D–14B(1)(B) of the Act that CMS shall exclude from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program. This approach would require that covered entities submit certain data elements from 340B-identified Part D claims to

[691] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

the repository. CMS solicited comments on such a requirement later in this section.

As described in the CY 2025 PFS proposed rule (89 FR 61971) and later in this section, CMS stated that a repository could receive data elements submitted by covered entities from 340B-identified claims for all drugs covered under Medicare Part D billed to Medicare. As requested by interested parties in comments on the initial Medicare Part D Drug Inflation Rebate Guidance, the repository could allow covered entities to submit these data directly to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors. CMS could consider all data elements received by the repository to be associated with 340B-identified claims; that is, the repository would not further verify the 340B status of a claim but rather would serve solely to store these data. Under this process, CMS could require an attestation from covered entities that the data elements from all claims submitted to the repository are from verified 340B claims. CMS stated that it is exploring approaches to confirming completeness and accuracy of the submission, and we solicited comments on methods to review and ensure the accuracy of reported data. CMS could then match the stored data elements to PDE records for each Part D rebatable drug dispensed during the applicable period. Units associated with PDE records that match to data elements stored in the repository could be considered those for which the manufacturer provides a discount under the 340B Program and therefore removed from the total number of units used to calculate the total rebate amount.

We received public comments in response to this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated support for CMS to implement the Part D claims repository as soon as possible or prior to January 1, 2026. A couple of commenters recommended that CMS allow manufacturers to submit data on 340B utilization for their products if CMS is not able to implement a repository or modifier process for identifying and excluding 340B units before 2026. A few commenters recommended that CMS temporarily pause invoicing for Part D inflation rebates until a 340B claims repository is operational, unless it adopts a 340B claims indicator policy. These commenters recommended that CMS account for repository data in the reconciliation process for past applicable periods beginning with 2026 if it does not pause invoicing until the repository is operational.

A couple of commenters recommended that CMS ensure that the repository is an independent entity, free from conflicts of interest related to relationships with parties involved with the 340B Program, including manufacturers and covered entities. One commenter recommended that the vendor selected for the repository be an entity currently active in the market that has extensive experience with data storage, exchange, and facilitation that is used to working with covered entities. A couple of commenters recommended that CMS ensure the protection of 340B-related claims information, as well as other sensitive or proprietary information that covered entities submit to the repository, including protection from potential cybersecurity threats. One commenter recommended CMS limit the scope of the repository to the collection of 340B-identified Part D claims to remove 340B units from the calculation of Part D inflation rebates. One commenter stated that if CMS considers additional uses for the repository beyond the Part D inflation rebate program, it should engage in notice-and-comment rulemaking.

Response: We appreciate the comments and recommendations. We will explore the establishment of a Medicare Part D claims data repository for removal of 340B units starting January 1, 2026 and may consider these comments for use in future rulemaking.

Comment: A couple of commenters opposed the repository because it relies on data submitted by covered entities without including a process to verify 340B data reported by covered entities or guaranteeing the exclusion of all 340B units from inflation rebate calculations.

Response: We appreciate the feedback in response to our comment solicitation and may consider these comments for use in future rulemaking.

Comment: Some commenters recommended CMS work with an independent, neutral entity that would serve as a clearinghouse for not only Part D claims data, but other payer claims data as well, and create full transparency to facilitate the exchange of information to identify 340B claims, prevent duplicate discounts across Medicaid and Medicare and other programs, and resolve disputes or other issues. Many commenters recommended that the repository would or should be like the model used in Oregon to identify 340B claims to avoid duplicate discounts between the 340B price and Medicaid rebates. One commenter provided detailed recommendations for a clearinghouse approach related to the registration process, account management, and data submission, resubmission, and validation requirements. The commenter noted that such service models are currently available on the market and could meet the January 1, 2026 timeline.

Response: We appreciate the comments and recommendations. We will explore the establishment of a Medicare Part D claims data repository for removal of 340B units starting January 1, 2026 and may consider these comments for use in future rulemaking.

After consideration of public comments, we plan to explore the establishment of a Medicare Part D claims data repository to use for removal of 340B units from the calculation of Part D inflation rebates starting January 1, 2026 to implement section 1860D–14B(b)(1)(B) of the Act. We plan to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking related to this topic and the exclusion of 340B units. We will also continue to explore requiring that covered entities and their contracted 340B third-party administrators (340B TPAs) report retrospectively at a minimum the 4 elements we described and solicited comment on in the CY 2025 PFS proposed rule (89 FR 61971). We welcome engagement with interested parties as we further review the comments on data submission requirements and timing. If CMS were to establish a Medicare Part D claims data repository in the future, we believe an important consideration would be consulting with HRSA as applicable about the need for guidance and education for covered entities regarding the final selected data elements for reporting and compliance measures.

(c) Comment Solicitation on Requiring Covered Entities To Submit 340B Claims Data to the Repository

We solicited comments on using our authority under section 1860D–14B(b)(1)(B) of the Act, as well as our authorities under sections 1102(a) and 1871(a)(1) of the Act, to require covered entities to enroll in a repository and submit certain data elements from 340B-identified claims for all covered Part D drugs billed to Medicare to this repository. CMS understands covered entities typically contract with 340B TPAs to determine 340B eligibility of claims using data submitted by covered entities and their contract

pharmacies.[692] CMS solicited comments on whether or how, to the extent a covered entity uses a 340B TPA, CMS could require or encourage TPAs to submit certain data elements to the repository on behalf of that covered entity.

Requiring covered entities to submit data elements from 340B-identified Part D claims to the repository could allow CMS to receive data directly from the entities that participate in the 340B Program to identify 340B units to exclude from Part D drug inflation rebate calculations without intermediary entities needing to develop processes to capture these data and relay it to CMS. We described in the CY 2025 PFS proposed rule (89 FR 61971) that we are considering requiring covered entities to submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); and (4) Dispensing Pharmacy NPI. CMS believes that these would be the minimum data elements required to match claims and remove 340B units from Part D drug inflation rebate calculations. We solicited comments from interested parties on this list of data elements and whether these data elements would be accessible to covered entities to submit to CMS.

We received public comments in response to this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: A few commenters recommended CMS minimize the data elements it requires covered entities to report to the repository and only require data elements that are necessary for identification and matching of 340B information with Part D claims. Many commenters recommended CMS require covered entities to submit the National Drug Code (NDC) or other product information to the repository in addition to the data elements CMS included in the comment solicitation in the proposed rule. Many commenters noted that the NDC would help CMS better crosswalk between the data submitted by the covered entity and the PDE records for Part D rebatable drugs dispensed during the applicable period. A few commenters recommended CMS collect other data elements from covered entities, including quantity dispensed, covered entity 340B ID, Part D Contract ID, and Part D Plan Benefit Package ID to help identify if two covered entities claimed a 340B discount for the same dispensed prescription and to verify that a 340B claim was dispensed to a Part D beneficiary. One commenter recommended that CMS require covered entities to submit the unit type data element to accurately identify 340B units to exclude them from Part D drug inflation rebate calculations. One commenter recommended that CMS require covered entities to submit the NCPDP Processor ID Number/Processor Control Number data element to the repository.

Response: We plan to explore the establishment of a Medicare Part D claims data repository to use for removal of 340B units from the calculation of Part D inflation rebates starting January 1, 2026. We appreciate the comments and recommendations and may consider them for use in any future rulemaking regarding policies and requirements related to the repository, including a potential requirement that covered entities and their contracted 340B TPAs retrospectively report, at a minimum, the 4 elements we described and solicited comment on in the CY 2025 PFS proposed rule (89 FR 61971). We welcome engagement with interested parties as we further review the comments on data submission requirements and timing.

Comment: A few commenters supported the repository leveraging existing data sources and allowing 340B TPAs to submit data in addition to covered entities and recommended CMS minimize burdens related to data sharing on covered entities. One commenter stated that the repository is similar to the existing process under which covered entities submit limited data elements to a commercially available 340B technology platform to continue receiving 340B discounts through contract pharmacy arrangements. One commenter noted concerns with the repository, arguing it would be an administrative burden for covered entities to provide data to CMS when many states already require data submission from covered entities.

One commenter recommended that, if data is needed from Part D plan sponsors, CMS should leverage existing data submitted by Part D plan sponsors, such as PDE data, and not impose additional reporting requirements on Part D plan sponsors for data submission to the repository. One commenter recommended CMS clarify how a retrospective claims repository model would function. One commenter thanked CMS for soliciting comments on a repository model rather than imposing a 340B indicator submission requirement on Part D participating pharmacies.

Response: We appreciate the comments and recommendation and may consider them for use in future rulemaking.

Comment: A few commenters supported CMS using the authority outlined in the CY 2025 PFS proposed rule (89 FR 61971–61972) to require covered entities to submit certain data elements from 340B-identified claims to a repository. A few commenters stated that CMS' statutory mandate to exclude 340B units from Part D drug inflation rebate calculations provides it with the authority to enact such a requirement. One commenter recommended that CMS explore authorities to ensure covered entity compliance with submission to a repository and remind covered entities of obligations to comply with statutes, regulations, and program instructions.

Response: We appreciate the comments and recommendations and will consider them for use in future rulemaking.

After consideration of public comments, we will explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program, through the establishment of a Medicare Part D claims data repository for removal of 340B units starting January 1, 2026 and may consider these comments for use in future rulemaking. We plan to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking related to this topic and the exclusion of 340B units. We will also continue to explore requiring that covered entities and their contracted 340B third-party administrators (340B TPAs) report retrospectively at a minimum the 4 elements we described and solicited comment on in the CY 2025 PFS proposed rule (89 FR 61971). We welcome engagement with interested parties as we further review the comments on data submission requirements and timing. If CMS were to establish a Medicare Part D claims data repository in the future, we believe an important consideration would be consulting with HRSA as applicable

[692] Covered entities may elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the covered entity enters a contract with the pharmacy to provide pharmacy services.

about the need for guidance and education for covered entities regarding the final selected data elements for reporting and compliance measures.

(d) Comment Solicitation on Timing Requirements for Potential Submissions to a Medicare Part D Claims Data Repository

We solicited comments on requiring covered entities to submit the fields specified by CMS to the repository within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, covered entities would be required to submit data elements from 340B-identified claims to CMS no later than March 31, 2028. The 340B units identified from these quarterly submissions could be removed from the total number of units and total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at §§ 428.401(b) and (c), respectively.

In accordance with the proposed § 428.401(d) to reconcile the rebate amount in the case of revised information, including a reconciliation of the total number of units detailed at § 428.401, we solicited comments on providing covered entities with additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the covered entity previously submitted to a repository in error or with errors in the requested data fields, or (2) new submission of data for a claim that the covered entity had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. For the first type of revision, we solicited comments on requiring that the covered entity resubmit the data from such claim using a field to indicate that such data should be removed from the repository's dataset of 340B-identified claims; if applicable, the covered entity could resubmit the claim with the correct information. We solicited comments on the process and timing for covered entities to submit this revised data to the repository after the end of the applicable period. Updates to the total number of units and total rebate amount based on this revised information from covered entities would be reflected in the reconciliation process detailed at § 428.401(d).

We solicited comments from interested parties on the feasibility of the proposed quarterly reporting timeline for covered entities to submit data elements from Part D 340B claims, as well as the additional time to submit data to reflect a revision to the 340B determination of claims.

We received public comments in response to this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the data submission timing CMS detailed in its comment solicitation on the repository, stating that providing 3 months after the end of a given calendar quarter would provide sufficient time to compile required data. A couple of commenters recommended CMS provide ample time for covered entities to submit data to a repository. Many commenters supported CMS allowing covered entities to revise data previously submitted to the repository or submit new data for claims that are newly identified as 340B-eligible. A couple of commenters recommended that CMS verify that any data submitted to the repository retroactively be final adjudicated claim information to ensure that information sent to the repository is final. One commenter recommended that covered entities share 340B claims data on a real-time basis or as close to real-time as possible with the repository.

Response: We appreciate the comments and recommendation and will consider them for use in future rulemaking.

After consideration of public comments, we will explore avenues to implement section 1860D–14B(b)(1)(B) of the Act, which requires the exclusion from the total number of units for a Part D rebatable drug those units for which a manufacturer provides a discount under the 340B Program, through the establishment of a Medicare Part D claims data repository for removal of 340B units starting January 1, 2026 and may consider these for use in future rulemaking. We will also continue to explore requiring that covered entities and their contracted 340B third-party administrators (340B TPAs) report retrospectively at a minimum the 4 elements we described and solicited comment on in the CY 2025 PFS proposed rule (89 FR 61971). We welcome engagement with interested parties as we further review the comments on data submission requirements and timing. If CMS were to establish a Medicare Part D claims data repository in the future, we believe an important consideration would be consulting with HRSA as applicable about the need for guidance and education for covered entities regarding the final selected data elements for reporting and compliance measures.

(e) Alternative Policy Considered: 340B Claims Identifier

As described in section 40.2.7 of the initial Medicare Part D Drug Inflation Rebate Guidance, CMS considered requiring that a 340B indicator be included on the PDE record at the time of dispense to identify drugs purchased under the 340B Program that were dispensed under Medicare Part D. As described in the ''Summary of Public Comments on the Initial Medicare Part D Drug Inflation Rebates Memorandum and CMS' Responses'' in the revised Medicare Part D Drug Inflation Rebate Guidance, many commenters—including covered entities, pharmacies, Part D plan sponsors, and pharmacy benefit managers—disagreed that the PDE record would be the most accurate way to identify 340B discounts for Part D drugs. A few commenters highlighted the operational challenges, administrative burden, and potential for increased dispensing fees and reimbursement issues with 340B claim identifiers. After further consideration of comments received in response to the initial guidance and of the process through which a claim is determined to have 340B status, we noted in the CY 2025 PFS proposed rule (89 FR 61972) that CMS is no longer pursuing this policy at this time but may consider it in future rulemaking.

We received public comments on this alternative considered. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for CMS' decision to not pursue a 340B claims indicator at this time and urged that CMS should not revisit the idea. These commenters explained that 340B-eligibility determinations are made after the point of sale and that 340B claims indicators are incompatible with the retrospective replenishment model [693] and would be unworkable for most 340B pharmacies.

Response: CMS thanks these commenters for their support. In this final rule, CMS maintains that we are not pursuing a 340B claims indicator policy at this time but may consider it in future rulemaking.

Comment: Many commenters supported use of a 340B claims

[693] Covered entities and their contract pharmacies can use a replenishment model in which they do not need to maintain a separate physical inventory for 340B-eligible drugs. Rather than maintain a physical inventory, they maintain a virtual inventory and a contract pharmacy can receive a replacement product, paid by the covered entity, after a full package size of the product has been dispensed to 340B-eligible patients.

indicator to identify 340B units and stated that the use of such an indicator would be operationally feasible, accurate, and consistent with the statutory requirement to remove 340B units from Part D drug inflation rebate calculations. Some commenters recommended that CMS require use of 340B and non-340B indicators (that is, to identify that a drug was not purchased under the 340B Program) on claims and that Part D plans reject claims if they do not include one of the two indicators. A couple of commenters stated that CMS' statutory mandate to exclude 340B units from Part D drug inflation rebate calculations provides it with the authority to enact such a requirement. A few commenters noted that CMS stated in the initial Medicare Part D Drug Inflation Rebate Guidance that requiring a 340B indicator be included on the PDE record is the most reliable way to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D; these commenters were concerned that CMS has moved away from an approach it previously stated was the most reliable.[694] A few commenters noted that a 340B modifier is utilized in the Part B program and argued that this indicates that employing a similar process in Part D is feasible. One commenter acknowledged the difficulty for some dispensing entities of identifying 340B eligibility at the point of sale and noted the discriminatory practices of payers when a 340B indicator is used, but urged CMS to continue to explore ways to improve identification of 340B claims at the point of sale in the absence of a comprehensive claims ''clearinghouse.'' Another commenter acknowledged the difficulties of implementing a 340B claims indicator but stated that the statute does not include any provision suggesting that minimizing disruptions for covered entities should take precedence.

Response: CMS appreciates the feedback. As stated in the CY 2025 PFS proposed rule (89 FR 61972), CMS understands that the 340B status of a Part D drug may not be known by the dispensing entity at the point of sale, and that covered entities may identify the 340B status of a Part D drug retrospectively. Although the current NCPDP Telecommunications Standard Version D.0 for pharmacy claims does include a field where a 340B indicator could be provided in a ''B1'' transaction,[695] it is optional for pharmacies to use, based on agreements with trading partners (for example, health plans, manufacturers, state Medicaid agencies). In addition, the standard specifies that the indicator in the ''B1'' transaction can only be used prospectively, so a pharmacy that makes the retrospective determination that the drug was purchased at or below the 340B ceiling price cannot apply this modifier retrospectively to the claim. The NCPDP does allow use of an ''N1'' transaction[696] to retrospectively identify drugs purchased under the 340B program, but CMS understands that requiring use of the N1 transaction would not be feasible as it has not been adopted by pharmacy information systems. CMS therefore believes there may be more reliable ways to identify drugs that are subject to a 340B discount that were dispensed under Medicare Part D than requiring a 340B indicator be included on the PDE record. In contrast, CMS requires 340B modifiers under Part B because dispensing entities are generally able to identify the 340B status of a Part B claim at or soon after the point of dispense.

Comment: Many commenters recommended that CMS use data submitted to a Part D 340B repository for purposes of implementing nonduplication between the Maximum Fair Price and the 340B ceiling price in the Medicare Drug Price Negotiation Program. One commenter stated that drug pricing changes under the Inflation Reduction Act could have mixed effects on people with HIV, including the removal of 340B units from certain calculations. The commenter noted that any affordability challenges to people with HIV are concerning. One commenter stated support for transparency for health plans when a drug is 340B-eligible and for legislation related to creating a 340B claims clearinghouse. One commenter recommended that CMS work with HRSA to issue guidance requiring identification of 340B units to facilitate a 36-month reconciliation timeline for excluding 340B units from Part D inflation rebates.

Response: While these comments are out of scope for this final rule because they address other programs and topics beyond the scope of the Medicare Part D Drug Inflation Rebate Program, we appreciate the feedback and may consider these recommendations for the Medicare Drug Negotiation Program.

After consideration of public comments, CMS maintains that we are not pursuing a 340B claims indicator requirement at this time but may consider it in future rulemaking.

v. Treatment of New Formulations of Part D Rebatable Drugs

Section 1860D–14B(b)(5)(B)(i) of the Act requires CMS to determine a formula for the rebate amount and the inflation-adjusted payment amount for a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form for an applicable period that is consistent with the formula applied under section 1927(c)(2)(C) of the Act for determining a rebate obligation for a rebate period under such section. Section 1927(c)(2)(C) of the Act provides for an alternative rebate calculation for line extension drugs under the MDRP, and CMS issued guidance on how this calculation is performed for these purposes.[697]

Section 1860D–14B(b)(5)(B)(ii) of the Act further states that for a Part D rebatable drug, the term line extension means, ''a new formulation of the drug, such as extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.'' This language is identical to the definition of ''line extension'' in section 1927(c)(2)(C) of the Act. Regulatory definitions of ''line extension'' and ''new formulation'' for the MDRP were adopted through rulemaking[698] and can be found at § 447.502. In alignment with CMS' policy in section 40.4 of the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed at § 428.200 to adopt the definitions of ''line extension'' and ''new formulation'' at § 447.502 of this title for the purposes of identifying new formulations of Part D rebatable drugs.

At § 428.204, we proposed CMS will determine the total rebate amount to be paid by manufacturers by taking the greater of (1) the total rebate amount

[694] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

[695] A pharmacy would use the value of ''20'' in the Submission Clarification Code (420–DK) field to indicate use of a 340B drug at the time of the adjudication or dispensing of the claim. See: National Council on Prescription Drug Program (NCPDP) 340B Information Exchange Reference Guide Version 2.0, June 2019, *https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.*

[696] If it is determined that a 340B drug was dispensed after the claim has been adjudicated, then an N1 transaction can be submitted with the 420–DK submission.

[697] See: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-calculation/unit-rebate-amount-calculation-for-line-extension-drugs-with-example/index.html.*

[698] See: 85 FR 87000, 87101 (December 31, 2020).

calculated at § 428.201(a) for the applicable period for the Part D rebatable drug that is a line extension, or (2) the alternative total rebate amount. This proposal is a modification to policy established in revised Medicare Part D Drug Inflation Rebate Guidance. While the revised guidance stated that CMS will compare the *per unit* rebate amount to the alternative *per unit* rebate amount, as described at § 428.204, we proposed that CMS will compare the *total* rebate amount calculated in at § 428.201(a) to the alternative *total* rebate amount, which we believe is consistent with the existing regulations for new formulations at § 447.509(a)(4), as explained in the CY 2025 PFS proposed rule (89 FR 61972). We further proposed at § 428.204 to codify the policy described in section 40.4 of the revised guidance to calculate the alternative inflation rebate amount for a Part D rebatable drug that is a line extension consistent with the formula applied under section 1927(c)(2)(C) of the Act. That is, CMS will determine an inflation rebate amount ratio for the initial drug identified by the manufacturer in accordance with § 447.509(a)(4)(i)(B) by dividing the inflation rebate amount for that initial drug for the applicable period by the AnMP for that initial drug for the applicable period, as calculated under § 428.202(b).

We stated in the CY 2025 PFS proposed rule (89 FR 61972–61973) that to identify the initial drug for the line extension, CMS will use information from the Medicaid Drug Program system and identify line extensions based on manufacturer reporting of drugs as line extensions and related pricing and product data in that system. We noted that Medicaid rebates are calculated quarterly, and a different initial drug may be identified in different quarters by the manufacturer for a particular line extension drug. Part D drug inflation rebates are calculated based on a 12-month applicable period, meaning there may be instances where a Part D rebatable line extension drug has multiple potential initial drugs during the applicable period that could be used for the alternative inflation rebate amount calculation. In such situations, for consistency, CMS will use the initial drug identified by the manufacturer in the last quarter of the Part D inflation rebate applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation. If an initial drug was not identified in the last quarter for a drug that is a line extension, we stated CMS will use the initial drug identified for a quarter most recently in that applicable period to identify the initial drug for the line extension drug alternative inflation rebate calculation.

We received public comments specific to the proposed definitions of ''line extension'' and ''new formulation'' at § 428.200 and responded to these comments above. We did not receive comments specific to the proposed provision at § 428.204, and we are finalizing as proposed at § 428.204.

d. Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage (§§ 428.300 Through 428.303)

Section 1860D–14B(b)(1)(C) of the Act requires the Secretary to reduce or waive the rebate amount owed by a manufacturer for a Part D rebatable drug with respect to an applicable period in three distinct cases: (1) when a Part D rebatable drug is described as currently in shortage on a shortage list in effect under section 506E of the FD&C Act at any point during the applicable period; (2) when CMS determines there is a severe supply chain disruption during the applicable period for a generic Part D rebatable drug or biosimilar, such as a disruption caused by a natural disaster or other unique or unexpected event; and (3) when CMS determines that without such a reduction or waiver, a generic Part D rebatable drug is likely to be described as in shortage on such shortage list during a subsequent applicable period. The statute does not describe how CMS should reduce or waive inflation rebates.

To implement the statutory requirement under section 1860D–14B(b)(1)(C) of the Act, we proposed to codify in subpart D of part 428 existing policies described in sections 40.5, 40.5.1, 40.5.2, and 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance to reduce the total rebate amount owed by a manufacturer in each of these three cases, as summarized in Table 60 and discussed later in this section.

TABLE 60: Determination of Rebate Reduction Amount for Part D Rebatable Drugs

	Drug Shortage		Severe Supply Chain Disruption	Likely to be in Shortage
Duration of Reduction	Indefinite for as long as drug is "currently in shortage"		One applicable period; manufacturer may request an extension for an additional applicable period for up to two applicable periods total	
Percent Reduction	Part D rebatable drug other than a plasma-derived product or generic Part D rebatable drug	Part D rebatable plasma-derived product or generic Part D rebatable drug	Part D rebatable biosimilar or generic Part D rebatable drug	Generic Part D rebatable drug
First applicable period	25%	75%	75%	75%
Second applicable period	10%	50%	75%	75%
Subsequent applicable periods	2%	25%	Not applicable	Not applicable

In the CY 2025 PFS proposed rule (89 FR 61973), we described that CMS would not fully waive the rebate amount owed in any case. We stated that we believe the proposed rebate reduction policies balance providing appropriate financial relief for manufacturers in certain circumstances, including when there is a severe supply chain disruption resulting from exogenous circumstances outside of a manufacturer's control, while not incentivizing manufacturers to delay taking appropriate steps to resolve a drug shortage or severe supply chain disruption, or maintain a situation in which a generic would be at risk of shortage to avoid an obligation to pay rebates. Additionally, we stated in the CY 2025 PFS proposed rule that we will continue to evaluate these policies and may update them in future years. We noted that most shortages involve multiple source generic drugs,[699] which are not Part D rebatable drugs and thus are not subject to Part D drug inflation rebates.

We solicited comments on these proposals. Comments regarding rebate reductions for drugs currently in shortage and drugs experiencing a severe supply chain disruption that are applicable to both Part B rebatable drugs and Part D rebatable drugs (for example, comments recommending a full waiver of the rebate amount and comments on the definitions) are summarized in the Part B drug inflation rebate section of this final rule. Rebate reduction comments specific to the Medicare Part D Drug Inflation Rebate Program (for example, comments on the likely to be in shortage policy) are summarized later in this section.

i. Definitions

We proposed at § 428.300 to define the following terms applicable to subpart D (§§ 428.300 through 428.303):

- ''Biosimilar''.
- ''Drug shortage'' or ''shortage''.
- ''Generic Part D rebatable drug''.
- ''Likely to be in shortage''.
- ''Plasma-derived product''.

We also proposed at § 428.300 to codify definitions established in the revised Medicare Part D Drug Inflation Rebate Guidance for the following terms:

- ''Currently in shortage''.
- ''Natural disaster''.
- ''Other unique or unexpected event''.
- ''Severe supply chain disruption'' .

We received public comments on these proposed definitions, which are applicable to both Part B rebatable drugs and Part D rebatable drugs and are summarized in the Part B drug inflation rebate section of this final rule. After consideration of comments received, we are finalizing the definitions as proposed at §§ 428.300 and 427.400.

ii. Reducing the Rebate Amount for Part D Rebatable Drugs Currently in Shortage

At § 428.301, we proposed to codify the policy established in section 40.5.1 of the revised Medicare Part D Drug Inflation Rebate Guidance whereby CMS would reduce the total rebate amount for a Part D rebatable drug that is currently in shortage based on the length of time the drug is in shortage during an applicable period and decrease the amount of the reduction over time. We stated in the CY 2025 PFS proposed rule (89 FR 61974) that CMS intends to use the shortage lists maintained by the FDA Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) to determine whether a Part D rebatable drug is currently in shortage [700] during an applicable period. We also stated that CMS will not consider an NDC–10 in the status of ''to be discontinued,'' ''discontinued,'' or ''resolved'' to be ''currently in shortage'' and that CMS would provide the same reduction in the rebate amount for Part D rebatable drugs currently in shortage regardless of the cause of the shortage.

We proposed that CMS will not provide a full waiver of the rebate amount for drugs currently in shortage, as providing a full waiver of the rebate amount could further incentivize manufacturers to delay taking appropriate steps that may resolve a shortage more expeditiously simply to maintain having the drug listed on FDA's drug shortage list to avoid an obligation to pay rebates for an extended period. Further, as explained in the CY 2025 PFS proposed rule (89 FR 61974), in a report analyzing the root causes of drug shortages between 2013 and 2017, FDA found that more than 60 percent of drug shortages were the result of manufacturing or product quality issues, and providing a full waiver of the rebate amount in situations that may be within a manufacturer's control could be perceived as rewarding manufacturers for poor quality management.[701]

We stated in the CY 2025 PFS proposed rule (89 FR 61974) that CMS will be responsible for monitoring the status of a Part D rebatable drug on an FDA shortage list, and manufacturers would not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part D rebatable drug that is currently in shortage.

To calculate the reduced total rebate amount for a Part D rebatable drug, at § 428.301(b)(1), we proposed the following formula:

Reduced *Total* Rebate Amount = the total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the applicable period)

For the purpose of this formula, for a Part D rebatable drug that is a generic drug or a plasma-derived product, at § 428.301(b)(2)(i), we proposed an applicable percent reduction of 75 percent for the first applicable period such Part D rebatable drug is currently in shortage, 50 percent for the second applicable period, and 25 percent for each subsequent applicable period. For a Part D rebatable drug (including a biosimilar) that is not a generic drug or a plasma-derived product, at § 428.301(b)(2)(ii), we proposed an applicable percent reduction of 25 percent for the first applicable period such Part D rebatable drug is currently in shortage, 10 percent for the second applicable period, and 2 percent for each subsequent applicable period.

Because drugs and biologicals on the FDA shortage lists are maintained at the NDC–10 level, and Part D drug inflation rebates are calculated at the NDC–9 level, we proposed at § 428.301(c) that if any NDC–10 for a Part D rebatable drug is currently in shortage, CMS will apply the rebate reduction to the entire Part D rebatable drug at the NDC–9 level. CMS will closely monitor market data for the Part D rebatable drugs for which the rebate is reduced to ensure the integrity of the application of the rebate reduction policy.

We proposed to provide a reduction in the rebate amount for as long as a Part D rebatable drug is currently in shortage. We stated in the CY 2025 PFS proposed rule (89 FR 61974) that we believe the rebate reduction should be proportional to the time the drug is currently in shortage and decrease over time to balance providing financial

[699] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

[700] For the purposes of this final rule, CMS uses the term ''currently in shortage'' to refer to Part D rebatable drugs that are in the status of ''currently in shortage'' on the CDER shortage list, as well as biological products listed on CBER's current shortages list.

[701] See: *https://www.fda.gov/media/131130/download?attachment#page=33.*

relief to manufacturers experiencing a drug shortage while not incentivizing manufacturers to delay taking appropriate steps to resolve a shortage simply to maintain having the drug listed on an FDA shortage list to avoid an obligation to pay rebates for an extended period.

To determine the percentage of time a Part D rebatable drug was currently in shortage during the applicable period, at § 428.301(b)(3), we proposed to determine the number of days such drug is currently in shortage in an applicable period and divide by the total number of days in that applicable period.

At § 428.301(b)(2), we proposed to codify the policy set forth in section 40.5.1 of the revised Medicare Part D Drug Inflation Rebate Guidance to apply a greater applicable percent reduction for generic Part D rebatable drugs, which, by definition, are sole source generic drugs, compared to brand-name drugs and biologicals, including biosimilars. CMS understands that generic drugs are often low-margin products whose prices are tied to the marginal cost of production and thus are vulnerable to potential market exit and shortage when input costs increase. CMS notes that the Medicare Part D Drug Inflation Rebate Program does not apply to multiple source generic drugs, which are the generic drugs most likely to be in shortage.[702] We also proposed applying a greater applicable percent reduction for plasma-derived products than non-plasma derived products because the former rely on a variable supply of donated blood plasma that can impact downstream production and therefore hamper the ability to promptly resolve a shortage.

When the status of a Part D rebatable drug changes from currently in shortage to ''resolved'' and either remains in the status of ''resolved'' or is removed from the list, and then reemerges on the list in the status of currently in shortage in the next applicable period, we proposed to apply the shortage reduction as if there was a continuous shortage and move to the applicable percent reduction for the second applicable period. (In this scenario, the applicable percent reduction would be 50 percent for the second applicable period for a generic Part D rebatable drug or plasma-derived product and 10 percent for a Part D rebatable drug that is not a generic drug or plasma-derived product.) When the status of a Part D rebatable drug changes from currently in shortage to ''resolved'' and either remains in the status of ''resolved'' or is removed from the list for at least one applicable period, and then subsequently reemerges on a shortage list, the subsequent shortage will be treated as a new shortage. In such case, the applicable percent reduction for the first applicable period in which the drug reemerges on the shortage list would be 75 percent for a generic Part D rebatable drug or plasma-derived product and 25 percent for a Part D rebatable drug that is not a generic or plasma-derived product.

We received public comments on these proposed provisions, which are applicable to rebate reductions for Part B rebatable drugs and Part D rebatable drugs and are summarized in the Part B drug inflation rebate section of this final rule.

Consistent with the policy described for rebate reductions for Part B rebatable drugs currently in shortage, after consideration of the comments received, we are finalizing this policy as proposed at § 428.301 with an additional provision at § 428.301(b)(2)(iii) to clarify the starting point for application of the rebate reduction. CMS adopted this provision to clarify CMS' intended policy, as highlighted by examples in the CY 2025 PFS proposed rule, that while CMS will generally apply the shortage reduction starting with the first applicable period that a drug or biological covered under Part D is described as currently in shortage, CMS acknowledges that for such drug or biological that has been granted a rebate reduction for a severe supply chain disruption or for such generic drug that has been granted a rebate reduction for a likely shortage, it would be appropriate to delay the start of the applicable percent reduction for being in shortage until after the conclusion of the severe supply chain disruption reduction or likely to be in shortage reduction if the shortage continues. The section below discusses this clarification in detail. Specifically, and as shown in Table 60, we are clarifying in this final rule that CMS will apply the greatest rebate reduction to the first applicable period that a drug or biological is described as currently in shortage regardless of whether the drug or biological meets the definition of a Part D rebatable drug or owes a rebate amount, starting with the applicable period that begins October 1, 2022. For example, if a generic drug or plasma-derived product was currently in shortage from October 1, 2021 through December 15, 2023, CMS would apply an applicable percent reduction of 75 percent for the applicable period beginning October 1, 2022 and ending September 30, 2023, followed by a 50 percent reduction for the applicable period beginning October 1, 2023 and ending September 30, 2024, even if such drug did not meet the definition of a Part D rebatable drug or there was no rebate amount owed to which to apply the reduction. Similarly, for a drug that is not a generic drug or plasma-derived product, in this example, CMS would apply an applicable percent reduction of 25 percent for the applicable period beginning October 1, 2022 and ending September 30, 2023, followed by a 10 percent reduction for the applicable period beginning October 1, 2023 and ending September 30, 2024, even if such drug did not meet the definition of a Part D rebatable drug or there was no rebate amount owed to which to apply the reduction.

[702] See: *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.*

TABLE 61: Application of Shortage Reduction

	Applicable period 1	Applicable period 2	Applicable period 3
In shortage on FDA shortage list	Yes	Yes	Yes
Meets definition of Part D rebatable drug	No	Yes	Yes
Owes a >$0 rebate	No	No	Yes
Applicable percent reduction applied for a Part D rebatable drug other than a plasma-derived product or generic	25%	10%	2%
Applicable percent reduction for a Part D rebatable plasma-derived product or generic Part D rebatable drug	75%	50%	25%

Note: CMS would "start the clock" for rebate reductions with applicable period 1. The highest percent reduction would thus apply to applicable period 1, regardless of how many days the Part D rebatable drug is in shortage during this applicable period. In this example, the 25 percent reduction (for a drug other than a generic or plasma derived product) or 75 percent reduction (for a generic drug or plasma-derived product) would apply to applicable period 1, even though there would be no rebate amount to which it applies.

We believe this clarification helps ensure clarity on CMS' policy in applying rebate reductions, which is intended to provide appropriate financial relief for drugs currently in shortage while limiting opportunities for manufacturers to manipulate a shortage start date to align with future price increases that coincide with the application of the reduction, as well as to decrease the amount of the rebate reduction the longer a drug is in shortage as described in the CY 2025 PFS proposed rule (89 FR 61974).

iii. Reducing the Rebate Amount for Generic Part D Rebatable Drugs and Biosimilars When There Is a Severe Supply Chain Disruption

At § 428.302, we proposed to codify the policy established in section 40.5.2 of the revised Medicare Part D Drug Inflation Rebate Guidance for rebate reductions when CMS determines there is a severe supply chain disruption during an applicable period. We proposed at § 428.302(b)(1) to provide a time-limited standard reduction of 75 percent in the total rebate amount for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event. We proposed that to receive a rebate reduction in accordance with § 428.302(b)(1), the manufacturer would have to submit to CMS a rebate reduction request that meets the eligibility requirements at § 428.302(c). A rebate reduction request should specify each NDC–11 to which the request applies, and if CMS grants a manufacturer's severe supply chain disruption rebate reduction request for an NDC–11, we proposed at § 428.302(b)(3) that the rebate reduction will apply to the entire generic Part D rebatable drug or biosimilar at the NDC–9 level. We refer manufacturers to the collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction requests.

We proposed at § 428.302(c)(4) to grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating that (1) a severe supply chain disruption has occurred during the applicable period, (2) the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer,[703] or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar, and (3) the severe supply chain disruption was caused by a natural disaster or other unique or unexpected event. CMS began accepting rebate reduction requests and rebate reduction extension requests upon completion of the Paperwork Reduction Act (PRA) process, including for severe supply chain disruptions caused by a natural disaster or other unique or unexpected event that occurred on or after October 1, 2022, but before completion of the PRA process.[704] We proposed at § 428.302(c)(2) that for a natural disaster or other unique or unexpected event occurring or beginning on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order for CMS to consider a rebate reduction.

We proposed that if a manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS will reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug or biosimilar for the applicable period in which the event that caused the severe supply chain disruption occurred or began or, the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period. CMS acknowledged that the 60-day advance submission requirement may pose a challenge to timing of the rebate reduction when the severe supply chain

[703] A contract manufacturer is a party that performs one or more manufacturing operations on behalf of a manufacturer(s) of active pharmaceutical ingredients (APIs), drug substances, in-process materials, finished drug products, including biological products, and combination products. See ''Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry,'' November 2016: *https://www.fda.gov/media/86193/download*.

[704] Consistent with the published collection of information approved under OMB control number 0938–1474, for a natural disaster or other unique or unexpected event that occurred or began on or after October 1, 2022 but before August 2, 2024 that the manufacturer believes caused a severe supply chain disruption, the manufacturer must have submitted the rebate reduction request no later than 11:59 p.m. PT on October 1, 2024 for CMS to consider a rebate reduction for the generic Part D rebatable drug or biosimilar.

disruption-causing event occurs late in one applicable period, and the request is not submitted until the next applicable period. In such circumstances, CMS will apply a rebate reduction to an applicable period based on the timing of the natural disaster or other unique or unexpected event causing a severe supply chain disruption and the timing of the submission of the request and may adjust the timing of the application of the rebate reduction as appropriate to meet the invoicing deadlines specified in statute and subpart E of proposed part 428.

We proposed at § 428.302(c)(5) that if a manufacturer believes severe supply chain disruption continues into a second, consecutive applicable period after the start of the natural disaster or other unique or unexpected event, the manufacturer may request a reduction of the total rebate amount for that second applicable period by submitting a rebate reduction extension request to CMS, along with any new supporting documentation. We refer manufacturers to the collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction requests. At § 428.302(c)(5)(ii), we proposed that a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of that second applicable period in order for CMS to consider a rebate reduction extension, except for when the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction applied.

We further proposed that if a manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount will be reduced by 75 percent for a second consecutive applicable period for that manufacturer's generic Part D rebatable drug or biosimilar in accordance with § 428.302(b)(2).

Consistent with the policy established in section 40.5.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed at § 428.302(c)(5) that a manufacturer may receive only one extension of the rebate reduction per generic Part D rebatable drug or biosimilar per CMS determination of a severe supply chain disruption. Said differently, CMS will limit the severe supply chain disruption rebate reduction to two consecutive applicable periods total per generic Part D rebatable drug or biosimilar per CMS determination of a severe supply chain disruption.

At § 428.302(b)(4)(i), we proposed that if the manufacturer believes there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic Part D rebatable drug or biosimilar and submits multiple rebate reduction requests for the same generic drug or biosimilar, CMS will grant no more than one rebate reduction for that generic drug or biosimilar for the applicable period. For example, if the manufacturer of a generic Part D rebatable drug or biosimilar is granted a severe supply chain disruption rebate reduction request for its product due to a natural disaster that occurred in January 2025 and then experiences a second severe supply chain disruption caused by a second, distinct natural disaster in July 2025, CMS will not grant the second rebate reduction request. That is, the manufacturer would receive the 75 percent reduction for one applicable period for the severe supply chain disruption caused by the first natural disaster but would not receive a rebate reduction for the second natural disaster. However, if the second natural disaster exacerbated the severe supply chain disruption caused by the first natural disaster, the manufacturer may reflect such circumstances in its request for an extension of the rebate reduction for a second applicable period.

At § 428.302(b)(4)(ii), we proposed that if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar, and the drug or biosimilar appears as currently in shortage during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS will apply the 75 percent reduction to the entire applicable period for which the severe supply chain disruption request was granted and would not grant any additional reduction for the shortage status during that applicable period. For any subsequent applicable periods that the generic Part D rebatable drug or biosimilar appears as currently in shortage, CMS will reduce the total rebate amount in accordance with the drug shortage reduction at § 428.301, starting with the highest reduction (that is, 75 percent for a generic Part D rebatable drug or plasma-derived product and 25 percent for a Part D rebatable drug that is not a generic drug or plasma-derived product). As explained in the example in the CY 2025 PFS proposed rule (89 FR 61976), if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar that was submitted on November 15, 2024, and that generic Part D rebatable drug or biosimilar is currently in shortage from September 15, 2025, until May 15, 2026, CMS would apply a 75 percent reduction in the total rebate amount for the duration of the applicable period for which the severe supply chain disruption rebate reduction request was granted (that is, October 1, 2024, to September 30, 2025), and then would apply the shortage reduction as proposed in § 428.301, beginning with a reduction of 25 percent for a biosimilar or 75 percent for a generic Part D rebatable drug or plasma-derived product that is a biosimilar for the applicable period beginning October 1, 2025.

At § 428.302(b)(4)(iii), we proposed that if a generic Part D rebatable drug or biosimilar that is currently in shortage experiences a severe supply chain disruption, the manufacturer may submit a severe supply chain disruption rebate reduction request. If CMS grants the rebate reduction request, the rebate amount would be reduced by 75 percent for the applicable period, and we will not grant any additional reduction under § 428.301 for the currently in shortage status during that applicable period. As described in the example in the CY 2025 PFS proposed rule (89 FR 61976), if a generic Part D rebatable drug or biosimilar that is currently in shortage in the applicable period beginning October 1, 2024 is granted a severe supply chain disruption rebate reduction request as a result of a natural disaster that occurs on April 5, 2025, CMS would apply a 75 percent reduction in the rebate amount for the duration of the applicable period in which the natural disaster occurred (that is, October 1, 2024, to September 30, 2025). In this same example, if the natural disaster instead occurs on September 5, 2025, CMS would apply the shortage reduction proposed in § 428.301 for the duration of the applicable period beginning October 1, 2024 (that is, October 1, 2024, to September 30, 2025), and then a 75 percent reduction under the severe supply chain disruption policy to the next applicable period beginning October 1, 2025 (that is, October 1, 2025, to September 30, 2026).

At § 428.302(c)(6), we proposed to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024. If a manufacturer's rebate reduction request does not meet the criteria at § 428.302(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements at § 428.302(c), we proposed that CMS will deny the request. We also proposed that if a manufacturer's rebate reduction extension request does not meet the criteria at § 428.302(c)(5), is incomplete or untimely based on the requirements at § 428.302(c)(5), or if a reduction under § 428.302(b)(1) was not provided for such generic Part D rebatable drug or biosimilar, CMS will deny the rebate reduction extension request. At § 428.302(c)(6)(iii), we proposed that CMS' decisions to deny a request will be final and not be subject to an appeals process.

At § 428.302(c)(7), we proposed CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. We proposed that information provided as part of a severe supply chain disruption rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 or 4 of the Freedom of Information Act (FOIA). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

We received public comments on these proposed provisions, which are applicable to both Part B rebatable drugs and Part D rebatable drugs and are summarized in the Part B drug inflation rebate section of this final rule.

After consideration of comments received, we are finalizing this policy as proposed at § 428.302, with a modification. For alignment with language in the preamble of the CY 2025 PFS proposed rule (89 FR 61975) and § 427.402(b)(1), we clarified at § 428.302(b)(1) that CMS will apply a severe supply chain disruption rebate reduction to the applicable period in which the event occurred or began or the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period. This application of a rebate reduction (initial or extension) applies regardless of whether a generic drug or biosimilar meets the definition of a Part D rebatable drug during that applicable period or whether a rebate amount is owed for such generic Part D drug or biosimilar for that applicable period. That is, regardless of whether the generic drug or biosimilar meets the definition of a Part D rebatable drug or whether a rebate amount is owed for such generic Part D drug or biosimilar for that applicable period, CMS will apply the 75 percent reduction in the total rebate amount as determined under § 428.302(b)(1), even if there is no rebate amount owed to reduce. For example, as shown in Table 61, if CMS grants a severe supply chain disruption rebate reduction request for a generic Part D drug or biosimilar for an applicable period, CMS will apply the rebate reduction beginning with the applicable period for which the reduction request was granted, regardless of whether the drug meets the definition of a Part D rebatable drug or is subject to a rebate amount.

TABLE 62: Application of Severe Supply Chain Disruption Reduction

	Applicable period 1	Applicable period 2	Applicable period 3
Meets definition of Part D rebatable drug	No	Yes	Yes
Owes a > $0 rebate	No	No	Yes
Applicable percent reduction applied	75%	0%	0%

Note: CMS would "start the clock" with applicable period 1 if the request was granted for applicable period 1. In this example, the 75% reduction would apply to applicable period 1, even though there would be no rebate amount in the applicable period to which the reduction applies.

We believe this clarification helps ensure clarity on CMS' policy in applying rebate reductions, which is intended to provide appropriate financial relief to a manufacturer experiencing a severe supply chain disruption while limiting opportunities for manufacturers to plan future price increases to coincide with the application of the reduction. If the reduction is applied to an applicable period in which there is no rebate amount to reduce, the manufacturer could still apply for an extension of the reduction, which would apply to the following applicable period.

In this final rule, we are also providing further clarification to the policy in the CY 2025 PFS proposed rule intended to address situations in which CMS grants a severe supply chain disruption rebate reduction request for a generic Part D rebatable drug or biosimilar, and the generic drug or biosimilar appears as currently in shortage during the same applicable period as for which the severe supply chain disruption rebate reduction was granted. This clarification is described in the next section in response to a comment regarding application of likely to be in shortage reductions.

iv. Reducing the Rebate Amount for Generic Part D Rebatable Drugs Likely To Be in Shortage

At § 428.303, we proposed to codify the policy established in section 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance for rebate reductions when a generic Part D rebatable drug is likely to be in shortage, as defined at § 428.300. We proposed at § 428.303(b)(1), to provide a time-limited standard reduction of 75 percent in the total rebate amount for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage. We proposed that to receive a rebate

reduction in accordance with § 428.303(b)(1), the manufacturer will have to submit to CMS a rebate reduction request that meets the eligibility requirements at § 428.303(c). A rebate reduction request should specify each NDC–11 to which the request applies and if CMS grants a manufacturer's likely to be in shortage rebate reduction request for an NDC–11, we proposed at § 428.303(b)(3) that the rebate reduction will apply to the entire generic Part D rebatable drug at the NDC–9 level. We refer manufacturers to the collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction requests.

We proposed at § 428.303(c)(4) to grant a reduction in the rebate amount owed if a manufacturer of an eligible drug submits to CMS a request in writing demonstrating that (1) the generic Part D rebatable drug is likely to be in shortage, (2) the manufacturer is taking actions to avoid the potential drug shortage, and (3) the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list. We proposed at § 428.303(c)(2) that a manufacturer must submit the rebate reduction request before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage in order for CMS to consider a rebate reduction.

We proposed that if the manufacturer makes a timely request that includes all the supporting documentation, and CMS determines, based on its review of the reduction request and supporting documentation, that a reduction should be granted, CMS will reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug for the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request.

We proposed at § 428.303(c)(5) that if a manufacturer believes the potential drug shortage continues for a second, consecutive applicable period, the manufacturer may request a reduction of the total rebate amount for that second applicable period by submitting a rebate reduction extension request to CMS, along with any new supporting documentation. We refer manufacturers to the collection of information approved under OMB control number 0938–1474, for further instructions for submitting rebate reduction extension requests. As proposed at § 428.303(c)(5)(ii), a rebate reduction extension request and any new supporting documentation must be submitted at least 60 calendar days before the start of the second applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage in order for CMS to consider a rebate reduction extension.

We further proposed that if a manufacturer submits a complete and timely extension request, and CMS determines that the information submitted warrants an extension of the rebate reduction, the total rebate amount would be reduced by 75 percent for a second consecutive applicable period for that manufacturer's generic Part D rebatable drug in accordance with § 428.303(b)(2).

Consistent with the policies established in section 40.5.3 of the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed at § 428.303(c)(5) that a manufacturer may receive only one extension of the rebate reduction per generic Part D rebatable drug per CMS determination of likelihood of shortage. Said differently, CMS will limit the likely to be in shortage rebate reduction to two consecutive applicable periods total per generic Part D rebatable drug per CMS determination of likelihood of shortage.

At § 428.303(b)(4), we proposed that if CMS grants a rebate reduction request for a generic Part D rebatable drug that is likely to be in shortage, and the drug appears as currently in shortage during the same applicable period as the one for which the likely to be in shortage reduction request was granted, CMS will apply the 75 percent reduction to the entire applicable period for which the likely to be in shortage request was granted and would not grant any additional reduction for the shortage status during that applicable period. For any subsequent applicable periods that the generic Part D rebatable drug appears as currently in shortage, CMS will reduce the total rebate amount in accordance with the drug shortage reduction proposed at § 428.301, starting with the highest reduction (that is, 75 percent for a generic Part D rebatable drug). For example, as stated in the CY 2025 PFS proposed rule (89 FR 61977), if CMS grants a likely to be in shortage rebate reduction request for a generic Part D rebatable drug that was submitted on August 15, 2024, and that generic Part D rebatable drug is currently in shortage from September 15, 2025, until May 15, 2026, CMS would apply a 75 percent reduction in the total rebate amount for the duration of the applicable period for which the likely to be in shortage rebate reduction request was granted (that is, October 1, 2024, to September 30, 2025), and then would apply the shortage reduction at § 428.301, beginning with a reduction of 75 percent for a generic Part D rebatable drug for the applicable period beginning October 1, 2025.

We proposed that if the manufacturer of a generic Part D rebatable drug that is currently in shortage believes such generic drug is likely to continue to be in shortage in the next applicable period, the manufacturer may submit a likely to be in shortage rebate reduction request to CMS. If the request meets the criteria described at § 428.303(c)(4), CMS will reduce the total rebate amount owed by a manufacturer by 75 percent for the manufacturer's generic Part D rebatable drug. Consistent with the evaluation criteria at § 428.303(c)(4), we do not intend to consider a generic Part D rebatable drug as likely to be in shortage based solely upon the drug being currently in shortage. However, if the manufacturer believes there are circumstances that may exacerbate the current shortage such that without the reduction the generic Part D rebatable drug is likely to be in shortage in the next applicable period, the manufacturer may reflect such circumstances in its rebate reduction request. As described in the example in the CY 2025 PFS proposed rule (89 FR 61977), if a generic Part D rebatable drug is currently in shortage during the applicable period beginning October 1, 2023 because the manufacturer had trouble meeting demand for the drug and then in August 2024, the manufacturer faces difficulties securing the API for such drug and believes this may worsen the shortage situation and result in the generic Part D rebatable drug being currently in shortage in the next applicable period, the manufacturer may submit a likely to be in shortage rebate reduction request to CMS providing information on the severity of the likely shortage.

At § 428.303(c)(6), we proposed to review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024. If a manufacturer's rebate reduction request does not meet the criteria at § 428.303(c)(4) or if the rebate reduction request is incomplete or untimely based on the requirements at § 428.303(c), we proposed that CMS will deny the request. We also proposed that if a manufacturer's rebate reduction extension request does not meet the criteria at § 428.303(c)(5), is incomplete or untimely based on the requirements at § 428.303(c)(5), or if a reduction under § 428.303(b)(1) was not provided for such generic Part D rebatable drug,

CMS will deny the rebate reduction extension request. At § 428.303(c)(6)(iii), we proposed that CMS' decisions to deny a request will be final and not be subject to an appeals process.

At § 428.303(c)(7), we proposed CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. We proposed that information provided as part of a likely to be in shortage rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information would be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 or 4 of FOIA. In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter requested CMS clarify how it will determine if a drug is likely to be in shortage during a subsequent applicable period. This commenter stated that one predictor of a drug vulnerable to shortage is a previous shortage and recommended CMS treat generic drugs exiting a shortage as being at risk of shortage and that CMS provide a transitional period of a gradually declining rebate reduction (that is, 75 percent in the first quarter, 50 percent in the second quarter, etc.).

Response: We thank the commenter for their recommendation. Consistent with the policy described in the CY 2025 PFS proposed rule (89 FR 61977), CMS does not intend to consider a generic drug as likely to be in shortage based solely upon the drug being currently in shortage. However, if a manufacturer believes there are circumstances that may exacerbate a current shortage such that without the rebate reduction the generic drug is likely to be in shortage in the next applicable period, the manufacturer may reflect such circumstances in its rebate reduction request.

If a generic drug is granted a likely to be in shortage reduction for an applicable period and such drug is currently in shortage in the following applicable period, CMS will apply the gradually declining reduction in the rebate amount under the shortage policy set forth in § 428.301 for the subsequent applicable periods in which such drug is currently in shortage. As described in the example in the CY 2025 PFS proposed rule (89 FR 61977), if CMS receives a likely to be in shortage rebate reduction request for a generic Part D rebatable drug that was submitted on August 15, 2024, and that generic Part D rebatable drug is currently in shortage from September 15, 2025, until May 15, 2028, CMS will apply a 75 percent reduction in the total rebate amount for the duration of the applicable period for which the likely to be in shortage rebate reduction request was granted (that is, October 1, 2024, to September 30, 2025), and then would apply the shortage reduction as set forth in § 428.301, beginning with a reduction of 75 percent for a generic Part D rebatable drug for the applicable period beginning October 1, 2025, followed by a reduction of 50 percent for the applicable period beginning October 1, 2026, and a 25 percent reduction for the applicable period beginning October 1, 2027.

In response to this comment, we are also providing further clarification to the policy in the proposed rule intended to address situations in which CMS grants a likely to be in shortage rebate reduction request for a generic Part D rebatable drug, and the drug appears as currently in shortage during the same applicable period as for which the likely to be in shortage rebate reduction was granted. First, we are providing a second, modified version of the example above to reflect a situation in which the likely to be in shortage rebate reduction is granted for the same applicable period as the generic Part D rebatable drug is currently in shortage, and the application of the shortage reduction precedes application of the likely to be in shortage reduction. For example, if CMS receives a likely to be in shortage rebate reduction request for a generic drug on August 15, 2024, and the generic drug is currently in shortage beginning September 15, 2024 instead of September 15, 2025 and until May 15, 2028, CMS would apply a 75 percent reduction under the shortage policy for the applicable period that begins October 1, 2023. CMS would then apply the likely to be in shortage rebate reduction of 75 percent for the applicable that begins on October 1, 2024, followed by a shortage reduction of 25 percent for the applicable periods that begin October 1, 2025, October 1, 2026, and October 1, 2027. In this example, if the generic Part D rebatable drug was currently in shortage prior to receiving the likely to be in shortage reduction and was granted a reduction under the shortages policy set forth in § 428.301 for that applicable period prior to receiving the likely to be in shortage reduction, the declining reduction in the rebate amount will continue for any subsequent applicable periods in which the drug is currently in shortage, as summarized in Table 63. For consistency, CMS is adopting the same approach for situations in which a generic Part D rebatable drug or biosimilar is currently in shortage prior to and following a severe supply chain disruption. That is, if a generic Part D rebatable drug that is currently in shortage from September 15, 2025, until May 15, 2028 receives a 75 percent reduction under the shortages policy for the applicable period that begins October 1, 2024, receives a 75 percent reduction under the severe supply chain disruption policy for the applicable period beginning October 1, 2025, then CMS would apply a shortage reduction percentage of 25 percent to the applicable periods beginning October 1, 2026 and October 1, 2027. For alignment with the Medicare Part D Drug Inflation Rebate Program, we have included parallel clarifications in the Part B rebate section of this final rule.

TABLE 63: Shortage Reductions Continuing after a Likely to be in Shortage or Severe Supply Chain Disruption Reduction for a Generic Part D Rebatable Drug

	Example 1	Example 2
Applicable period beginning October 1, 2023	Not applicable	75% (shortage reduction)
Applicable period beginning October 1, 2024	75% (likely to be in shortage or severe supply chain disruption reduction)	75% (likely to be in shortage or **severe supply chain disruption** reduction)
Applicable period beginning October 1, 2025	75% (shortage reduction)	25% (shortage reduction)
Applicable period beginning October 1, 2026	50% (shortage reduction)	25% (shortage reduction)
Applicable period beginning October 1, 2027	25% (shortage reduction)	25% (shortage reduction)

Note: This table illustrates the application of the initial likely to be in shortage and severe supply chain disruption rebate reductions. A manufacturer may still apply for a rebate reduction extension request. Example 1 illustrates the application of the rebate reduction for a generic drug when a likely shortage or severe supply chain disruption precedes a shortage, and the likely to be in shortage or severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of an applicable period. Example 2 illustrates the application of the rebate reduction for a generic drug when the likely to be in shortage or severe supply chain disruption rebate reduction request is submitted less than 60 days before the end of an applicable period for a generic drug that is currently in shortage during the same applicable period as in which the request is submitted.

We believe this clarification is consistent with the policy set forth in §§ 428.302(b)(4) and 428.303(b)(4) whereby CMS will not apply multiple rebate reductions for the same Part D rebatable drug and applicable period. If CMS instead applied the shortage reduction beginning with the first applicable period in which a drug is in shortage (that is, applying the shortage reduction for the days beginning September 15, 2025 through September 30, 2025 for the first applicable period the drug is in shortage in the example above), this would result in CMS applying both the shortage reduction at § 428.301 and the likely to be in shortage reduction at § 428.303 or the severe supply chain disruption reduction at § 428.302 for the same drug for the same applicable period (that is, the applicable period beginning October 1, 2024 through September 30, 2025). We believe this clarification is also consistent with the policy articulated in the proposed rule and throughout this final rule to continue the shortage reduction clock once it begins in other scenarios such as for drugs that fluctuate on and off the shortage list within a timespan less than a full applicable period. Further, we believe this approach is consistent with CMS' policy goals of providing a time-limited standard reduction of 75 percent in the rebate amount when there is a severe supply chain disruption or likely shortage, which supersede the reduction under the shortage policy to mitigate the likelihood or severity of a shortage, and providing gradually decreasing financial relief to manufacturers for a drug currently in shortage. We believe transitioning the manufacturer from the severe supply chain disruption reduction or the likely to be in shortage reduction to the shortage reduction, by beginning the shortage reduction clock as set forth in § 428.301(b)(2)(i)(A) or (b)(2)(ii)(A) after the severe supply chain disruption reduction or likely to be in shortage reduction no longer applies, and gradually declining the rebate reduction over time could help prevent exacerbation of the shortage. Because the timing of the application of a severe supply chain disruption or likely to be in shortage rebate reduction depends on the timing of submission of the rebate reduction request, the highest reduction under the shortages policy may be applied for an applicable period that precedes or follows the severe supply chain disruption or likely to be in shortage reduction. CMS will not start the shortage reduction clock during an applicable period subject to a severe supply chain disruption reduction or a likely to be in shortage reduction as set forth in § 428.301(b)(2)(iv), but intends to continue the shortage reduction clock once it starts for as long as a drug is currently in shortage.

After consideration of comments received, we are finalizing this policy as proposed § 428.303, with a modification. For alignment with language in the preamble of the CY 2025 PFS proposed rule (89 FR 61977) and the clarification made to § 428.302(b)(1) as described above, we have clarified in this final rule at § 428.303(b)(1) that CMS will apply a likely to be in shortage rebate reduction to the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request. CMS will not delay the application of the reduction until the generic drug meets the definition of a Part D rebatable drug or until a rebate amount is owed for such drug. For example, as shown in Table 64, if CMS grants a likely to be in shortage rebate reduction request for a generic Part D drug for an applicable period, CMS will apply the rebate reduction beginning with the applicable period for which the reduction request was granted, regardless of whether the drug meets the definition of a Part D rebatable drug or is subject to a rebate amount.

TABLE 64: Application of Likely to be in Shortage Reduction

	Applicable period 1	Applicable period 2	Applicable period 3
Meets definition of Part D rebatable drug	No	Yes	Yes
Owes a > $0 rebate	No	No	Yes
Applicable percent reduction applied	75%	0%	0%

Note: CMS would "start the clock" with applicable period 1 if the request was granted for applicable period 1. In this example, the 75 percent reduction would apply to applicable period 1, even though there would be no rebate amount in applicable period 1 to which it applies.

We believe this clarification helps ensure clarity on CMS' policy in applying rebate reductions, which is intended to provide appropriate financial relief to a manufacturer experiencing a potential shortage while limiting opportunities for manufacturers to plan future price increases to coincide with the application of the reduction. If the reduction is applied to an applicable period in which there is no rebate amount to reduce, the manufacturer could still apply for an extension of the reduction, which would apply to the following applicable period.

e. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments (§§ 428.400 Through 428.405)

Section 1860D–14B(a)(1) of the Act requires the Secretary to report to each manufacturer of a Part D rebatable drug the following information not later than 9 months after the end of the applicable period: (1) the amount, if any, of the excess AnMP increase described in section 1860D–14B(b)(1)(A)(ii) of the Act for each Part D rebatable drug and (2) the rebate amount for each Part D rebatable drug. In compliance with section 1860D–14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug must provide a rebate for each Part D rebatable drug no later than 30 calendar days after the receipt of the information provided by the Secretary in section 1860D–14B(a)(1) of the Act.

To fulfill this statutory requirement, we proposed to send a Preliminary Rebate Report followed by a Rebate Report, as set forth in § 428.401(b) and (c), to all manufacturers of a Part D rebatable drug, even if the amount due is $0; all rebate amounts would be subject to reconciliation as set forth in § 428.401(d). As proposed at § 428.401(b), CMS will not send notice to manufacturers for drugs that are not considered rebatable under proposed § 428.20.

Additionally, section 1860D–14B(b)(6) of the Act states that CMS shall provide a method and process under which CMS adjusts the calculation of the rebate amount for a Part D rebatable drug for an applicable period if CMS determines such an adjustment is necessary based on revisions to the number of units of a rebatable covered Part D drug dispensed submitted by a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan. The statute also specifies that CMS must reconcile any underpayments in the rebate amount paid by the manufacturer of the applicable Part D rebatable drug due to such an adjustment and underpayments must be paid no later than 30 days from the date of receipt of information from CMS about the adjustment. To fulfill this statutory obligation and to address the completeness and accuracy of the rebate amount, we proposed to conduct regular reconciliations at two points in time to determine whether the rebate amount must be adjusted due to updated claims and payment data used in the calculation of such rebate amount (specified at § 428.401(d)(1)): (1) 12 months after the issuance of the Rebate Report, and (2) 36 months after the issuance of the Rebate Report. As discussed in the CY 2025 PFS proposed rule (89 FR 61980–61981), the reporting process for each reconciliation will be the same process described for the original Rebate Report, with payment due for any outstanding rebate amount 30 days after receipt of a report with a reconciled rebate amount. In addition to regular reconciliations, we proposed a process to conduct reconciliations of the rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a rebate amount was inaccurate due to manufacturer misreporting.

Comments regarding Reports of Rebate Amounts, Suggestion of Error, Reconciliation of a Rebate Amount, and Enforcement of Manufacturer Payment of Rebate Amounts that are applicable to both Part B rebatable drugs and Part D rebatable drugs (for example, comments recommending that the Suggestion of Error period be extended) are summarized in the Part B drug inflation rebate section of this final rule. Comments specific to the Medicare Part D Drug Inflation Rebate Program on the aforementioned topics are summarized later in this section.

i. Definitions

As set forth in § 428.400, we proposed to define the following term applicable to subpart E (§§ 428.400 through 428.405):

- ''Date of receipt'' is the calendar day following the day in which a report of a rebate amount (as set forth in §§ 428.401(b), (c), and (d) and 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS.

For example, if CMS issues a Rebate Report through the method and process described in proposed § 428.404 on June 30, 2026, then July 1, 2026, will be the date of receipt and day one of the 30-calendar-day payment period.

We did not receive public comments on this proposed definition, and we are finalizing as proposed in § 428.400.

ii. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance involving preliminary and final reports, we proposed to codify a multi-step process to provide a manufacturer as set forth in § 428.20 with the rebate information specified under section 1860D–14B(a) of the Act. As stated in the CY 2025 PFS proposed rule (89 FR 61981), we considered the following factors in determining a method and process for providing the rebate information: meeting statutorily provided deadlines in section 1860D–14B(a) of the Act (for example, dates by which to provide the rebate amount owed to the manufacturer); the operational time to acquire the relevant information specified in part 428; the operational time to calculate the rebate amount specified in subparts B and C of part 428; clarity of the information provided as well as potential burden on manufacturers; and how to ensure the accuracy of the rebate amount.

We proposed at § 428.401 the use of an initial Preliminary Rebate Report and a subsequent Rebate Report, with an

opportunity for manufacturers to identify certain mathematical errors (see § 428.403 and discussed in further detail later in this section) and two regular reconciliations of the rebate amount to account for updates to claims and payment data at 12 months and 36 months after the Rebate Report is issued as set forth in § 428.401(d).

We proposed at § 428.401 that the multi-step reporting process for providing rebate information to a manufacturer would include: (1) an initial report, which we proposed to entitle the ''Preliminary Rebate Report'' as set forth in § 428.401(b) and (2) a second report, which we proposed to entitle the ''Rebate Report'' as set forth in § 428.401(c). The Rebate Report would serve as the invoice for the rebate amount due, if any, for each product determined to be a Part D rebatable drug for the applicable period, as set forth in § 428.101. We stated in the CY 2025 PFS proposed rule (89 FR 61981) that manufacturers of Part D rebatable drugs would receive a Rebate Report for their rebatable drugs even if the amount due is $0. We proposed at § 428.401(d)(1) two regular reconciliations of the rebate amount to occur 12 months and 36 months after issuance of the subsequent Rebate Report as set forth in § 428.401(c), which will include restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the rebate calculation specified in subpart C of this part.

As we described in the CY 2025 PFS proposed rule (89 FR 61981), as the first step in the reporting process, as proposed at § 428.401(b) and consistent with section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, CMS will provide each manufacturer of a Part D rebatable drug with the preliminary rebate amount through a Preliminary Rebate Report at least 1 month prior to the issuance of the Rebate Report as set forth in § 428.401(c) for an applicable period (that is, approximately 8 months after the end of the applicable period unless otherwise specified). To facilitate manufacturer understanding of the Preliminary Rebate Report, we proposed at § 428.401(b)(1) that the Preliminary Rebate Report will include the following information: the NDC(s) for the Part D rebatable drug as determined under § 428.20; the total number of units for the Part D rebatable drug for the applicable period as determined under § 428.203 (which will remove units when a generic drug is no longer a Part D rebatable drug as determined under § 428.203(b)(1) and will exclude units acquired through the 340B Program as determined under § 428.203(b)(2)); the benchmark period manufacturer price as determined under § 428.202(d); the AnMP for the Part D rebatable drug for the applicable period as determined under § 428.202(b); the applicable benchmark period and applicable period CPI–Us as determined under §§ 428.202(e) and 428.20; the inflation-adjusted payment amount as determined under § 428.202(f); the amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period as determined under § 428.202(a); any applied reductions as determined under §§ 428.301, 428.302, and 428.303; and the rebate amount due as determined under § 428.201(a). As proposed under § 428.204, in cases where a Part D rebatable drug is a line extension, we proposed to include the same elements described above in the Preliminary Rebate Report as well as: the NDC for the initial drug; the inflation rebate amount ratio for the initial drug; and the alternative rebate amount (see § 428.401(b)(2)).

In the CY 2025 PFS proposed rule (89 FR 61979), we stated that when determining what information should be included on rebate reports, we considered the statutory requirements outlined in section 1860D–14B(a)(1) of the Act to determine which data elements are necessary to review the Preliminary Rebate Report for error (described later in this section) and to protect proprietary information. In response to comments on the initial Medicare Part D Drug Inflation Rebate Guidance, we proposed to disclose data elements as suggested by interested parties that are not enumerated in the statute, such as NDCs for Part D rebatable drugs and the applicable period CPI–U. We acknowledged requests from interested parties to provide additional data elements including claim-level data such as days' supply, fill number, and prescription ID number on rebate reports that are not included in this proposal. We considered these requests in development of the proposed rule but do not believe it necessary to provide this further information to fulfill CMS' statutory obligation and believe that the potential benefit to manufacturers of additional data are outweighed by the administrative burdens additional reporting would impose to the agency. We also stated that the elements listed previously provide sufficient information for a manufacturer to review the Preliminary Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide. At § 428.203(b)(2)(i)(A) and (B), we proposed CMS will exclude 340B units beginning with January 1, 2026, which is the second calendar quarter in the applicable period starting October 1, 2025, and beyond (as discussed in further detail in section III.I.3.c.iv.2. of this final rule). We proposed this exclusion applies to all Preliminary Rebate Reports, Rebate Reports, and reconciliations of a rebate amount that include the applicable period starting with October 1, 2025, and beyond with claims for service dates on or after January 1, 2026. As such, 340B units would not be excluded from the Rebate Reports for the applicable periods beginning October 1, 2022, October 1, 2023, and October 1, 2024, as determined under § 428.402.

As stated in the CY 2025 PFS proposed rule (89 FR 61979), by structuring the Rebate Report process to include a Preliminary Rebate Report before the Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary Rebate Report before the rebate amount is invoiced via the Rebate Report. While CMS is not required to provide a preliminary report, we stated in the proposed rule that we seek to facilitate manufacturer understanding of the Rebate Report and believes it would be beneficial for manufacturers to review the report for mathematical errors that could be corrected before invoicing via the Rebate Report. Further, a Preliminary Rebate Report would provide additional notice to manufacturers regarding whether they may owe a rebate amount.

At § 428.403, we proposed a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary Rebate Report. For example, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error; the Suggestion of Error would be due at 11:59 p.m. PT on June 10, 2026, in this example. We reviewed comments on the 10-day Suggestion of Error period submitted in response to the initial Medicare Part D Drug Inflation Rebate Guidance, many of which suggested that manufacturers receive at least 30 days to review the Preliminary Rebate Report. We considered a 10-day, 15-day, and 30-day Suggestion of Error period and believes a 10-calendar-day period as (see § 428.403(c)) is sufficient after considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as

a Suggestion of Error, and the operational time necessary for CMS to provide a Rebate Report within 9 months of the end of the applicable period as required under section 1860D–14B(a)(1) of the Act. However, we proposed at § 428.402(c)(1)(i) to expand the Suggestion of Error period to 30 calendar days for the Preliminary Rebate Reports for the first two applicable periods (beginning October 1, 2022, and October 1, 2023). As explained in the CY 2025 PFS proposed rule (89 FR 61979), this extended Suggestion of Error period will provide additional time and flexibility during the first invoicing cycle of the Medicare Part D Drug Inflation Rebate Program.

Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units, whether a drug is a Part D rebatable drug, and the calculation of the rebate amount (see § 428.403(a)(1)). Therefore, we stated in the CY 2025 PFS proposed rule (89 FR 61980) that the Suggestion of Error process will be limited to mathematical steps involved in determining the rebate amount and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Additionally, we stated in the proposed rule that we will not provide an administrative dispute resolution process. We intend to consider all in-scope submissions under the Suggestion of Error process (for example, suggestions regarding a mathematical error) as set forth in § 428.403(a). We do not intend to review suggestions of error that are out-of-scope or submissions for a rebatable drug with an amount due of $0.

As the second step in the reporting process, we proposed at § 428.401(c) to provide the rebate amount to the manufacturer through the Rebate Report no later than 9 months after the end of the applicable period. As proposed at § 428.401(c)(1), the Rebate Report would include the same data elements as the Preliminary Rebate Report (as set forth in § 428.401(b)(1)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error as set forth in § 428.403, or any CMS-determined recalculations as set forth in § 428.401(d)(2), if applicable. Manufacturers must pay the rebate amount within 30 calendar days from the date of receipt of the Rebate Report (see § 428.405(a)). For example, if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.

At §§ 428.404 and 428.405, we proposed to establish a standard method and process to issue Rebate Reports and accept manufacturer rebate payments. This method and process may include an online portal administered by a CMS contractor which would provide manufacturers with access to their Rebate Report, the ability to submit a Suggestions of Error, and pay a rebate amount due. We intend to provide technical instructions separate from this rulemaking to manufacturers of Part D rebatable drugs regarding how to access Rebate Reports and how to receive notifications alerting the manufacturer when information is available. We stated in the CY 2025 PFS proposed rule (89 FR 61980) that CMS also intends to issue reminder notices to manufacturers regarding the due date of rebate payments. At § 428.404(a), we noted that the manufacturer that may access Rebate Reports and make applicable rebate amount payments is the manufacturer responsible for paying a rebate, and as stated above, we proposed to identify the manufacturer that is responsible for paying a rebate using the same approach used for reporting AMP data.

We received public comments on these proposals. Because the comments received are applicable to both the Medicare Part B and Part D Drug Inflation Rebate Programs, please refer to the corresponding section in Part B for a summary of comments and our responses on this topic.

After consideration of public comments, we are finalizing § 428.401 as proposed, with modification. In this final rule, we are revising § 428.401(b)(iii) and § 428.401(d)(i)(B) to reflect that the Rebate Reports shall include the payment amount benchmark period, in addition to the benchmark period manufacturer price, and the corresponding cross-reference at § 428.202(c) to identify both the payment amount benchmark period and the price in the benchmark period within the report information.

iii. Reconciliation of a Rebate Amount

As discussed in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, we considered options consistent with section 1860D–14B(b)(6) of the Act to establish a method and process to determine adjustment to the rebate amount in the case of a Part D plan sponsor submitting revisions to the number of units of a Part D rebatable drug. As is also discussed in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, we considered options for establishing a standardized method and process at regular intervals to determinate any appropriate adjustments to the rebate amount for a Part D rebatable drug for an applicable period to account for additional revised information as well as options for recalculation based on CMS identifying an agency error or determining manufacturer data was misreported. We proposed policies for reconciliation, including with respect to enforcement of payment of any reconciled rebate amount, consistent with both the statutory framework for the Medicare Part D Drug Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Prescription Drug Inflation Rebate Program.

As proposed at § 428.401(d), we noted in the CY 2025 PFS proposed rule (89 FR 61980) that we believe that it is necessary and appropriate for CMS to recalculate the rebate amount for an applicable period at regular intervals to include updated information about key data elements included in the calculation of the rebate amount, not limited to those data described in section 1860D–14B(b)(6) of the Act. These data elements as set forth in § 428.401(d)(1)(i) include: total units; the benchmark period manufacturer price; the payment amount in the payment amount benchmark period; the AnMP; and updated data on line extension calculations. Updating these calculation inputs at regular reconciliation intervals will result in a rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of PDE records in CMS' internal PDE database. Because the information extracted represents the PDE records' status in CMS' internal PDE database at that moment in time, additional run-out may yield different information, either because more PDE records with dispensing dates during the applicable period were finalized and added to the database or because the status of the existing PDE records changed. CMS refers to ''X months of run-out'' as the period between the end of the applicable period and the date when CMS accesses information about the PDE records; for example, ''3 months of run-out'' means that PDE records are accessed for PDE records with dispensing dates during an applicable period 3 months after the end of such applicable period. Conducting a reconciliation of the rebate amount with additional claims run-out will improve the accuracy of the rebate amount.

Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of the payment amounts in other CMS programs (such as the Coverage Gap Discount Program) that provide for a reconciliation period.

As noted in the CY 2025 PFS proposed rule (89 FR 61980), the reconciliation of a rebate amount, whether during a reconciliation as set forth in § 428.401(d)(1) or a discretionary reconciliation as set forth in § 428.401(d)(2) discussed further below, will not create a separately payable and distinct rebate amount. Rather, reconciliation updates the prior rebate amount owed to CMS, if any, by a manufacturer of a Part D rebatable drug so that the rebate amount ultimately reflects a more precise calculation of the rebate amount, as required by section 1860D–14B(a)(1) of the Act, to account for shifts in the underlying data following additional time for claims run-out after the Rebate Report is issued as well as subsequently identified data integrity issues. Moreover, because the reconciled rebate amount is an adjustment of the prior rebate amount, we proposed at § 428.405(a)(1) for a report of a reconciled rebate amount to also identify the difference between the rebate amount due as specified on the Rebate Report set forth in § 428.401(c) and the reconciled rebate amount. We noted in the proposed rule that CMS will only collect the net rebate amount due, if any, upon reconciliation, so as to prevent any duplicate payments. We also proposed to refund any overpayment made by a manufacturer, as determined during reconciliation, as set forth in § 428.405(b).

Additionally, as suggested in section 50 of the revised Medicare Part D Drug Inflation Rebate Guidance, we considered multiple options for establishing a standardized method and process to occur at regular intervals to determine an appropriate adjustment to the rebate amount for a Part D rebatable drug for an applicable period to account for revised information prior to proposing the policy described here for two proposed regular reconciliations of the Part D inflation rebate amount. We considered the length of time needed to capture relevant changes to data inputs for recalculation, whether the timing should align with the reconciliation of Part B rebate amounts, and manufacturer burden. Specifically, we considered the average time span needed to ensure submission of the majority of Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act, and the average time span needed for the submission of the majority of manufacturer restatements of AMP data. We also considered the 36-month period provided by MDRP for AMP restatements as determined under § 447.510(d)(3) of this title and whether consistency among program reconciliation timelines is beneficial.

As stated in the proposed rule, we believe a longer period of claims run-out (at least 12 and 36 months of run-out time in the proposed approach) would ensure that CMS more fully accounts for capturing of revised units. Further, the first reconciliation would be performed to include at least 13 months of claims run-out for the applicable period and would be issued 12 months after the Rebate Report for the same applicable period. The second reconciliation would include 37 months of claims run-out for the applicable period and would be issued 36 months after the Rebate Report for the same applicable period. The first reconciliation, issued 12 months after the Rebate Report, would provide sufficient time to capture the majority of updates to the data determined under § 428.401(b)(1). The second reconciliation, to be issued 36 months after the Rebate Report, is sufficient to capture the remainder of the run-out for MDRP AMP restatements (that do not require CMS review as set forth in § 447.510) while also closing out the calculation of the rebate amount for a Part D rebatable drug for an applicable period within a reasonable time period after the Rebate Report is issued (except for the circumstances set forth in § 428.401(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting).

Further, as discussed in the CY 2025 PFS proposed rule (89 FR 61981), in considering whether consistency across CMS programs is critical, we believe that consideration for the completeness of data, as discussed above, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the rebate amount, we prioritized that, to the extent feasible, completeness and accuracy of the data elements contributing to the calculation of the rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. Finally, we noted in the proposed rule that we believe that solely updating total units without updating other elements of the rebate calculation would lead to an inaccurate rebate amount, and therefore proposed to update additional calculation inputs as determined under § 428.401(d)(1)(i)(A) through (F). We believe that a restatement of each data element determined under § 428.401(d)(1) to reconcile the rebate amount provided in the Rebate Report set forth in § 428.401(c) is appropriate to capture an updated rebate amount and is in line with other CMS programs that provide for a reconciliation period. While some data points may not change, we proposed to review the data to determine if there are any updates in the data and use the updated data in the reconciliation to provide a reconciled rebate amount to the manufacturer.

Based on these considerations, similar to the multi-step process for the Rebate Report set forth in § 428.401(b) and (c), we proposed a multi-step process to provide each manufacturer of a Part D rebatable drug with a reconciled rebate amount on a regular basis. At both the 12-month reconciliation point and the 36-month reconciliation point, we proposed a reconciliation process that will include: (1) a preliminary reconciliation of the rebate amount, which CMS will provide to manufacturers of Part D rebatable drugs as set forth in § 428.401(d)(1)(i) and (d)(2) a reconciled rebate amount, which CMS will provide to manufacturers of a Part D rebatable drug as set forth in § 428.401(d)(1)(ii). We also proposed to apply the Suggestion of Error process as set forth in § 428.403 to each preliminary reconciliation.

In detail, first, as set forth in § 428.401(d) and similar to the Preliminary Rebate Report process set forth in § 428.401(b), for each reconciliation we proposed to provide the manufacturer with information about the preliminary reconciliation of the rebate amount at least 1 month prior to the issuance of the reconciled rebate amount (see § 428.401(d)) to each manufacturer of a Part D rebatable drug for an applicable period. We proposed at § 428.401(d)(1) that the preliminary reconciliation will include, at a minimum, the same information outlined for the Rebate Report and the following updated information, if applicable: updated total number of rebatable units, including updates submitted by a PDP or MA–PD plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods determined under § 428.203(b)(2)(i)(A) and (B)), or units otherwise excluded as determined under § 428.203(b); the benchmark period manufacturer price if any inputs are restated within the reconciliation run-out period as determined under § 428.202(d); the AnMP if any inputs are restated within the reconciliation run-out period as determined under § 428.202(b); the excess amount by which the AnMP exceeds the inflation-

adjusted payment amount for the applicable period as determined under § 428.202(a), using the most recent AMP (if any inputs are restated within the reconciliation run-out period); updated data on line extension calculations, including the initial drug identified in accordance with § 447.509(a)(4)(iii)(B), the inflation rebate amount ratio, and the alternative total rebate amount as set forth at § 428.204 if any inputs are restated within the reconciliation run-out period; the reconciled rebate amount as set forth at § 428.201(a); and the difference between the total rebate amount due as specified on the Rebate Report set forth at § 428.201(a) and the reconciled rebate amount as set forth at § 428.201(a). We also noted that changes to status of 5i drugs (defined at § 447.507) are captured through AMP restatements.

As set forth in § 428.403(a), similar to the Suggestion of Error process proposed for the Preliminary Rebate Report set forth in § 428.401(b), within 10 calendar days after date of receipt of the information about the preliminary reconciliation of the rebate amount, we proposed that a manufacturer may suggest to CMS that the manufacturer believes the preliminary reconciliation of the rebate amount contains a mathematical error. As stated in the CY 2025 PFS proposed rule (89 FR 61981), we believe a 10-calendar-day period is sufficient due to the same considerations of data volume, the narrow set of in-scope items for review, and the operational time necessary for CMS to publish the reconciled rebate amount. The preclusions in section 1860D–14B(f) of the Act on administrative and judicial review apply to the reconciliation process.

Second, in detail, we proposed at § 428.401(d)(1)(ii) to provide a reconciled rebate amount to the manufacturer within 12 months and 36 months after the Rebate Report was issued for each applicable period. As set forth in § 428.401(d)(1)(ii), the information in the report for a reconciled rebate amount would include the same data elements as provided in the information provided to the manufacturer of a Part D rebatable drug regarding the preliminary reconciliation of a rebate amount (set forth in § 428.401(d)(1)(i)) and will include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error set forth in § 428.403. A reconciliation of the rebate amount may result in an increase, decrease, or no change to the rebate amount, compared to the Rebate Report for an applicable period or a previous reconciliation in the case of reconciliation conducted 36 months after issuance of the Rebate Report (see § 428.401(d)(3)).

Additionally, as suggested in section 50 the revised Medicare Part D Drug Inflation Rebate Guidance, we considered options for establishing circumstances where a recalculation of the rebate amount may be appropriate for an applicable period after issuing the Rebate Report and/or a reconciled rebate amount based on CMS identifying an error or CMS determining that the information used by CMS to calculate a rebate amount was inaccurate due to false reporting or similar fault by the manufacturer. We also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

As stated in the CY 2025 PFS proposed rule (89 FR 61982), based on these considerations, we believe that, to capture an accurate rebate amount and consistent with reconciliations of pricing data submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances merit reconciliation of the rebate amount separate from the 12- and 36-month reconciliations proposed at § 428.401(d)(1). Specifically, we proposed at § 428.401(d)(2) that CMS may reconcile a rebate amount of an issued Rebate Report when CMS identifies either: (1) an agency error such as a mathematical error or an error in the information specified in a Rebate Report as determined under § 428.401(c) or report of a reconciled rebate amount as determined under § 428.401(d), including reporting system or coding errors; or (2) CMS determines that information used to calculate the rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly calculating the billing units per Part D rebatable drug or the mechanism that provides a Rebate Report to the manufacturer or the Rebate Report incorrectly displays a rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the reporting individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate manufacturer pricing or product data under section 1927(b)(3) of the Act). This does not include standard restatements to AMP or other data outside of the standard process of issuing the reconciled rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS Office of Inspector General, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12- or 36-month reconciliation of the rebate amount set forth in § 428.401(d)(1), CMS may choose to include a correction based on the circumstances set forth in § 428.401(d)(2) concurrently with the 12- or 36-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, we proposed that the agency will limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the Rebate Report (set forth in § 428.401(c)) or the report of the reconciled rebate amount (set forth in § 428.401(d)) unless the correction directly impacts additional data fields. For example, corrections to an AMP file may not change the AnMP for the applicable period.

In addition, as noted in the CY 2025 PFS proposed rule (89 FR 61982), because reconciling a rebate amount imposes substantial administrative burden on CMS to reprocess the rebate amount, retest the reporting system, and reissue a Rebate Report, we proposed at § 428.401(d)(2) that CMS may exercise discretion not to initiate recalculation of the rebate amount in these situations which are outside of the regular reconciliation process proposed at § 428.401(d)(1).

We proposed that for a recalculation due to an agency error, the error must be identified within 5 years of the date of receipt of the Rebate Report for the applicable period (see § 428.401(d)(2)(i)). Identification means that CMS has knowledge the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the rebate amount within the 5-year period. CMS will timely complete these steps and determine, when reconciliation does impact the rebate amount, whether the reconciliation must be included in a discretionary revision or within an upcoming reconciled rebate amount for the applicable period. We proposed 5 years for Part D (as opposed to the 3-year limit proposed for Part B) to account for the additional time of the second reconciliation for Part D rebatable drugs to be conducted at 36-

months as set forth in § 428.401(d)(1). We stated in the proposed rule that we believe a 5-year period dating from the issuance of the Rebate Report allows for sufficient time to include AMP restatements in the MDRP while also placing a reasonable time limit on potential discretionary reconciliations, after which a manufacturer of a Part D rebatable drug will not receive additional Rebate Reports for the applicable period.

We proposed at § 428.401(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, CMS will not bound by the 5-year time limit for revision of the rebate amount. For example, if a determination is made that a manufacturer misreported AMP data, which affected the calculation of the AnMP, then CMS may recalculate the rebate amount owed for a Part D rebatable drug. We requested comments on the proposals related to manufacturer misreporting.

We proposed at § 428.405(a)(1) that upon receipt of a reconciled rebate amount, manufacturers must pay that reconciled rebate amount within 30 calendar days from the date of receipt of the reconciled rebate amount. A 30-day payment deadline aligns with the payment period set forth in statute at section 1860D–14B(b)(6) of the Act. As set forth in § 428.404, we will use the same method and process for issuing Rebate Reports and submission of payments for reports with a reconciled rebate amount. We state that we will provide notice to manufacturers for reports with a reconciled rebate amount. We proposed at § 428.405(b) that if a refund is owed to a manufacturer based on a reconciled rebate amount, we will initiate the process to issue such refund within 60 days from the date of receipt of the reconciled rebate amount (proposed at § 428.401(d)). CMS will issue additional information on this method and process through additional program communications.

We received public comments on these proposals. Please refer to the corresponding section in Part B for a summary of comments and our responses where the comments received are applicable to both the Medicare Part B and Medicare Part D Drug Inflation Rebate Programs. The following is a summary of the comments we received and our responses specific to this topic for the Medicare Part D Drug Inflation Rebate Program.

Comment: A few commenters expressed support for the proposed 12-month and 36-month reconciliation process. One commenter appreciated CMS having a reconciliation adjustment for underpayments and overpayments.

Response: We thank the commenters for their feedback. As part of the 12-month reconciliation, CMS will incorporate updates to the data as set forth in § 428.401(b)(1), and as set forth in § 428.401(d)(1). This will include any updates to AMP data that have been processed by CMS prior to the 12-month reconciliation and the 36-month reconciliation. We believe that having these reconciliation periods will capture the remainder of the run-out for MDRP AMP restatements and provide a more accurate rebate amount.

After consideration of public comments, we are finalizing § 428.401 as proposed, with modification. In this final rule, we are revising § 428.401(d)(1)(i)(C) to specify that the reconciliation will include updated payment amount benchmark period, in addition to the benchmark period manufacturer price, and the corresponding cross-reference as determined under § 428.202(c), to identify both the payment amount benchmark period and the price in the benchmark period within the report information. In this final rule, we also are revising § 428.401(b)(iii) and § 428.401(d)(1)(i)(B) to specify that the reconciliation will include any updated payment amount benchmark period, in addition to the benchmark period manufacturer price, and to clarify in §§ 428.401(d)(1)(i)(B), (D), and (E) that updates to inputs included in the reconciliation calculations will include newly reported information, in addition to restated AMP. We believe that these revisions provide further clarity regarding how CMS will conduct the reconciliation process, including in the event that AMP data are missing when CMS issues the Rebate Report for a Part D rebatable drug, and further implement CMS' proposals described in the proposed rule. For example, with respect to missing AMP policies, we proposed to consider any restatements to the AMP data used to calculate the benchmark period manufacturer price during reconciliation, including where the benchmark period manufacturer price is identified under §§ 428.202(c)(3) and (4). The revisions at § 428.401(b)(iii) and § 428.401(d)(1)(i)(B) make clear that in the event a manufacturer has not reported AMP for any quarters during the payment amount benchmark period determined under §§ 428.202(c)(1) and (2) at the time CMS issues the Rebate Report, including information such as base date AMP overlapping with such period, but the manufacturer later reports such information, CMS would use such later reported information to identify the payment amount benchmark period as determined under §§ 428.202(c)(1) and (2) and (d)(3), as well as calculate the benchmark period manufacturer price.

Similarly, with respect to Part D rebatable drugs excluded from Part D rebate calculations, we proposed to reexamine whether the manufacturer was required to report AMP for any part of the applicable period for the Part D rebatable drug when performing the reconciliation set forth in § 428.401(d). The revisions set forth in §§ 428.401(d)(1)(i)(B), (D), and (E) clarify that in the event CMS identifies a Part D rebatable drug as subject to exclusion from the Part D rebate calculations under § 428.201(b) at the time CMS issues the Rebate Report, but the manufacturer later reports information under the MDRP, CMS may use that later reported information such as AMP and base date AMP to calculate the inflation-adjusted payment amount and the excess amount by which the AnMP exceeds the inflation-adjusted payment amount for the applicable period, as well as any line extension calculations that may be affected by such newly reported information.

iv. Rebate Reports for the Applicable Periods Beginning October 1, 2022, and October 1, 2023

Section 1860D–14B(a)(3) of the Act provides CMS with the option to delay sending the information required by section 1860D–14B(a)(1) of the Act for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025. As set forth in § 428.402, consistent with section 50.2 of the revised Medicare Part D Drug Inflation Rebate Guidance, we proposed to issue a Preliminary Rebate Report for each applicable period followed by issuance of the Rebate Report for each applicable period no later than December 31, 2025. For these reports, we proposed at § 428.402 to provide an extended 30 calendar day Suggestion of Error period for these Preliminary Rebate Reports.

As stated in the CY 2025 PFS proposed rule (89 FR 61982), because this approach provides for 13 months of claims run-out for the Rebate Report for the applicable period beginning October 1, 2022, we intend to conduct a single reconciliation 21 months after issuance of the Rebate Report for this applicable period (see § 428.402(c)(1)(ii)). As set forth in § 428.402(c)(2)(ii), for the applicable period beginning October 1, 2023, the rebate amount would be reconciled twice, in alignment with the reconciliation process discussed previously. The first reconciliation

would occur 9 months after issuance of the Rebate Report to include 13 months of claims run-out and payment data; the second reconciliation will occur 24 months after the first reconciliation and will include 37 months of claims run-out and payment data. We stated in the proposed rule that this approach aligns claims and payment data run-out with the run-out used during a regular invoicing cycle. The Suggestion of Error period would be 10 calendar days for the reconciliations of the rebate amount for the applicable periods beginning October 1, 2022, and the applicable period beginning October 1, 2023.

As noted in the proposed rule, this approach also minimizes the number of reports issued to manufacturers as a result of the delay in reporting and simplifies payment procedures, thereby minimizing manufacturer burden. Starting with the applicable period beginning October 1, 2024, reporting will begin a standard cadence and follow the procedures otherwise proposed in subpart E of this part 428.

We did not receive public comments on this proposed provision, and we are finalizing § 428.402 as proposed.

f. Enforcement of Manufacturer Payment of Rebate Amounts (§ 428.500)

Section 1860D–14B(e) of the Act gives CMS the authority to impose a civil money penalty equal to 125 percent of the rebate amount for each drug for each applicable period on a manufacturer that fails to pay the rebate amount, for each dosage form and strength for each rebatable drug. Subpart F will implement this section of the Act and establish the procedures for determining and collecting a civil money penalty.

In accordance with sections 1860D–14B(a)(2) and 1860D–14B(b) of the Act and § 428.405(a), manufacturers must provide to CMS a rebate amount owed within 30 calendar days of receipt of the rebate amount due. As set forth in § 428.500(a), we proposed CMS may impose a civil money penalty when a manufacturer fails to pay the rebate amount in full by the payment deadlines set forth in § 428.405(a). This means a manufacturer may be subject to a civil money penalty if the manufacturer fails to pay the full rebate amount as invoiced in the Rebate Report or any reconciled rebate amount that is greater than the amount invoiced in the Rebate Report. More specifically, as described in the CY 2025 PFS proposed rule (89 FR 61983), a manufacturer could be subject to a civil money penalty when a manufacturer fails to pay a rebate amount due by any payment deadline set forth in § 428.405(a)(1), for: (1) a Rebate Report set forth in § 428.401(c); (2) a reconciled rebate amount greater than the amount reflected in the Rebate Report set forth in at § 428.401(d); or (3) a Rebate Report and a reconciled rebate amount greater than the amount reflected in the Rebate Report, if applicable, for the applicable periods beginning October 1, 2022, and October 1, 2023 set forth in § 428.402. As discussed earlier in section III.I.3.e. of this final rule, we noted that the reconciled or corrected rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled rebate amount is an update to the rebate amount owed to CMS by a manufacturer of a Part D rebatable drug.

As stated in the CY 2025 PFS proposed rule (89 FR 61983), civil money penalties are a point-in-time penalty tied to the rebate amount due at the applicable payment deadline, which occurs 30 days after the date of receipt of a Rebate Report. At § 428.500(b), we proposed to establish the methodology for determining the amount of the civil money penalty as equal to 125 percent of the rebate amount for such drug for such applicable period, and that this penalty will be due in addition to the rebate amount due. That is, we proposed a manufacturer will be responsible for paying the full rebate amount due in addition to any civil money penalty imposed because of late payment. We proposed this approach to civil money penalties based on section 1860D–14B(a)(2) of the Act, which establishes a requirement by the manufacturer to provide CMS with a rebate not later than 30 days after receipt from CMS of the report on the amount of the excess annual manufacturer price increase. As noted in the proposed rule, we believe that the ability to assess civil money penalties is necessary in all circumstances where a payment is due for a rebate amount to CMS to ensure compliance with the rebate program's requirements. The civil money penalty would be calculated based on the outstanding rebate amount due at the payment deadline, which is defined at § 428.405(a)(1) as 30 calendar days after the date of receipt of a Rebate Report containing any rebate amount due; once a civil money penalty is assessed due to a late payment, the penalty will remain in effect even if the manufacturer pays the outstanding rebate amount as the penalty is initiated due to a missed payment deadline. Because the payment deadline is clearly defined in section 1860D–14B(a)(2) of the Act, any late payments of a rebate amount due, including late payment of any reconciled rebate amounts greater than the amount reflected in the Rebate Report, would be considered a violation potentially subject to a civil money penalty. Any civil money penalty would be assessed before the next 12- or 36-month reconciliation.

We proposed at § 428.500(b) that civil money penalties may be calculated at several points in time associated with missing a payment deadline for the rebate amount due reflected in the Rebate Report or missing a payment deadline associated with any rebate amount determined after a reconciliation to be greater than the amount invoiced in the Rebate Report. As these separate events can result in distinct assessments of civil money penalties, this means that CMS will not modify a civil money penalty from a prior missed payment deadline based on changes to the rebate amount due following reconciliation, including scenarios where the rebate amount is reduced following reconciliation. However, in the event that the rebate amount due on a Rebate Report was not paid and a civil money penalty was issued for violation of the payment deadline, CMS will not issue a second civil money penalty on a reconciled rebate amount if reconciliation decreased the rebate amount stated on the Rebate Report. As stated in the CY 2025 PFS proposed rule (89 FR 61983), we believe that enforcing this requirement after each payment deadline, regardless of what rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the program and consistency of the implementation of the program. Further, we proposed this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

For examples of how this approach to civil money penalties will work in practice, see section III.I.2.g. of this final rule. We proposed that civil money penalties will function in the same way for both the Part B and Part D rebate programs. Given that the Part D rebate program has two proposed regular reconciliations, payment will be due no later than 30 days after issuance of a report of a reconciled rebate amount for each reconciliation under Part D.

Further, we noted in the proposed rule that payment of any civil money penalty does not obviate the requirement for the manufacturer to pay any outstanding rebate amount due, including any rebate amount due following a reconciliation. Therefore, paying a civil money penalty does not satisfy the obligation to pay the underlying rebate amount on which the civil money penalty is calculated. In

addition, we are evaluating all available options to ensure manufacturers' timely compliance with their rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

At § 428.500(c), we proposed that if CMS makes a determination to impose a civil money penalty on a manufacturer for violation of a payment deadline, we will send a written notice of the decision to impose a civil money penalty that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, we proposed applying existing appeal procedures for civil money penalties in 42 CFR 423, subpart T of this title to manufacturers appealing a civil money penalty imposed under the Medicare Part D Drug Inflation Rebate Program. CMS has utilized this appeals process for many years for civil money penalty determinations affecting MA organizations and Part D sponsors. Therefore, we proposed to use this well-established process for civil money penalty appeals from manufacturers that do not make inflation rebate payments by the payment deadline. We also proposed at § 428.500(e)(1) that the scope of appeals is limited to: (1) CMS determinations relating to whether the rebate payment was made by the payment deadline; and (2) the calculation of the penalty amount. Section 1860D–14B(f) of the Act precludes judicial review of specific data inputs or calculations related to the underlying Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Section 1860D–14B(e) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A(a) of the Act. We proposed to codify this requirement at § 428.500(f). In alignment with the procedure outlined in section 1128A of the Act, we proposed at § 428.500(d) that collection of the civil money penalty will follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the civil money penalty is upheld, CMS will initiate collection of the civil money penalty once the administrative decision is final. We solicited comment on proposals related to the violations of payment deadlines and issuance of a civil money penalty.

We proposed at § 428.500(g) that in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or civil monetary penalties owed by the manufacturer.

We received public comments on these proposals. Because the comments received are applicable to both the Medicare Part B and Part D Drug Inflation Rebate Programs, please refer to the corresponding section in Part B for a summary of comments and our responses on this topic.

After consideration of public comments, we are finalizing § 428.500 as proposed.

g. Severability (§ 428.10)

At § 428.10, we proposed that were any provision of part 428 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions will be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. As stated in the CY 2025 PFS proposed rule (89 FR 61984), while the provisions in part 428 are intended to present a comprehensive approach to implementing the Medicare Part D Drug Inflation Rebate Program, we intend that each of them is a distinct, severable provision. We also stated our intent that a finding that a provision of part 428 is invalid or unenforceable would not affect similar provisions in the Medicare Part B Drug Inflation Rebate Program. As discussed in the proposed rule, the Part D drug inflation rebate proposals are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, we stated that we intended the policies we proposed related to exclusion of units acquired through the 340B Program (§ 428.203(b)(2)) to be distinct and severable from the proposals related to determination of Part D Rebatable drugs (§§ 428.100 and 428.101). As stated in the proposed rule, even where one provision refers to a second provision, the preamble and the regulatory text clarify the intent of the agency that the two provisions will be severable if one provision were to be invalidated in whole or in part. For example, CMS would still be able to calculate a Part D drug inflation rebate even if the provision identifying the payment amount benchmark period for a Part D rebatable drug as the first calendar year in which such drug has at least 1 quarter of AMP in certain instances of missing AMP is deemed invalid (§§ 428.202(c)(3) and (c)(4)).

We solicited public comments on our proposed severability policy. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters disagreed with CMS' proposal that each regulatory provisions in part 428 are severable and distinct. One of these commenters stated that the preamble seeks to dictate to the courts how each regulatory provision should be evaluated for the purposes of severability. This commenter recommended CMS indicate an intent for severability but delete preamble or regulatory language related to the courts' evaluation of the issue. One of these commenters wrote that courts have rejected similar severability clauses, particularly in instances where a regulation's provisions were too intertwined to sever. This commenter also noted that CMS does not provide a legal or policy rationale for how it believes the Part D inflation rebates regulations can operate independently from one another. As a result, the commenter writes, a court would likely find the Part D inflation rebate regulations should be treated as a ''single, integrated proposal.''

Response: We appreciate these commenters sharing their feedback. We disagree with the commenters' contention that the policies in this final rule are not individual and severable. Under the Administrative Procedure Act (APA), an ''agency action'' may be either ''the whole or a part of an agency rule.'' 5 U.S.C. 551(13). Thus, the APA permits a court to sever a rule by setting aside only the portion of the rule found invalid. Courts have stated that in determining if an agency action is severable, they look at the agency

intent,[705] and if parts of the action are ''intertwined'' or if ''they operate entirely independently of one another.'' [706] Even if a court were to strike down some provision of this final rule, CMS' intent is that other portions of this rule would remain in effect. CMS' intent is evidence by § 428.10, which states that were any provision of part 428 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from part 428 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. We believe severability applies to each provision of the Part D inflation drug rebate regulation, because deeming any particular provision to be invalid or illegal would not result in a material change to the Medicare Part D Inflation Rebate Program so as to cause all of the requirements that compose the program to be invalid.

Contrary to the commenter's assertion, CMS did explain how the Part D inflation rebate regulations can operate independently from one another. As noted above, CMS provided examples that are illustrative of how the provisions of part 428 would operate independently from one another; for instance, CMS would still be able to calculate a Part D drug inflation rebate even if the proposed provision identifying the payment amount benchmark period for a Part D rebatable drug as the first calendar year in which such drug has at least 1 quarter of AMP in certain instances of missing AMP is deemed invalid (§§ 428.202(c)(3) and (c)(4)).

After consideration of public comments, CMS is finalizing this policy as proposed at § 428.10.

J. Request for Information: Building Upon the MIPS Value Pathways (MVPs) Framework To Improve Ambulatory Specialty Care

In the CY 2025 PFS proposed rule (89 FR 61984 through 61991), we solicited comment on a Request for Information (RFI), Building upon the MIPS Value Pathways (MVPs) Framework to Improve Ambulatory Specialty Care. We refer readers to the CY 2025 PFS proposed rule to review this RFI.

We received public comments in response to this RFI, and we appreciate the thoughtful input. We will consider the comments received for future rulemaking, technical assistance, and work related to the design of a future ambulatory specialty model.

K. Modifications to Coverage of Colorectal Cancer Screening

Medicare coverage provisions for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Social Security Act (the Act)), regulation (42 CFR 410.37), and a National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). The statute and regulations expressly authorize the Secretary to add other tests and procedures (and make modifications to tests and procedures) for colorectal cancer screening with such frequency and payment limits as the Secretary finds appropriate based on consultation with appropriate organizations. (Section 1861(pp)(1)(D) of the Act; § 410.37(a)(1)(v)). We proposed to exercise our authority at section 1861(pp)(1)(D) of the Act to update and expand coverage for CRC screening by:

- Removing coverage for the barium enema procedure in regulations at § 410.37,
- Adding coverage for the computed tomography colonography (CTC) procedure in regulations at § 410.37, and
- Expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3).

1. Background

The Center for Disease Control and Prevention (CDC) describes CRC as ''a disease in which cells in the colon or rectum grow out of control. . . Sometimes abnormal growths, called polyps, form in the colon or rectum. Over time, some polyps may turn into cancer. Screening tests can find polyps so they can be removed before turning into cancer. Screening also helps find colorectal cancer at an early stage, when treatment works best.'' [707] The National Cancer Institute reports that CRC is the fourth most common type of cancer and estimates that the United States experienced 153,020 new cases and 52,550 new deaths from CRC in 2023. In addition, the rate of new cases and new deaths from CRC is more common in men than women and significantly greater for those of African American and Non-Hispanic American Indian/Alaska Native descent compared to all races.[708]

At § 410.37(a)(4), we define the barium enema procedure as a screening double contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure); or in the case of an individual whose attending physician decides that he or she cannot tolerate a screening double contrast barium enema, a screening single contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure). The CDC describes CTC, (also called a virtual colonoscopy), as ''a screening test that uses X-rays and computers to produce images of the entire colon, which are displayed on a computer screen for the doctor to analyze.'' [709]

The U.S. Preventive Services Task Force (USPSTF) first included CTC as a CRC screening method in their June 2016 revised Final Recommendation Statement.[710] With respect to CTC, the USPSTF cautioned in the 2016 recommendation that ''[t]here is insufficient evidence about the potential harms of associated extracolonic findings, which are common.'' The USPSTF further wrote, ''[t]here are numerous screening tests to detect early-stage colorectal cancer, including stool-based tests (gFOBT, FIT, and FIT–DNA), direct visualization tests (flexible sigmoidoscopy, alone or combined with FIT; colonoscopy; and CT colonography), and serology tests (SEPT9 DNA test). The USPSTF found no head-to-head studies demonstrating that any of these screening strategies are more effective than others, although they have varying levels of evidence supporting their effectiveness, as well as different strengths and limitations.'' [711] The USPSTF again included CTC as a CRC screening method in the most recent May 2021 revised Final Recommendation Statement, which

[705] *Davis Cnty. Solid Waste Mgmt.* v. *U.S. E.P.A.,* 108 F.3d 1454, 1459 (D.C. Cir. 1997).

[706] *Wilmina Shipping AS* v. *United States Dep't of Homeland Sec.,* 75 F. Supp. 3d 163, 171 (D.D.C. 2014).

[707] CDC website: *https://www.cdc.gov/colorectal-cancer/about/?CDC_AAref_Val=https://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm.*

[708] NCI website: *https://seer.cancer.gov/statfacts/html/colorect.html.*

[709] CDC website: *https://www.cdc.gov/colorectal-cancer/screening/?CDC_AAref_Val=https://www.cdc.gov/cancer/colorectal/basic_info/screening/tests.htm.*

[710] USPSTF June 2016 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[711] USPSTF June 2016 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

included the topline recommendations ''[t]he USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years (Grade A)'' and ''[t]he USPSTF recommends screening for colorectal cancer in adults aged 45 to 49 years (Grade B)''.[712] We described our consultations with additional organizations and our review of clinical guidelines later in our proposal.

2. Statutory Authority

Section 4104 of the Balanced Budget Act of 1997 (Pub. L. 105–33) authorized the benefit colorectal cancer screening tests under Medicare Part B. Section 1861(s)(2)(R) of the Act includes CRC screening tests in the definition of medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(pp) of the Act defines colorectal cancer screening tests and specifically names the following tests:

- Screening fecal-occult blood test;
- Screening flexible sigmoidoscopy; and
- Screening colonoscopy.

Section 1861(pp)(1)(D) of the Act also authorizes the Secretary to include in the definition of CRC screening tests ''other tests or procedures, and modifications to the tests and procedures described under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.''

3. Regulatory and NCD Authority

In the CY 1998 PFS final rule (62 FR 59048), after consulting with appropriate organizations, we finalized regulations to cover barium enema procedures for CRC screening in § 410.37. Barium enema screening examinations have to be ordered by the beneficiary's attending physician (§ 410.37(h)). Currently, the regulations cover barium enemas as a CRC screening test subject to frequency limitations and whether or not the individual was at high risk for colorectal cancer. As described in the CY 1998 PFS final rule (62 FR 59048), we consulted with a number of appropriate organizations such as the American Cancer Society, American College of Physicians, American Gastroenterological Association and USPSTF, and the decision to cover the barium enema procedure was based on the prevailing clinical guidelines and recommendations at the time. In the CY 2023 PFS final rule (87 FR 69404), we lowered the age limit for barium enema procedures for CRC screening to age 45 at § 410.37(i)(1).

In May 2009, we established a non-coverage policy for CTC in NCD 210.3 CTC Screening Tests. We noted in the Final Decision Memorandum, ''there is insufficient evidence on the test characteristics and performance of screening CTC in Medicare aged individuals and that the evidence is not sufficient to conclude that screening CTC improves health benefits for asymptomatic, average risk Medicare beneficiaries.'' [713] At that time, the October 2008 USPSTF revised Final Recommendation Statement read, ''[t]he USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer. (Grade I)'' [714] As described in the Final Decision Memorandum, guidelines from Professional Societies were mixed. A joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology concluded ''[i]n terms of detection of colon cancer and advanced neoplasia, which is the primary goal of screening for CRC and adenomatous polyps, recent data suggest CTC is comparable to Optical Colonoscopy for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied.'' [715] The American Gastroenterological Association issued the following recommendation statement in 2008, ''[t]he AGA does not endorse CTC as a first-line colon cancer screening test. While AGA supports CTC as a screening option, colonoscopy is the definitive test for colorectal cancer screening and prevention. Colonoscopy is the only test that can both detect cancer at an early curable stage and prevent cancer by removing pre-cancerous polyps. At this time, while CTC may be another technology for colorectal cancer screening, many questions about CTC remain to be answered.'' [716] The American Society for Gastrointestinal Endoscopy published guidelines in 2006 that concluded ''virtual colonoscopy is an evolving technique and is not currently recommended as the primary method of screening for CRC.'' [717]

In the 2023 PFS final rule (87 FR 69404) we expanded the regulatory definition of CRC Screening to include a complete colorectal cancer screening, which includes a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result (§ 410.37(k)). Although we have previously viewed a colonoscopy after a positive non-invasive stool-based CRC screening test to be a diagnostic colonoscopy, the clinical recommendations and guidance of medical professional societies and screening experts have since evolved for stool-based colorectal cancer screening due to the relative number of false positive results, low follow-up colonoscopy rates and patient access barriers. Published evidence highlighted that individuals who did not get a follow-up colonoscopy were about twice as likely to die of colorectal cancer compared to individuals who had one. Since the overall goal of programmatic cancer screening using any CRC screening test is to prevent cancer, allowing for early detection and treatment and reducing cancer mortality, the follow-up colonoscopy was found to be integral with non-invasive stool-based CRC screening, since improvements in health outcomes would not be possible without the follow-up colonoscopy. Our goal was that the patient and their healthcare professional make the most appropriate choice in CRC screening, which included considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. In that

[712] USPSTF January 2021 Revised Final Recommendation Statement *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[713] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: *(https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

[714] USPSTF October 2008 Final Recommendation Statement: *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-2008.*

[715] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: (*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer).*

[716] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: (*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

[717] National Coverage Analysis CAG–00396N Screening Computed Tomography Colonography (CTC) for Colorectal Cancer on Medicare Coverage Database: (*https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer*).

final rule, we also described that CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and screening colonoscopy tests in terms of invasiveness and burdens to the patient and healthcare system. We recognized there are several advantages to choosing a non-invasive stool-based CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of unnecessary burdensome preparation and invasive procedures.

We noted in preamble of the CY 2023 PFS final rule (87 FR 69404) that many commenters requested that CMS further expand our approach of a complete colorectal cancer screening. Many requested that we remove the text ''stool-based'' from our proposed regulations at § 410.37(k), resulting in a complete CRC screening including a follow-on screening colonoscopy after a Medicare covered non-invasive screening test. Many commenters requested that a complete CRC screening include a screening colonoscopy after a positive result from a blood-based biomarker test, as well as a stool-based test. We responded to these public comments by writing that ''we disagree with the commenters that requested a further expansion of a complete colorectal cancer screening that would include additional first step tests beyond a non-invasive stool-based test. We believe the stool-based tests are unique to other CRC screening tests in terms of their non-invasiveness, the fact that stool-based tests can be implemented by the patient at home and mailed into the lab, the absence of bowel preparation and anesthesia and the comparatively lighter burden and mitigated potential for over servicing of the patient and the healthcare system.'' We further wrote, ''[w]e agree that blood-based biomarker CRC screening tests have significant potential and we expanded coverage to include them in the reconsidered NCD 210.3, effective January 2021.'' We also recognized that blood-based biomarker CRC screening tests continue to be an emerging and quickly evolving technology. However, we also noted that, as of September 2022, no blood-based biomarker tests for CRC screening had achieved the coverage requirements of NCD 210.3 and that the May 2021 USPSTF revised Final Recommendation Statement did not include serum tests.

In the CY 2023 PFS final rule (87 FR 69404) we also established regulations at § 410.37(k) that the frequency limitations described for screening colonoscopy shall not apply in the instance of a follow-on screening colonoscopy test. We wrote that we aimed to avoid disruption to the existing conditions of coverage and payment for CRC screening for this unique scenario and continuum of screening.

4. Proposed Revisions

We proposed to exercise our authority in section 1861(pp)(1)(D) of the Act to remove coverage for the barium enema procedure from CRC screening in regulations at § 410.37. We have consulted with appropriate organizations and heard that, while the barium enema procedure was reasonable and necessary for CRC screening when it was initially covered in the CY 1998 PFS final rule (62 FR 59048), circumstances have since changed. The organizations have expressed that barium enema procedures no longer meet modern clinical standards, are no longer recommended in clinical guidelines, and would not be an appropriate CRC screening test given the advancement of alternatives such as stool-based tests, colonoscopies, and CT colonography. In developing our proposal, we also considered that the June 2016 and the May 2021 USPSTF revised Final Recommendation Statements did not include the barium enema procedure as a CRC screening method in their revised Final Recommendation Statements.[718] [719] We also considered the 2017 U.S. Multi-Society Task Force of Colorectal Cancer (MSTF) recommendation statement, which reads, ''CT colonography has replaced double-contrast barium enema as the test of choice for colorectal imaging for nearly all indications. CT colonography is more effective than barium enema and better tolerated.'' [720] The 2018 American Cancer Society (ACS) Colorectal Cancer Screening for Average-Risk Adults Guideline Update also reads, ''double-contrast barium enema is no longer included as an acceptable screening option.'' [721]

During the CY 2023 PFS, we received a joint public comment from the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) [722] that brought to our attention that barium enema is not a recommended CRC screening modality in guidance from the USPSTF or the U.S. Multi-Society Task Force on Colorectal Cancer. The public comment also noted that while the barium enema procedure once was considered a CRC screening modality and has been included in guidelines in the past, barium enema is no longer included in any recent CRC guidelines and is rarely performed today as it is considered inadequate for the exclusion of CRC. They urged CMS to remove barium enema as a covered CRC screening test for all individuals. An internal claims analysis indicates that Medicare only paid claims for barium enema for CRC screening for 72 beneficiaries in CY 2022.

A 2016 study titled ''[n]ew era of colorectal cancer screening,'' states, ''double-contrast barium enema (DCBE) is a non-invasive radiological test, which provides a complete evaluation of the large intestine. The sensitivity and specificity of barium enema for polyps of any size is 38 percent and 86 percent, respectively. One study comparing barium enema to CTC and colonoscopy showed that DCBE has the lowest sensitivity and specificity with sensitivity of 41 percent for lesions ≥ 6 mm and sensitivity and specificity of 48 and 90 percent respectively for lesions ≥ 10 mm. These results are consistent with a meta-analysis comparing the performance of barium enema to that of CTC showing CTC is more sensitive and more specific than barium enema for large polyps (≥ 10 mm) and small polyps (6–9 mm) in average-risk and high-risk populations. In the United States, CTC has largely replaced DCBE as a radiographic option for CRC screening.'' [723]

In light of the new evidence and our consultations with appropriate organizations, we proposed to remove barium enema as a colorectal screening test under § 410.37(a)(1)(iv). We solicited comments from the public and appropriate organizations. We also solicited public comment on the proposal to remove all references to barium enemas in § 410.37.

[718] USPSTF June 2016 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016.*

[719] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.*

[720] Am J Gastroenterol 2017; 112:1016–1030; *doi: 10.1038/ajg.2017.174;* published online 6 June 2017.

[721] The 2018 American Cancer Society (ACS) Colorectal Cancer Screening for Average-Risk Adults Guideline Update, doi: 10.3322/caac.21457. Available online at *cacancerjournal.com.*

[722] CY 2023 PFS Public Comment CMS–2022–0113–21851_attachment_1.

[723] El Zoghbi M, Cummings LC. *New era of colorectal cancer screening. World J Gastrointest Endosc. 2016 Mar 10;8(5):252–8.* doi: 10.4253/wjge.v8.i5.252. PMID: 26981176; PMCID: PMC4781905.

We also proposed to exercise our authority in section 1861(pp)(1)(D) of the Act to add coverage for the CTC procedure for CRC screening in regulations at § 410.37. We stated that if finalized, we will address and revise the current non-coverage policy for CTC in NCD 210.3. In developing our proposal to expand coverage for the CTC procedure, we consulted with appropriate organizations and considered a number of potential benefits, risks, and tradeoffs described in guidelines and recommendations by professional societies and government bodies.

In developing the proposed rule, we considered that the USPSTF included the CTC procedure as a CRC screening method in their June 2016 and May 2021 revised Final Recommendation Statements.[724] [725] In terms of benefits, the USPSTF wrote in their May 2021 revised Final Recommendation Statement, that CTC usually allows for greater colon visualization compared to flexible sigmoidoscopy. In terms of risks and tradeoffs, USPSTF noted that CTC, like colonoscopy and flexible sigmoidoscopy, requires the burden of bowel preparation. The USPSTF wrote ''[u]nlike Colonoscopy and Flexible Sigmoidoscopy, CTC may reveal extracolonic findings that require additional workup, which could lead to other potential benefits or harms.'' The USPSTF went on to state, ''[h]arms from CT colonography are uncommon (19 studies; n = 90 133), and the reported radiation dose for CT colonography ranges from 0.8 to 5.3 mSv (compared with an average annual background radiation dose of 3.0 mSv per person in the U.S.). Accurate estimates of rates of serious harms from colonoscopy following abnormal CTC results are not available.'' Regarding extracolonic findings, the USPSTF wrote, ''[e]xtracolonic findings on CTC are common. Based on 27 studies that included 48,235 participants, 1.3 percent to 11.4 percent of examinations identified extracolonic findings that required workup. Three percent or less of individuals with extracolonic findings required definitive medical or surgical treatment for an incidental finding. A few studies suggest that extracolonic findings may be more common in older age groups. Long-term clinical follow-up of extracolonic findings was reported in few studies, making it difficult to know whether it represents a benefit or harm of CT colonography.'' The USPSTF recommends screening CTC frequency every 5 years.[726]

In a study titled ''Incidental Extracolonic Findings on CT Colonography: The Impending Deluge and Its Implications,'' Lincoln L. Berland, MD, describes extracolonic findings as findings on CTC that have potential deleterious health effects and are asymptomatic, unsuspected, and unrelated to the colon. The study goes on to state, ''as CT image quality has improved, there has been an increase in the frequency of detecting ''incidental findings,'' defined as findings that are unrelated to the clinical indication for the imaging examination performed. These 'incidentalomas,' as they are also called, often confound physicians and patients with how to manage them. Although it is known that most incidental findings are likely benign and often have little or no clinical significance, the inclination to evaluate them is often driven by physician and patient unwillingness to accept uncertainty, even given the rare possibility of an important diagnosis.'' [727] The potential for extracolonic findings, both clinically significant and insignificant, is an important tradeoff to be considered by the patient and clinician when considering CTC as a CRC screening option.

We also considered the 2018 ACS Colorectal Cancer Screening for Average-Risk Adults Guideline Update, which includes the CTC procedure with their recommended tests and procedures for CRC Screening.[728] In terms of benefits, the ACS guideline describes CTC sensitivity and specificity for cancer and advanced adenomas comparable to colonoscopy, longer recommended screening intervals compared to stool-based tests, and no need for sedation (compared to colonoscopy). In terms of risks and tradeoffs, the ACS guideline notes incidental extracolonic findings may require workup (with unclear benefit-burden balance), exposure to low-dose radiation and requires full bowel cleansing. The ACS guidelines recommended screening CTC frequency of every 5 years.

We also considered the United States Multi-Society Task Force (MSTF) of Colorectal Cancer, which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, 2017 Colorectal Cancer Screening recommendations [729], which include CTC as a ''Tier 2'' procedure alongside FIT-fecal DNA and Flexible Sigmoidoscopy. The recommendation states that ''CRC screening tests are ranked in 3 tiers based on performance features, costs, and practical considerations. The first-tier tests are colonoscopy every 10 years and annual fecal immunochemical test (FIT). Colonoscopy and FIT are recommended as the cornerstones of screening regardless of how screening is offered. Thus, in a sequential approach based on colonoscopy offered first, FIT should be offered to patients who decline colonoscopy. Colonoscopy and FIT are recommended as tests of choice when multiple options are presented as alternatives. A risk-stratified approach is also appropriate, with FIT screening in populations with an estimated low prevalence of advanced neoplasia and colonoscopy screening in high prevalence populations. The second-tier tests include CTC every 5 years, the FIT-fecal DNA test every 3 years, and flexible sigmoidoscopy every 5 to 10 years. These tests are appropriate screening tests, but each has disadvantages relative to the tier 1 tests.'' In terms of benefits of CTC, the MSTF describes lower risk of perforation compared with colonoscopy and write, ''CTC appeals to a niche of patients who are willing to undergo bowel preparation and are concerned about the risks of colonoscopy.'' In terms of risks and tradeoffs, the MSTF describe the requirement for bowel preparation, extracolonic findings, and inferior sensitivity compared to other screening tests and radiation exposure. The MSTF writes, ''[e]vidence that CT colonography reduces CRC incidence or mortality is lacking.''

We also considered the online resource RadiologyInfo™,[730] which is an online public information resource

[724] USPSTF June 2016 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-june-2016*.

[725] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening*.

[726] USPSTF January 2021 Revised Final Recommendation Statement, *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening*.

[727] Lincoln L. Berland, Incidental Extracolonic Findings on CT Colonography: The Impending Deluge and Its Implications, Journal of the American College of Radiology, Volume 6, Issue 1, 2009, Pages 14–20, ISSN 1546–1440, *https://doi.org/10.1016/j.jacr.2008.06.018*.

[728] 2018 ACS Colorectal Cancer Screening for Average-Risk Adults Guideline Update, doi: 10.3322/caac.21457. Available online at *cacancerjournal.com*.

[729] Am J Gastroenterol 2017; 112:1016–1030; doi: 10.1038/ajg.2017.174; published online 6 June 2017.

[730] RadiologyInfo website: *https://www.radiologyinfo.org/*.

developed by health care professionals in collaboration with patients. RadiologyInfo is sponsored by the Radiological Society of North America (RSNA) and the American College of Radiology (ACR). In terms of benefits of CTC, RadiologyInfo described CTC as less invasive than a colonoscopy, though for CTC a small tube is inserted into the rectum to allow for inflation with carbon dioxide or air. In addition, CTC does not require sedation (and transportation accommodations) and carries less risk of bowel perforation compared to colonoscopy. In addition, CTC can identify precancerous polyps that may not be detected by stool-based and blood-based tests. CTC may be a less burdensome first option for patients who are medically fragile or have complex or unusual anatomy. In terms of risks and tradeoffs, RadiologyInfo describes a very small risk of perforated bowel (during inflation), a small risk of secondary cancer due to radiation exposure and it being not recommended for individuals who are pregnant. RadiologyInfo reports that CTC applies a patient radiation exposure similar to barium enema at 6 millisieverts (mSv), which is greater than other preventive screenings, such as CT lung cancer screening at 1.5mSv and screening digital mammography at 0.21 mSv.[731]

After considering the above recommendations and guidelines from appropriate organizations, we stated that we believe CTC to be reasonable and necessary as CRC screening test, especially for patients and clinicians who seek a direct visualization procedure as a first step in CRC screening that is less invasive and less burdensome on the patient and healthcare system compared to screening colonoscopy. Our goal is that the patient and their clinician make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and tradeoffs for each covered test or procedure. We expect that clinicians who order CTC for CRC screening will educate their patients on risks and context of radiation exposure and potential extracolonic findings. A shared decision-making tool is not mandated but may be helpful for clinicians and patients to weigh their options for CRC screening.

We proposed to add CTC as a covered CRC screening test at § 410.37. We proposed to describe in regulatory text that CTC means a test that uses X-rays and computers to produce images of the entire colon (including image processing and a physician's interpretation of the results of the procedure). We also proposed to codify in regulatory text that Medicare Part B pays for a screening computed tomography colonography if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist. We also proposed the following limitations of coverage for CTC:

- In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 59 months have passed following the month in which the last screening computed tomography colonography or 47 months have passed following the month in which the last screening flexible sigmoidoscopy or screening colonoscopy was performed.
- In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 23 months have passed following the month in which the last screening computed tomography colonography or the last screening colonoscopy was performed.

Congress has eliminated Part B coinsurance (section 1833(a)(1)(Y) of the Act, § 410.152(l)(5)) and deductibles (section1833(b)(1) of the Act) for covered prevention services recommended with a grade of A or B by the USPSTF. As described earlier in our proposal, the USPSTF included CTC as a screening method in their May 2021 revised Final Recommendation Statement on CRC screening (Grade A). Thus, if finalized, CTC will require no Part B coinsurance nor deductible when furnished as a CRC screening procedure. We clarify that CTC will continue to require Part B coinsurance and deductible when furnished as a diagnostic or other non-preventive/screening procedure.

We also proposed to exercise our authority in section 1861(pp)(1)(D) of the Act to expand our approach to a ''complete CRC screening'' finalized in § 410.37(k). We proposed to add a Medicare covered blood-based biomarker CRC screening test (as described and authorized in NCD 210.3) alongside the Medicare covered non-invasive stool-based CRC screening test within our approach of a ''complete CRC screening.''

Our goal is for the patient and their healthcare professional to make the most appropriate choice in CRC screening, which include considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step. CRC screening presents a unique scenario where there are significant differences between screening stool-based tests and direct visualization procedures such as colonoscopy, flexible sigmoidoscopy and CTC tests in terms of invasiveness and burdens to the patient and healthcare system. We recognize there are several advantages to choosing a non-invasive CRC screening test as a first step compared to a screening colonoscopy, including relative ease of administering the test and potentially reducing the experience of burdensome preparation and invasive procedures. Since the CY 2023 PFS final rule we have heard from many interested parties, including a number of professional societies, that Medicare covered blood-based biomarker tests would be appropriately placed alongside covered non-invasive stool-based tests within a complete colorectal cancer screening context. We have reconsidered our position that Medicare covered blood-based biomarker tests would not belong alongside covered non-invasive stool-based tests within our approach to a complete CRC screening. We consider that some patients may consider a blood test less uncomfortable than administering a stool-based test, especially if the blood draw is concurrent to a routine blood draw for other covered routine bloodwork. We have also heard that some patients may prefer a non-invasive test as their first step but view the stool sample collection process for stool-based tests as a meaningful barrier.[732] We also consider that a blood test may be more accessible to many patients in rural and underserved communities than facilities that furnish screening colonoscopies, flexible sigmoidoscopies and CTC.

NCD 210.3 requires that blood-based biomarker tests for CRC screening must have Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer screening; and proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74 percent and specificity greater than or equal to 90 percent in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels, based on the pivotal studies included in

[731] *https://www.radiologyinfo.org/en/info/safety-xray.*

[732] Kolata, Gina. ''A Blood Test Shows Promise for Early Colon Cancer Detection'' The New York Times, March 13, 2024. *https://www.nytimes.com/2024/03/13/health/colon-cancer-blood-test.html.*

the FDA labeling. We have heard from interested parties that blood-based biomarker tests for CRC screening may achieve the coverage requirements described in NCD 210.3 within the near term and thereafter quickly become adopted as a non-invasive option within the healthcare system and patient community. Given our existing coverage policy for blood-based biomarker tests for CRC screening (NCD 210.3), we believe our proposal is appropriately proactive, provides for consistent regulatory treatment between blood and stool-based tests, and will ready our regulatory policies for the quickly evolving state of medical technology in methods for CRC screening. We note that while blood-based biomarker tests were not included as a screening method within the May 2021 USPSTF revised Final Recommendation Statement on CRC Screening, they do not require beneficiary cost sharing (coinsurance and deductible) because blood-based biomarker tests will be paid under the Clinical Laboratory Fee Schedule (CLFS). For additional information, see the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs*.

We proposed to revise the regulatory text describing a complete CRC screening at § 410.37(k) to state that colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test or a Medicare covered blood-based biomarker CRC screening test returns a positive result. We also proposed to revise the regulatory text at § 410.37(k) to state the instance of the follow-on colonoscopy in the context of a complete colorectal cancer screening shall not apply to the frequency limitations for colorectal cancer screenings. We believe this statement in regulatory text is clearer and recognizes, outside the context of a complete colorectal cancer screening, the instance of a screening colonoscopy is factored into the calculation of frequency limitations of other covered CRC screening tests and procedures in addition to a subsequent screening colonoscopy.

5. Proposal Summary

In summary, we proposed to exercise our authority at section 1861(pp)(1)(D) of the Act update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure for CRC screening; (2) adding coverage of the CTC procedure for CRC screening; and (3) expanding our approach to a ''Complete CRC Screening'' to include a covered blood-based biomarker test alongside a covered non-invasive stool-based test.

Our proposal to update and expand CRC screening aligns with the administration's strategic pillar to advance health equity by addressing the health disparities that underlie our health system. In addition, our proposal supports Executive Order 13985 by advancing racial equity and support for underserved communities in the Medicare program. We believe our proposal will directly advance health equity by promoting access and removing barriers for much needed cancer prevention and early detection within rural communities and communities of color that are especially impacted by the incidence of CRC. Our proposal to expand colorectal cancer screening directly supports the Administration's Cancer Moonshot Goal of reducing the deadly impact of cancer and improving patient experiences in the diagnosis, treatment, and survival of cancer.[733]

Our proposal is also supportive of the Administration's Proclamation of March as National Colorectal Cancer Awareness Month in 2024, which includes the statement, ''As a country, we have made impressive progress in the struggle to end cancer over the past several decades due to advancements in prevention, early-detection measures, and new medicines and therapies. Despite remarkable breakthroughs, every year, more Americans are diagnosed with cancer under the age of 50. Earlier detection and improved treatment of colorectal cancer continue to be critical goals of medical research. Further progress is also needed to improve outcomes for those who are disproportionately impacted by this disease—including Americans over the age of 45, Native Americans, Black Americans, and people with a family history of colorectal cancer. There is still more work to be done to ensure more Americans can prevent, detect, treat, and survive colorectal cancer.'' [734]

We solicited comments with the public and appropriate organizations these several proposals.

7. Discussion of Comments and Final Policy

We received public comments on each of the proposals discussed above. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to exercise our authority in section 1861(pp)(1)(D) of the Act to remove coverage for the barium enema procedure from the CRC screening regulations at § 410.37. They agreed that barium enema procedures no longer meet modern clinical standards, are no longer recommended in clinical guidelines, and would not be an appropriate CRC screening test given the advancement of alternatives. One commenter agreed that barium enema is an infrequently used screening method but also stated that it can be an important option for some patients.

Response: We thank the majority of commenters for supporting our proposal to exercise our authority in section 1861(pp)(1)(D) of the Act to remove coverage for the barium enema procedure from CRC screening in the regulations at § 410.37. While the barium enema procedure was once a CRC screening modality, it is no longer included in any recent CRC guidelines, including the USPSTF and the U.S. Multi-Society Task Force on Colorectal Cancer, and is rarely performed today as it is considered inadequate. Therefore, we will finalize removal of coverage for barium enema, as proposed. We are not adopting the policy recommended by a single commenter to retain coverage of screening barium enemas just in case it might provide another option for some patients.

Comment: The majority of commenters supported our proposal to exercise our authority in section 1861(pp)(1)(D) of the Act to add coverage for the CTC procedure for CRC screening in regulations at § 410.37. The commenters acknowledged that adding CTC is a significant advancement in preventive care and ensures equity in prevention and early detection of colon cancer.

Response: We appreciate the majority of comments supporting the proposal to expand coverage to include CTC as a colorectal cancer screening test in the regulation at § 410.37. We agree that CTC is included in current recommendations and guidelines as a recommended screening modality for detecting and preventing colorectal cancer and polyps. CTC provides an option for patients and clinicians who seek a direct visualization procedure as a first step in CRC screening that is less invasive and less burdensome on the patient. We strive to offer a variety of appropriate CRC screening options to ensure greater access. Patients and their clinician can choose from the appropriate CRC screening test for the individual. Therefore, we are finalizing the addition of CTC, as proposed.

[733] *https://www.whitehouse.gov/cancermoonshot/*.

[734] *https://www.whitehouse.gov/briefing-room/presidential-actions/2024/02/29/proclamation-on-national-colorectal-cancer-awareness-month-2024/*.

Comment: Three commenters did not support adding coverage for the CTC procedure for CRC screening. These commenters stated there is a lack of evidence supporting clinical benefit in the Medicare population and the impact of potential harms have not been adequately studied.

Response: We disagree with the commenters that there is insufficient evidence to support expanding coverage of the CTC procedure as an appropriate CRC screening test. As noted in the proposed rule, we have consulted with appropriate organizations that have supported this expansion. While we acknowledge that the available data on CTC predominantly includes individuals under 65 years old, the studies on the general population evaluating CTC have shown that the CRC detection rates have been high. In addition, current guidelines, including those of the USPSTF and the American Cancer Society, largely rest on the consistent findings of high sensitivity and specificity of CTC for clinically significant mucosal lesions in the general population. After considering all of the public comments, we are finalizing our proposal to expand coverage to include CTC as a colorectal cancer screening test in the regulation at § 410.37.

Comment: The majority of commenters supported our proposal to codify in regulatory text that Medicare Part B pays for a screening CTC if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist. One commenter suggested that Medicare beneficiaries should be able to refer themselves directly for a CTC without the requirement for an order from a clinician. The commenter noted that CTC should follow screening mammography for breast cancer detection and not require an order for the examination.

Response: We appreciate the comment about patient-directed screenings. Unlike mammography, there are multiple options for CRC screening. We expect that the patient and their clinician will make the appropriate choice in CRC screening for the individual, which includes considerations of the risks, burdens and tradeoffs for each covered test or procedure. Therefore, we are finalizing our proposal that a screening CTC must be ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialists, as proposed.

Comment: The majority of commenters supported our proposed frequency limitations of coverage for CTC. One commenter, while supporting expanding screening to include CTC, requested CMS reconsider the limitations on time between screenings. The other commenter did not believe the coverage of a CTC 47 months after a screening colonoscopy was performed was necessary. They suggested the coverage of CTC for individuals with average risk should be 10 years following the last screening colonoscopy.

Response: The frequency limitations of coverage for CTC average risk and high risk individuals described in our provision are in alignment with clinical evidence-based recommendations by the USPSTF; American Cancer Society; and the United States Multi-Society Task Force (MSTF) of Colorectal Cancer, which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. Therefore, we are finalizing the frequency limitations to coverage, as proposed, with one minor editorial modification for grammatical clarity in paragraph § 410.37(i)(1) adding the words ''was performed'' after the word colonography in the phrase ''59 months have passed following the month in which the last screening computed tomography colonography . . .''.

Comment: Most commenters supported our proposal to add CTC to the definition of CRC screening methods, acknowledging that in accordance with sections 1833(a)(1)(Y) and 1833(b)(1) of the Act, and § 410.152(l)(5)) of the CFR, because CTC has been given Grade A by the USPSTF, Part B coinsurance and deductibles will be eliminated for the preventive screening procedure. The commenters stated that by reducing or eliminating financial barriers, it enhances patient access to these cancer screening tools without the burden of out-of-pocket costs.

Response: We thank commenters for supporting our proposal to add CTC to the regulatory definition of colorectal cancer screening tests. As we noted in the proposal, CTC will continue to require Part B coinsurance and deductible when furnished as a diagnostic or other non-preventive/screening procedure.

Comment: One commenter stated that Medicare should cover CTC provided by outpatient imaging centers, hospitals, and independent diagnostic testing facilities (IDTFs).

Response: We appreciate the comment and support access to CRC screening. This regulation is not placing limitations on appropriate places of service beyond the existing Medicare rules.

Comment: Many commenters supported our proposal to exercise our authority in section 1861(pp)(1)(D) of the Act to expand our approach to a ''complete CRC screening'' at § 410.37(k) to add a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) alongside the Medicare covered non-invasive stool-based CRC screening test within the definition of a ''complete CRC screening.'' Commenters appreciated CMS' recognition that CRC screening would not be complete with a positive blood-based biomarker test alone and noted that a positive test requires a follow-up colonoscopy to confirm the presence of polyps and/or cancer. Commenters stated it is critical that patients complete the full continuum of screening without cost being a barrier.

Response: We thank the commenters for supporting this change.

Comment: All commenters supported our proposal to revise the regulatory text at § 410.37(k) to state the instance of the follow-on colonoscopy in the context of a complete colorectal cancer screening shall not apply to the frequency limitations for colorectal cancer screenings. Commenters supported that this statement in regulatory text is clearer and recognizes, outside the context of a complete colorectal cancer screening, the instance of a screening colonoscopy is factored into the calculation of frequency limitations of other covered CRC screening tests and procedures in addition to a subsequent screening colonoscopy.

Response: We thank commenters for their support. We are finalizing § 410.37(k) with editorial modification of the regulatory text at § 410.37(k) for additional clarity, removing the sentence, ''The instance of the follow-on screening colonoscopy in the context of a complete colorectal cancer screening must not apply to the frequency limitations for colorectal cancer screening.'' We are replacing that sentence with, ''A follow-on screening colonoscopy in the context of a complete colorectal cancer screening is not subject to the frequency limitations for colorectal cancer screening in § 410.37(g)(2) or (3)''.

Comment: Several commenters requested that CMS exercise our authority in section 1861(pp)(1)(D) of the Act to expand our approach to a ''complete CRC screening'' to also add CTC along with the Medicare covered blood-based biomarker CRC screening test and the Medicare covered non-invasive stool-based CRC screening test

within the definition of a ''complete CRC screening''.

Response: We disagree with commenters that requested a further expansion of a complete colorectal cancer screening to include CTC. CTC is a visualization procedure along with colonoscopy and flexible sigmoidoscopy whereas stool-based and blood-based CRC screening tests are non-visualization tests. CTC provides visualization of the contours of the whole colon and demonstrates mucosal surface abnormalities consistent with polyps and tumors. These tests are unlike noninvasive modalities such as stool-based and blood-based CRC screening, which present a binary positive/negative result with variable specificity and may result (in the case of a positive test) in the need for a visualization study to confirm the derived suspicion of adenoma or cancer. The follow-on colonoscopy represents an extension of screening in a patient who has converted from average risk to increased risk as a result of the positive test. In the case of CTC, visualization of the colonic mucosal contour, as well as the remainder of the colonic wall and surrounding structures, has already been achieved and the determination of a suspicious finding has been made. Polyps over the size threshold prompt a referral for diagnostic/therapeutic colonoscopy for the purpose of polypectomy. Therefore, the follow-up screening colonoscopy after a positive non-visualization test is necessary to confirm the presence of polyps and/or cancer. A follow-up colonoscopy after an abnormal finding from a CTC would be considered a diagnostic colonoscopy to biopsy or remove visualized polyps and/or cancer.

Comment: A few commenters requested CMS, when necessary, take the same approach with future screening tests for ''a complete CRC screening.''

Response: We appreciate the feedback and will consider future tests as necessary.

Comment: Two commenters requested that CMS exercise the same authority in section 1861(pp)(1)(D) of the Act to add coverage for the newly FDA-approved CRC screening test using multi-target mRNA stool for in regulations at § 410.37.

Response: The first multi-target mRNA stool CRC screening test received FDA approval in May 2024. Medicare currently covers multi-target stool DNA CRC screening tests in regulations at § 410.37, but not multi-target mRNA tests as a CRC screening test. CMS has accepted a formal NCD reconsideration request and added it to the public facing NCD Dashboard available on our website at *https://www.cms.gov/files/document/ncd-dashboard.pdf*. We look forward to opening the NCD tracking sheet in the future and we will also consult with appropriate organizations as required by section 1861(pp)(1)(D) of the SSA. We note that we did not propose to add mRNA stool CRC screening tests in this proposed rule, as there should be an opportunity for the public to review and provide comment about this relatively new test. The NCD process will provide an opportunity for public participation and for CMS to consider additional relevant scientific and medical information. However, if an mRNA stool test is covered through a reconsideration of the NCD, such a test would qualify as an additional non-invasive stool-based colorectal cancer screening test.

Comment: Another commenter noted that two new colorectal cancer screening tests have recently been FDA-approved; one being a multi-target mRNA stool test and the other being a blood-based biomarker test. The commenter requested that CMS review these tests to determine Medicare coverage.

Response: We appreciate the comment about the newly FDA-approved CRC screening tests. As described above, the multi-target mRNA stool test received FDA approval in May 2024 and CMS accepted a formal NCD reconsideration request in June 2024. The blood-based biomarker test just received FDA approval in July 2024 and met the coverage criteria set forth in NCD 210.3 and therefore, became coverable on the same day of FDA approval.

Comment: One commenter encouraged CMS to consider opportunities to enhance patient outreach and education on these CRC screening services.

Response: We thank the commenters for the feedback and agree on the importance of outreach and educating beneficiaries and stakeholders. We plan to provide implementation instructions for our contractors that will include coding and payment instructions, through the CMS Transmittals online platform. In addition, CMS may provide additional educational articles through the Medicare Learning Network online platform or through the Medicare.gov preventive services website at *https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html*.

After consideration of public comments, we are finalizing the proposals made in the CY 2025 PFS proposed rule to update and expand colorectal cancer screening and reduce barriers to access to CRC cancer prevention, early detections and improved health outcomes. We are removing coverage for the barium enema procedure from CRC screening in regulations at § 410.37 and adding coverage for the CTC procedure to the definition of CRC screening in the regulations at § 410.37. We are finalizing the associated regulatory language as proposed, with one minor modification for grammatical clarity regarding frequency limitations in paragraph § 410.37(i)(1) adding the words ''was performed'' after the word colonography in the phrase ''59 months have passed following the month in which the last screening computed tomography colonography . . .''.

We are exercising our authority in section 1861(pp)(1)(D) of the Act to finalize expansion of our approach to a ''complete CRC screening'' at § 410.37(k), by adding a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) alongside the Medicare covered non-invasive stool-based CRC screening test within our definition of a ''complete CRC screening''. Additionally, we are finalizing revisions of the regulatory text at § 410.37(k), with modification, to state that the normal frequency time limits established by regulation are not applicable with respect to a follow-on colonoscopy in the context of a complete colorectal cancer screening.

L. Requirements for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Previous Regulatory Action

Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271, October 24, 2018) generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules, we finalized policies for the CMS Electronic Prescribing for Controlled Substances (EPCS) Program requirements specified in section 2003 of the SUPPORT Act. We refer readers to 85 FR 84802 through 84807, 86 FR 65361 through 65370, 87 FR 70008 through 70014, and 88 FR

79285 through 79292 for the details of those finalized policies. Specifically, in the CY 2021 PFS final rule, we established a requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances covered under the Medicare prescription drug program, subject to any exceptions, which HHS may specify, using the NCPDP SCRIPT standard version 2017071 with an effective date of January 1, 2021, and a compliance date of January 1, 2022 (85 FR 84807). In the CY 2022 PFS final rule, we finalized a policy to require prescribers to electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs, except in cases where an exception or waiver applies (86 FR 65366); and finalized multiple proposals related to the classes of exceptions specified by section 2003 of the SUPPORT Act (86 FR 65366 through 65369). We also extended the earliest date of compliance actions to no earlier than January 1, 2023 (86 FR 65364). For prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care (LTC) facility, we extended the earliest date of compliance actions to no earlier than January 1, 2025 (86 FR 65364 and 65365). We also finalized our proposal to limit compliance actions, with respect to compliance through December 31, 2023, to a non-compliance notice (86 FR 65370).

In the CY 2023 PFS final rule (87 FR 70012 through 70013), we extended the non-compliance action of sending notices to non-compliant prescribers, which we had finalized for the CY 2023 CMS EPCS Program implementation year (January 1, 2023, through December 31, 2023), to the CY 2024 Program implementation year (January 1, 2024, through December 31, 2024). We also finalized a change to the data sources used to identify the geographic location of prescribers for purposes of the recognized emergency exception at § 423.160(a)(5)(iii) (87 FR 70011 through 70012) and finalized our proposal to use the Prescription Drug Event (PDE) data from the current evaluated year instead of the preceding year when CMS determines whether a prescriber qualifies for an exception based on issuing 100 or fewer Part D controlled substance prescriptions per calendar year (87 FR 70009 through 70011).

In the CY 2024 PFS final rule (88 FR 79285 through 79287), we identified certain terms for use in the CMS EPCS Program and clarified that, by virtue of the cross reference in § 423.160(a)(5) to ''the applicable standards in paragraph (b) of this section,'' which refers to the standards in § 423.160(b), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. Additionally, we finalized our proposals to remove the same entity exception from the CMS EPCS Program and to add ''subject to the exemption in paragraph (a)(3)(iii) of this section'' to § 423.160(a)(5) (88 FR 79287 through 79288). As a result, prescriptions that are prescribed and dispensed within the same legal entity are included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers are not exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II through V controlled substances that are Part D drugs—but such prescriptions have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii). We also finalized a policy to count only the unique prescriptions in the measurement year for the purposes of CMS EPCS Program compliance threshold calculations (88 FR 79288). Furthermore, for the exceptions that we moved to § 423.160(a)(5)(ii) and (iii), we modified the exceptions to permit prescribers to apply for waivers in times of an emergency and disaster and to limit the emergencies or disasters that will trigger the recognized emergency exception. We also modified the duration of both exceptions and established timing requirements for submitting a waiver application (88 FR 79288 through 79291). Lastly, we stated that we will send notices of non-compliance for each measurement year a prescriber is non-compliant and will provide educational opportunities to support prescribers in becoming compliant (88 FR 79291 through 79292).

2. Timeline for Including Prescriptions Written for Beneficiaries in Long-Term Care (LTC) Facilities in CMS EPCS Program Compliance Calculation

a. Background

In the CY 2021 PFS final rule (85 FR 84807), we adopted the requirement for all Schedule II, III, IV, and V controlled substances for covered Part D drugs prescribed electronically to be prescribed using the applicable standards in § 423.160(b), including the NCPDP SCRIPT standard version 2017071. In the CY 2022 PFS final rule (86 FR 65364), we finalized a policy to extend the date on or after which we will pursue compliance actions against prescribers based on Part D controlled substance prescriptions those prescribers write for beneficiaries in long-term care (LTC) facilities to January 1, 2025. We acknowledged that prescribers who work in LTC facilities or who provide care to residents in LTC facilities faced technological barriers that other prescribers did not face. One such barrier was that the NCPDP SCRIPT standard version 2017071 lacked appropriate guidance for EPCS in LTC facilities. We also noted that NCPDP was in the process of creating a new version of the SCRIPT standard that would be better suited for use by prescribers serving LTC facilities, which would allow willing partners to enable three-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede use of the NCPDP SCRIPT standard version 2017071 for EPCS in the LTC setting (86 FR 65364).

We received public comments on the CY 2022 PFS proposed rule requesting that we exempt prescribers writing Part D controlled substance prescriptions for beneficiaries in LTC facilities from having to conduct EPCS until after NCPDP SCRIPT standard version 2022011 was adopted. In response to those comments, in the CY 2022 PFS final rule, we noted that our intent when extending the date on or after which we will pursue compliance actions against prescribers based on Part D controlled substance prescriptions those prescribers write for beneficiaries in LTC facilities was to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping to ensure that these facilities eventually implement, and receive the benefits of EPCS (86 FR 65364). Furthermore, we noted that we were not persuaded to further delay commencing compliance actions to await publication of the NCPDP SCRIPT standard version 2022011. We acknowledged that three-way communication is not as seamless in the NCPDP SCRIPT standard version 2017071 as it may be in upcoming versions. We also stated that three-way communication is still possible with some modifications to EPCS, and therefore, we did not believe it would be appropriate to adopt a further delay on this basis alone (86 FR 65364).

In the 2024 PFS final rule (88 FR 79286 through 79287), we clarified that based on the existing regulatory text at § 423.160(a)(5), the CMS EPCS Program will automatically adopt the electronic prescribing standards at § 423.160(b) as they are updated. We noted that in the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the

Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' proposed rule (CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule) (87 FR 79550), we proposed to update provisions related to e-prescribing standards at § 423.160(b), including, after a transition period, requiring the NCPDP SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b) and retiring NCPDP SCRIPT standard version 2017071 by January 1, 2025.

Although we did not propose any policy changes regarding the NCPDP SCRIPT standard version in the CY 2024 PFS proposed rule (88 FR 52532), we received public comments requesting clarification on when the new NCPDP SCRIPT standard version would be adopted and the implications for measuring EPCS compliance in LTC. In response to those comments, in the CY 2024 PFS final rule (88 FR 79286), we acknowledged that we had not finalized our proposal regarding the NCPDP SCRIPT standard version 2022011 that was proposed in the CY 2024 Medicare Advantage and Part D Policy and Technical Changes proposed rule. We also acknowledged that some prescribers prescribing for beneficiaries in LTC facilities have adopted EPCS, but that others have waited for the standard to be updated (88 FR 79286 through 79287). We noted that if the requirement to use an updated version of the NCPDP SCRIPT standard is finalized for a date after January 1, 2025, we may explore whether a waiver is appropriate for prescribers who are not compliant solely as a result of prescriptions they have written for beneficiaries in LTC facilities or we may revisit the compliance start date, if needed, through future rulemaking (88 FR 79287).

In the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (89 FR 51242 through 51247), which appeared in the June 17, 2024 **Federal Register** (hereinafter referred to as the June 2024 Part D and Health IT Standards final rule), we finalized at § 423.160(b)(1) the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, must comply with a standard in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration date adopted by the Office of the National Coordinator for Health Information Technology (hereinafter ONC) [735], as described in the June 2024 Part D and Health IT Standards final rule (89 FR 51258 through 51259), § 423.160(b)(1) will require use of NCPDP SCRIPT standard version 2023011, which ONC adopted at 45 CFR 170.205(b)(2), beginning January 1, 2028, and retire use of NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) and to which it is applying an expiration date of January 1, 2028. ONC finalized January 1, 2028, as the expiration date for NCPDP SCRIPT standard version 2017071 instead of January 1, 2027, in consideration of public comments requesting that the date be delayed. As a result of these policies being finalized, the NCPDP SCRIPT standard version 2023011 will be required for the CMS EPCS Program by January 1, 2028. As both NCPDP SCRIPT standard version 2017071 and NCPDP SCRIPT standard version 2023011 will be adopted at 45 CFR 170.205(b) and unexpired as of the effective date of the June 2024 Part D and Health IT Standards final rule, entities subject to the requirement at § 423.160(b)(1) may use either version of the NCPDP SCRIPT standard during the transition period beginning July 17, 2024, the effective date of the June 2024 Part D and Health IT Standards final rule, and ending December 31, 2027, which is the last day before NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use.

b. Barriers to Electronic Prescribing of Controlled Substances for Beneficiaries in LTC and the Role of Three-Way Communication in the NCPDP SCRIPT Standard

We understand the challenges of conducting EPCS in the LTC setting to be multifactorial. The specific challenges include prescribers being responsible for covering multiple LTC facilities, each with different electronic health record (EHR) systems; reliance on LTC nursing staff to communicate prescriptions to the pharmacy on behalf of the prescriber; and with respect to NCPDP SCRIPT standard version 2017071, lack of three-way (or multi-party) communication between the prescriber, the LTC facility, and the pharmacy.

When conducting EPCS using the NCPDP SCRIPT standard version 2017071, prescribers can submit prescriptions electronically to the pharmacy, but the prescriber must subsequently contact the LTC facility separately to give an order for the medication so the LTC facility can administer the medication to the patient as prescribed. In cases where EPCS is being conducted and the prescriber has not communicated a separate order to the LTC facility, the pharmacy may deliver a prescription to the LTC facility and if the facility staff has no record of the order, then the LTC facility staff must contact the prescriber for an order to be able to administer the drug to the patient.

To conduct EPCS without having to separately communicate an order to the LTC facility, prescribers can use a web portal to enter an order in the LTC facility's EHR and then, if the EHR supports the necessary EPCS capability,[736] the prescription can be transferred to the pharmacy. However, not all LTC facilities have EHRs with this functionality. Additionally, each LTC facility may have its own web portal, making the number of portals and credentials overly burdensome for prescribers who treat patients who reside in multiple different LTC facilities. After providing an order to the LTC facility, prescribers often rely on LTC facility nursing staff to relay verbal prescription orders to pharmacies as permitted under 21 CFR 1306.03(b) and 1306.21(a).

NCPDP SCRIPT standard version 2023011 permits three-way communication that would better facilitate LTC workflows in a way that NCPDP SCRIPT standard version 2017071 does not. In comments NCPDP submitted in response to the CY 2025 Medicare Advantage and Part D Policy and Technical Changes proposed rule, NCPDP confirmed that it attempted to create guidance on three-way communication using the NCPDP SCRIPT standard version 2017071, but it was not realistic in that version of the

[735] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

[736] According to the Drug Enforcement Administration (DEA), for an electronic prescribing system to be used to transmit controlled substance prescriptions, a third party must audit the electronic prescribing application for compliance with the requirements of 21 CFR part 1311, or a certifying organization whose certification process has been approved by DEA must verify and certify that the application meets the requirements of 21 CFR part 1311. See *https://www.deadiversion.usdoj.gov/ecomm/thirdparty.html*.

standard.[737] In NCPDP SCRIPT standard version 2023011, through use of a MessageIndicatorFlag, an RxFill transaction may be sent as a copy to inform or synchronize systems.[738] Through use of this functionality, a prescriber can electronically send a controlled substance prescription (including for a covered Part D drug) to a pharmacy, and the pharmacy can use the MessageIndicatorFlag in an RxFill transaction when dispensing the prescription to inform the LTC facility of the medication order. This functionality streamlines prescribers' workflows and ensures that the LTC facility responsible for providing the controlled substance to the patient is aware of the order.

c. Timeframe for Including Prescriptions Written for Beneficiaries in LTC in the CMS EPCS Program Compliance Calculation

We received multiple public comments in response to the proposal in section III.B.4. of the CY 2025 Medicare Advantage and Part D Policy and Technical Changes proposed rule (88 FR 78489) to require NCPDP SCRIPT standard version 2023011 and retire NCPDP SCRIPT standard version 2017071, requesting that we reconsider the current January 1, 2025 compliance date for when we will include prescriptions written for covered Part D drugs for Part D eligible individuals in a LTC facility in the CMS EPCS Program compliance calculation. Commenters requested that we align the CMS EPCS Program compliance date for prescriptions written for beneficiaries in LTC with the date that NCPDP SCRIPT standard 2023011 will be required. In the June 2024 Part D and Health IT Standards final rule, we indicated that we would consider a change to the CMS EPCS Program compliance date for LTC through the annual Medicare PFS rulemaking process (89 FR 51247).

In the CY 2025 PFS proposed (89 FR 61999) rule, we proposed to revise § 423.160(a)(5) to state that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028. We did not otherwise propose to revise § 423.160(a)(5).

As of the effective date of the June 2024 Part D and Health IT Standards final rule, which was July 17, 2024, Part D sponsors, prescribers, and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, may use NCPDP SCRIPT standard version 2023011. However, there will be a transition period where both NCPDP SCRIPT standard version 2023011 and NCPDP SCRIPT standard version 2017071 can be used. ONC finalized an expiration date for NCPDP SCRIPT standard version 2017071 of January 1, 2028 (rather than January 1, 2027, as proposed), in part due to commenters' concern about implementing the new standard in LTC facilities (89 FR 51247).

In the CY 2025 PFS proposed (89 FR 61999) rule, we recognized the administrative burden prescribers could potentially face when implementing EPCS for prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities using NCPDP SCRIPT standard version 2017071, particularly with the lack of guidance. We also stated that we believe even though prescribers can use NCPDP SCRIPT standard version 2023011 as of July 17, 2024, it may not be feasible to have electronic prescribing systems configured to NCPDP SCRIPT standard version 2023011 by January 1, 2025, the current date by which prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation. By delaying the inclusion of prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities in the CMS EPCS Program compliance threshold calculation to January 1, 2028, we would be aligning CMS EPCS Program compliance calculations to the date by which the NCPDP SCRIPT standard version 2017071 is retired and the new NCPDP SCRIPT standard version 2023011 is required for prescribers when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals. We stated that we believe doing so would provide sufficient time for prescribers and pharmacies to adopt the new standard. Moreover, we acknowledged that LTC facilities will need to configure their EHR systems to be able to receive the MessageIndicatorFlag from the pharmacy, indicating that the prescription has been filled, and establish the necessary policies or operations to convert such a message into an order for the patient in the LTC facility.

We discussed that we considered an alternative where we would permit prescribers to apply for a waiver for circumstances beyond their control rather than modify the date to include prescriptions for beneficiaries in LTC in the compliance threshold calculation. In 2022, approximately 4.7 percent (4.5 million) of Part D Schedule II, III, IV, and V controlled substance prescriptions were written for beneficiaries in LTC facilities, with roughly 52 percent (2.4 million) of them not meeting the CMS EPCS Program standards for e-prescribing. If we kept the existing start date of January 1, 2025, as in the current regulatory text at § 423.160(a)(5) for the CMS EPCS Program, we estimate at least 6,800 additional prescribers would become non-compliant. These estimates are prior to considering emergency and disaster exceptions and waivers, which could reduce these numbers. If we do not extend the current date by which prescriptions written for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation, then starting with the CY 2025 measurement year, thousands of prescribers may become non-compliant, and those prescribers would potentially apply for a waiver. We explained (89 FR 62000) that we would expect that by the CY 2028 measurement year, many of these prescribers would be compliant and would not need to apply for a waiver because beginning January 1, 2028, NCPDP SCRIPT standard version 2023011 will be the required standard for prescribing and dispensing Part D drugs to Part D eligible individuals and commenters have indicated that this version of the standard will facilitate EPCS in LTC. We reminded prescribers that the CMS EPCS Program compliance rate is calculated using the Prescription Origin Code data element in the PDE record (88 FR 79287), and the PDE is a record of the prescription dispensing event.[739] We noted that we believe that the three-way communication in the NCPDP SCRIPT standard version 2023011 improves communication of

[737] *https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2024/NCPDP-Letter-to-CMS-regarding-CMS-4205-P.pdf.*

[738] National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011. Approval Date for American National Standards Institute (ANSI): January 17, 2023., April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at *https://standards.ncpdp.org/Access-to-Standards.aspx.*

[739] CMS Memorandum. ''Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE).'' April 27, 2006. Available from: *https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCPDEGuidance.pdf/$FILE/PDEGuidance.pdf.*

the controlled substance prescription as a medication order to the LTC facility's EHR when the pharmacy fills the prescription, but we solicited comment on how the NCPDP SCRIPT standard version 2023011 will improve prescribers' ability to conduct EPCS to the pharmacy dispensing the prescription for individuals in LTC facilities.

We noted in the CY 2025 PFS proposed rule (89 FR 62000) that should we finalize our proposal, we would encourage prescribers who write Schedule II, III, IV, or V controlled substance prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities to use the additional time to prepare for when such prescriptions for beneficiaries in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation by working to adopt the new standard or investing in technology necessary to conduct EPCS.

We solicited public comment on our proposals to extend the date after which prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in our CMS EPCS Program compliance threshold calculation from January 1, 2025, to January 1, 2028, and that related non-compliance actions would commence on or after January 1, 2028. We additionally solicited public comment on how NCPDP SCRIPT standard version 2023011 is expected to improve prescribers' ability to conduct EPCS to pharmacies dispensing covered Part D drugs to Part D eligible individuals in LTC facilities (89 FR 62000).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposals to extend the date after which prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities would be included in the CMS EPCS Program compliance threshold calculation from January 1, 2025, to January 1, 2028, and for related non-compliance actions to commence on or after January 1, 2028. The commenters supported the alignment between the CMS EPCS Program timeline and the NCPDP SCRIPT standard version 2023011 requirement, noting their belief that this will simplify compliance timelines. A few commenters expressed their belief that the extra time will allow prescribers and LTC facilities to address technical and administrative issues and minimize burden related to adopting multiple standards and configuring EHRs. One commenter agreed that it may not be feasible to have electronic prescribing systems configured to NCPDP SCRIPT standard version 2023011 by January 1, 2025. One commenter noted that while most LTC-based prescribers already prescribe electronically and most LTC pharmacies already process electronic prescriptions from outside prescribers, this proposal will provide sufficient time for others to come into full compliance. One commenter noted that this proposal would prevent a large number of waiver applications.

Response: We thank the commenters for their support and agree with their feedback. The proposal to extend the compliance date for the CMS EPCS Program for covered Part D drugs prescribed for Part D eligible individuals in LTC facilities will simplify timelines for adopting NCPDP SCRIPT standard version 2023011 and will provide additional time for prescribers working in LTCs to adopt the electronic prescribing technology. We also agree this policy will prevent many prescribers who prescribe covered Part D drugs for Part D eligible individuals in LTC facilities from potentially having to apply for a waiver. We remind prescribers that delaying inclusion of Schedule II, III, IV, and V controlled substance prescriptions written for covered Part D drugs for beneficiaries in LTC facilities in the CMS EPCS Program compliance calculation does not exempt prescribers from CMS EPCS Program compliance for Schedule II, III, IV, and V controlled substance prescriptions written for covered Part D drugs for beneficiaries who do not reside in LTC facilities. That is, prescribers who work in both LTC and non-LTC settings may still be subject to compliance actions on the basis of Schedule II, III, IV, and V controlled substance prescriptions written for covered Part D drugs for beneficiaries in non-LTC settings if such prescribers do not otherwise qualify for an exception or waiver.

Comment: A few commenters expressed their concerns about conducting EPCS in LTC facilities. Commenters noted the difficulty prescribers experience working with multiple EHRs in different LTCs and the necessary workarounds when the technology has not been adopted uniformly. Some commenters stated their belief that not all LTCs have EHRs because LTC facilities were excluded from funding in the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, Feb. 17, 2009). To close this gap, a few commenters requested cost-effective approaches or incentives for LTC facilities, like skilled nursing facility providers, to accept e-prescriptions by January 1, 2028. One commenter stated that unless there is more focus on providing incentives for LTC facilities to upgrade their systems, independent adoption of the NCPDP SCRIPT standard version 2023011 may not be sufficient to overcome these unique e-prescribing challenges among LTC settings.

Response: We appreciate commenters' concerns about difficulties they face working with multiple EHRs in different facilities. We note that the CMS EPCS Program measures prescriber compliance with requirements for electronic prescribing of the applicable controlled substances using information from the PDE data and does not measure electronic communication within LTC facilities. In cases where a prescriber is prescribing from their own health IT systems, the prescriber does not need the LTC facility to have EPCS functionality to be compliant with the CMS EPCS Program, because compliance is measured based on the prescriber sending the applicable prescriptions to the pharmacy electronically using the appropriate standards. We did not propose to establish an incentives program as part of the CMS EPCS Program to incentivize LTC facilities to adopt this technology, and we are not finalizing such a program in this rule. We do believe, however, that LTC facilities having EPCS capabilities with NCPDP SCRIPT standard version 2023011 could simplify the communication between prescribers and LTC facilities, and we encourage LTC facilities to adopt this technology as soon as possible. Finally, if a prescriber is unable to conduct electronic prescribing of controlled substances due to circumstances beyond the prescriber's control, the prescriber may apply for a waiver as permitted under § 423.160(a)(5)(iii).

Comment: A few commenters noted that technical challenges of electronic prescribing of controlled substances in LTC facilities would exist even after the NCPDP SCRIPT standard version 2023011 was adopted. Some prescribers may lack access to EPCS technology or find it disruptive to their workflow to use multiple facility EHR systems. Commenters elaborated and advised that prescribers would continue to use their own systems to issue prescriptions to the pharmacy and communicate to the facility via phone, fax, or non-NCPDP electronic interoperability methods. One commenter noted that in addition to not having compatible health IT across different settings, the

current resolution by means of accessing a portal adds significant burden to prescribers and pharmacies that serve multiple LTC facilities. The commenter stated that this situation creates a risk for delays in LTC short- and long-stay residents receiving necessary medications in a timely manner, resulting in unnecessary pain and other negative clinical outcomes. One commenter noted that NCPDP SCRIPT standard version 2017071 enables pharmacy-to-facility notification, but it occurs too late in the workflow, causing delays and compliance challenges for facilities and that NCPDP SCRIPT standard version 2023011 will not address this challenge. The commenter recommended that prescribers explore methods for directly transmitting copies of prescriptions: prescriber-to-the-facility, in addition to prescriber-to-the-pharmacy as required by the Drug Enforcement Agency (DEA). One commenter noted the potential compliance and operational challenges where prescribers send prescriptions directly to pharmacies, which are then responsible for notifying the facility of the order. The commenter noted LTC facilities must have signed prescriber orders on file to comply with medication management regulations, and the pharmacy's copy typically does not include the prescriber's signature, creating a potential gap in compliance with LTC facility requirements. LTC facilities have direct communication of all orders from prescribers to facility staff. The staff then transcribes and relays these orders, along with any necessary supplementary information, to pharmacies, laboratories, and other relevant parties. The commenter noted that NCPDP SCRIPT standard version 2023011 has limited potential as EPCS adoption increases, since the communication of orders from the pharmacy to the facility is already feasible today.

Response: We appreciate that prescribers who prescribe covered Part D drugs for beneficiaries in LTC facilities may still have challenges even after NCPDP SCRIPT standard version 2023011 is required. While we recognize the functionality the 3-way communication in NCPDP SCRIPT standard version 202311 offers, it is outside the scope of our proposal to address whether such communication meets other, separate requirements for medication orders in LTC facilities. The CMS EPCS Program does not impose requirements for internal communication of medication orders for controlled substances within LTC facilities and does not include such orders in CMS EPCS Program compliance calculations. Rather, CMS EPCS Program requirements at § 423.160(a)(5) specify that *prescribers* must electronically prescribe at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs using applicable standards.

As described in the CY 2022 PFS proposed rule (86 FR 65364), we must balance being responsive to stakeholder concerns surrounding the increased implementation barriers faced by prescribers who prescribe applicable prescriptions for beneficiaries in LTC facilities with encouraging the adoption of EPCS due to the benefits of electronic prescribing. We believe that delaying the date for when applicable prescriptions for beneficiaries in LTC facilities are included in the CMS EPCS Program compliance threshold to align with the January 1, 2028 date on which use of NCPDP SCRIPT standard version 2023011 will be required will provide additional time for prescribers, pharmacies, and LTC facilities to adopt EPCS. We do not believe that we should indefinitely exclude Schedule II, III, IV, and V controlled substance prescriptions written for covered Part D drugs for beneficiaries in LTC facilities from the CMS EPCS Program compliance threshold. As discussed in the CY 2021 and CY 2022 PFS final rules (85 FR 84805 and 86 FR 65363), we believe there are many benefits to EPCS, including fraud deterrence, improved patient safety and workflow efficiencies, adherence management, and reduced burdens. Given these benefits, we continue to encourage prescribers to adopt the technology necessary for EPCS, irrespective of whether LTC facilities have adopted other or related technology, because the CMS EPCS Program measures compliance based on prescriptions sent by the prescriber to the pharmacy. We expect that with the delay, both prescribers and LTC facilities have an opportunity to focus their resources to adopt the NCPDP SCRIPT standard version 2023011, as use of that standard should reduce potential inconsistencies and duplication of communicating the prescription to the pharmacy and the medical order to the LTC facility.

Comment: A few commenters noted the benefits of NCPDP SCRIPT standard version 2023011. A few commenters explained that under NCPDP SCRIPT version 2017071, prescribers can transmit electronic prescriptions for controlled substances to the pharmacy but additionally need to contact the LTC facility to give a separate order for the facility staff to administer the medication to the patient. NCPDP SCRIPT standard version 2023011 is expected to resolve these issues. One commenter acknowledged that CMS recognized the administrative burden prescribers could potentially face when implementing EPCS for prescriptions using NCPDP SCRIPT standard version 2017071, particularly with the lack of guidance. The commenter further elaborated that LTC facilities will need to configure their EHR systems to receive the MessageIndicatorFlag from the pharmacy, indicating that the prescription has been filled, and establish the necessary policies or operations to convert the message into an order for the patient in the LTC facility.

Response: We thank the commenters for their comments regarding limitations of the NCPDP SCRIPT standard version 2017017 and their recognition of the improved 3-way communication benefits of NCPDP SCRIPT standard version 2023011. We acknowledge that LTC facilities may need to configure their EHR systems to support NCPDP SCRIPT standard version 2023011 and are mindful that these updates may result in changes in workflow and may require training for staff. We reiterate that the CMS EPCS Program measures compliance based on the prescriber's use of electronic prescribing for the applicable prescriptions the prescriber transmits to the pharmacy. By delaying the date for which we include prescriptions for beneficiaries in LTC facilities, we are allowing additional time for prescribers to adapt to changes associated with the implementation of the new version of the NCPDP SCRIPT standard.

Comment: One commenter recommended facilitating EPCS adoption earlier than January 1, 2028, for prescriptions for covered Part D drugs for Part D eligible individuals in LTC facilities. The commenter stated that EHR technology companies and senior care providers made significant investments to stay compliant with the CMS EPCS Program timeline of January 1, 2025, and EPCS adoption will provide practical insight on any remaining challenges. The commenter also expressed their belief that the delay will continue to pose operational challenges for both LTC facilities and pharmacies associated with non-electronic communication, such as risk of diversion, paper prescription management, and storage of paper for audits.

Response: We appreciate that LTC facilities have made investments in EPCS and are mindful that NCPDP SCRIPT standard version 2023011 may not resolve all the workflow issues

related to EPCS in LTC facilities. However, we believe that delaying the date for including the applicable prescriptions for beneficiaries in LTC facilities in the CMS EPCS Program compliance calculation is warranted to minimize confusion as prescribers, pharmacies, and LTC facilities move to NCPDP SCRIPT standard version 2023011. We remind commenters that prescribers of Schedule II, III, IV, and V controlled substance prescriptions for covered Part D drugs for beneficiaries in LTC facilities may currently use EPCS and may continue to do so prior to and after January 1, 2028. We encourage prescribers, pharmacies, and LTC facilities to adopt this technology as soon as feasible regardless of whether such prescriptions are included in CMS EPCS Program compliance calculations.

Comment: A few commenters provided additional considerations related to the CMS EPCS Program timeline for LTC. One commenter urged CMS to work with the LTC pharmacy community to evaluate if additional barriers to implementation exist and to consider additional delays in enforcing compliance as needed. Another commenter requested CMS consider a waiver for rural locations utilizing small or homegrown software systems needing additional time to implement electronic prescribing technology. One commenter noted that many LTC facilities have pharmacies that already accept commercial prescriptions and asked CMS to ensure that the extension does not inadvertently place additional burden on providers who may need to employ a different method of prescribing when treating patients in LTC facilities.

Response: We acknowledge the potential challenges of EPCS within LTC settings. By delaying the date by which we will include Schedule II, III, IV, and V controlled substance prescriptions for covered Part D drugs for beneficiaries in LTC facilities in the CMS EPCS Program compliance calculation, we are acknowledging that LTC facilities and their pharmacies may need additional time to implement EPCS technology, which may ultimately impact prescribers' ability to send prescriptions electronically to such LTC pharmacies. We believe that the proposed extension, to January 1, 2028, provides adequate additional time. We did not propose to extend the compliance deadline beyond January 1, 2028, when NCPDP SCRIPT standard version 2023011 will be the required standard for transmitting prescriptions and prescription-related information for Part D drugs for Part D eligible individuals, because public comments discussed in the June 2024 Part D and Health IT Standards final rule generally indicated that this version of the standard would facilitate prescriber use of EPCS for beneficiaries in LTC facilities (89 FR 51246 through 51247). However, we remind prescribers that they may apply for a waiver under § 423.160(a)(5)(iii) if they are unable to conduct electronic prescribing due to circumstances beyond their control. Additionally, the CMS EPCS compliance threshold at § 423.160(a)(5) is 70 percent of applicable prescriptions, which allows the prescriber to be compliant as long as no more than 30 percent of applicable prescriptions are not prescribed electronically. We do not believe our proposal will impact prescribers who already submit their prescriptions electronically to LTC pharmacies, and we encourage all pharmacies and prescribers to adopt EPCS as soon as possible.

After consideration of public comments, we are finalizing our proposals to revise § 423.160(a)(5) to state that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028.

M. Expand Hepatitis B Vaccine Coverage

Hepatitis B vaccines are currently covered as a Medicare Part B benefit under section 1861(s)(10)(B) of the Act. Medicare beneficiaries who are at high or intermediate risk of contracting hepatitis B can receive hepatitis B vaccines, with no cost to the beneficiary. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B by issuing regulations. The Secretary, through past rulemaking, defined high and intermediate risk groups for hepatitis B vaccine at 42 CFR 410.63. This definition was last updated in the CY 2013 PFS final rule (77 FR 69363, November 16, 2012). Beneficiaries with coverage under Medicare Part D whose level of risk falls outside high or intermediate may have their vaccine covered under the Part D benefit.[740]

Medicare coverage of hepatitis B vaccination is outdated in light of more recent information about the risks of contracting hepatitis B. As explained in more detail in this section, we proposed to improve access and utilization of hepatitis B vaccines by expanding the list of individuals who are at high or intermediate risk of contracting hepatitis B in § 410.63(a).

1. Background

Hepatitis B is a vaccine-preventable liver disease caused by the hepatitis B virus.[741] The vaccine consists of a series of typically 2–3 doses depending on the formulation delivered at various intervals.[742] Hepatitis B virus is transmitted when body fluid (blood, semen, or other) from a person infected with the virus enters the body of someone who is uninfected.[743] This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; transmission from the gestational parent to baby during pregnancy or at birth; direct contact with blood or open sores; or sharing contaminated items such as toothbrushes, razors, or medical equipment (such as a glucose monitor) of a person who has hepatitis B.[744] Hepatitis B can be an acute, short-term illness and it can develop into a long-term, chronic infection. Chronic hepatitis B can lead to serious health problems, including cirrhosis, liver cancer, and death. Treatments for hepatitis B are available but no cure exists. There are currently an estimated 2.4 million individuals in the U.S. living with hepatitis B virus and an estimated 20,000 new infections every year.[745] Acute hepatitis B infections among adults leads to chronic hepatitis B disease in an estimated 2–6 percent of

[740] Sayed, BA, Finegold, K, Ashok, K, Schutz, S, De Lew, N, Sheingold, S, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. (Issue Brief No. HP–2023–05). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2023. Retrieved from *https://aspe.hhs.gov/sites/default/files/documents/407d41b6534e7af6702eb280b3945d00/aspe-ira-vaccine-part-d.pdf*.

[741] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm*.

[742] CDC. Hepatitis B: Hepatitis B vaccine administration. Atlanta, GA: U.S. HHS, CDC; 2024. Retrieved from *https://www.cdc.gov/hepatitis-b/hcp/vaccine-administration/index.html*.

[743] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm*.

[744] CDC. Hepatitis B: Hepatitis B vaccine administration. Atlanta, GA: U.S. HHS, CDC; 2024. Retrieved from *https://www.cdc.gov/hepatitis-b/hcp/vaccine-administration/index.html*.

[745] Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC recommendations—United States, 2023. *MMWR Recomm Rep.* 2023;72(1):1–25. Retrieved from *https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm*.

cases.[746] Rates of reported cases of acute hepatitis B have steadily increased among persons aged 40–49, 50–59 years, and 60 years and older from 2015–2019.[747] In 2020, rates declined in all adult age groups. In 2021, rates among all age groups remain stable or declined compared to 2020. The highest rates were among persons 40–49 years (1.6 cases per 100,000 population) and 50–59 years (1.0 case per 100,000 population). The rates for people aged 60 years and older were 0.5 cases per 100,000 population.

Hepatitis B vaccines are safe and effective in preventing hepatitis B virus.[748] The number of reported hepatitis B cases has declined substantially since the vaccine was introduced in 1982, which was achieved through incremental expansion of groups for whom the vaccine was recommended. However, vaccination coverage among adults has been deficient and further reduction in hepatitis B infections in the U.S. has stalled. Approximately 34 percent of adults aged ≥19 years have been vaccinated against hepatitis B.[749] Furthermore, an estimated 20 percent of adults aged ≥60 years have been vaccinated against hepatitis B.

Since 2011, rates of reported cases of acute hepatitis B decreased among children and adolescents aged 0–19 years and persons aged 20–29 years.[750] The Centers for Disease Control and Prevention (CDC) states that this is due, in part, because of the childhood hepatitis B vaccine recommendations that were first implemented in 1991. The Advisory Group for Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the U.S. and the CDC updates the U.S. adult and childhood immunization schedules consistent with ACIP recommendations.[751] As the cohort of persons vaccinated as children have grown older, rates of acute hepatitis B among persons aged 30–39 years began to consistently decrease beginning in 2015.[752] Conversely, rates of reported cases of acute hepatitis B have steadily increased among persons aged 40–49, 50–59 years, and 60 years and older from 2015–2019 (see Table 65). Overall, the rate of acute hepatitis B cases increased 11 percent from 2014 (0.9 per 100,000) to 2018 (1.0 per 100,000).[753] Injection drug use and sexual transmission are known risk factors associated with rising acute hepatitis B cases. For example, acute hepatitis B infections increased 114 percent from 2006 to 2013 in three states particularly affected by the opioid epidemic (Kentucky, Tennessee, and West Virginia).[754]

TABLE 65: Rates of Reported Acute Hepatitis B Virus Infection, by Age Group – United States

Age (years)	2015	2016	2017	2018	2019
0–19	0.0	0.0	0.0	0.0	0.0
20–29	0.8	0.6	0.6	0.6	0.5
30–39	2.6	2.4	2.3	2.0	1.8
40–49	2.4	2.2	2.5	2.6	2.7
50–59	1.4	1.5	1.6	1.6	1.6
≥60	0.5	0.5	0.6	0.6	0.6
Source: CDC, National Notifiable Diseases Surveillance System.					
* Rates per 100,000 population. Beginning in 2021, single-race population estimates are used for rate calculations. For prior years, bridged-race population estimates are used.					
† Reported confirmed cases. For the case definition, see *https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/*.					

2. Statutory Authority

Section 1861(s)(10)(B) of the Act provides a benefit category under Part B for hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis. The statute expressly authorizes the Secretary to determine who is at high or intermediate risk of contracting hepatitis B for coverage of the hepatitis B vaccine.

3. Regulation

Medicare Part B pays for the hepatitis B vaccine as defined in § 410.63(a), which describes individuals who are at high or intermediate risk of contracting hepatitis and eligible for coverage of

[746] Weng, M., Doshani, M., Khan, M., Frey, S., et al. Universal hepatitis B vaccination in adults aged 19—59 years: Updated recommendations of the Advisory Committee on Immunization Practices—United States, 2022. *MMWR,* April 1, 2022, Vol 71(13);477–483.

[747] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[748] Weng, M., et al. 2022. Universal hepatitis B vaccination.

[749] CDC. 2023. Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021. Retrieved from *https://www.cdc.gov/adultvaxview/publications-resources/vaccination-coverage-adults-2021.html.*

[750] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[751] CDC. ACIP. Retrieved from *https://www.cdc.gov/acip/?CDC_AAref_Val=https://www.cdc.gov/vaccines/acip/index.html.*

[752] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[753] CDC 2020. Viral hepatitis surveillance report 2018—Hepatitis B. Retrieved from *https://archive.cdc.gov/#/details?url=https://www.cdc.gov/hepatitis/statistics/2018surveillance/HepB.htm.*

[754] HHS. 2016. Viral Hepatitis in the United States: Data and Trends. Retrieved from *https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html.*

hepatitis B vaccinations under Part B. In the CY 2013 PFS final rule (77 FR 69363), we expanded the definition of individuals at risk of contracting hepatitis B, citing updated ACIP recommendations about increased risk for diabetes patients to support the change. The ACIP stated that the hepatitis B outbreaks were associated with adults with diabetes receiving assisted blood glucose monitoring.[755] Today, the regulations are outdated as these risk categories have been shown to be ineffective and are no longer the focus of how the medical community discusses hepatitis B infection and prevention. In 2019, risk behavior and exposure data were missing for 37 percent of case reports (1,183 of 3,192) of acute hepatitis B infections received by CDC.[756] ACIP also cited a large national survey of family medicine and internal medicine physicians assessing barriers to adult hepatitis B vaccination and found that 68% cited patients' non-disclosure of risk factors.[757]

4. Proposed Regulatory Revisions

Since 1991, hepatitis B vaccination has been recommended by ACIP and the CDC for infants at birth, completing the vaccination series by 16 months of age.[758] This is important because in the U.S., the age cohorts who have received the completed series have low to no risk of contracting the hepatitis B virus, as evidenced by the rate of zero acute hepatitis B virus infections for the 0–19 age group.[759] The infant and childhood recommendations were not in place for most of today's adults which is evidenced by no other age group reaching a rate of zero acute hepatitis B virus infections. Given this information, we consider the population of people who have completed the vaccination series to be at low risk of contracting the hepatitis B virus. Individuals who remain unvaccinated against hepatitis B are at intermediate risk, at minimum, of contracting hepatitis B virus.

We conclude that anyone who is not fully vaccinated to be at intermediate risk of contracting the hepatitis B virus as their risk would be above zero. Additionally, rates of reported cases of acute hepatitis B steadily increased among age groups 40 and over between 2015 and 2019, with stabilizing or declining rates between 2020 and 2021, which may be due to the COVID–19 pandemic.[760] While it is encouraging to see declining rates, these populations remain at intermediate risk given their reported cases remained above zero. Therefore, we proposed to revise § 410.63(a)(2), Intermediate Risk Groups, by adding a new paragraph (a)(2)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. We included the latter group in this proposal because the CDC has stated that it is not harmful to receive either extra doses or a repeat vaccination series.[761] This will allow these individuals to receive a covered vaccination series when medical history may not be available. Also, the CDC states that screening for hepatitis B virus is not a requirement for vaccination, and in settings where screening is not feasible, vaccination of persons recommended to receive the vaccine should continue.

We noted that § 410.63(a)(3) provides an exception to individuals considered intermediate or high risk of contracting hepatitis B for individuals who have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B. We noted that, as proposed, § 410.63(a)(2)(iv) would remain subject to this exception because individuals with previous infection would not benefit from the vaccine. However, we note that the CDC states it is not harmful to vaccinate people who are immune to hepatitis B virus because of current or previous infection or vaccination, nor does it increase the risk for adverse events.[762]

5. Proposal Summary

As noted previously, we proposed to revise § 410.63(a)(2), *Intermediate Risk Groups,* by adding paragraph (a)(2)(iv) to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown. We stated that the proposal is in the best interest of the Medicare program and its beneficiaries because it would help protect Medicare beneficiaries from acquiring hepatitis B infection and contribute to eliminating viral hepatitis as a public health threat in the United States. We solicited comments on the proposal.

6. Comments/Responses and Summary of the Final Policy

We received public comments on the proposed revisions to the hepatitis B vaccine coverage. The following is a summary of the comments we received and our responses.

Comment: All the commenters supported the proposals to expand access to the hepatitis B vaccine in order to increase utilization. The commenters stated that our proposals address concerns about disparities in access to the vaccine for people with Medicare. Some commenters suggested that the proposals would provide greater consistency with other preventive Medicare Part B covered vaccines, including the influenza, pneumococcal, and COVID vaccines.

Response: We appreciate the commenters' support of CMS's efforts to improve access and utilization of the hepatitis B vaccine.

Comment: One commenter asked CMS to exercise enforcement discretion as providers and pharmacies navigate the migration of this vaccine from Part D to Part B coverage and asked that CMS clarify documentation requirements needed and whether an incomplete vaccination record would be sufficient to administer the vaccine.

Response: We are not adopting the commenter's suggestion to exercise enforcement discretion. Hepatitis B vaccines are currently covered as a Medicare Part B benefit under section 1861(s)(10)(B) of the Act. The finalized proposals, which expand coverage under Part B for beneficiaries, will be effective for services furnished on or after January 1, 2025. We believe only a small number of beneficiaries may be receiving the vaccine under Part D. In response to the public comment, we are clarifying that when the rule is effective, an individual whose vaccination history is unknown may receive the hepatitis B vaccine, meaning that a vaccination

[755] CDC. 2011. Use of Hepatitis B Vaccination for Adults with Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 60(50);1709–1711. Retrieved from *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm#:~:text=Based%20on%20the%20Work%20Group,made%20(recommendation%20category%20A).*

[756] Weng, M., et al. 2022. Universal hepatitis B vaccination.

[757] Daley MF, Hennessey KA, Weinbaum CM, et al. Physician practices regarding adult hepatitis B vaccination: a national survey. Am J Prev Med 2009;36:491–6. PMID:19362798 *https://doi.org/10.1016/j.amepre.2009.01.037.*

[758] CDC, 2024. Vaccine safety: Hepatitis B vaccines. Retrieved from *https://www.cdc.gov/vaccine-safety/vaccines/hepatitis-b.html?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/vaccines/hepatitis-b-vaccine.html.*

[759] CDC. Viral hepatitis. 2021 viral hepatitis surveillance report. Atlanta, GA: U.S. HHS, CDC; 2023. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b/figure-2.4.htm.*

[760] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[761] CDC. Hepatitis B: Hepatitis B vaccine administration. Atlanta, GA: U.S. HHS, CDC; 2024. Retrieved from *https://www.cdc.gov/hepatitis-b/hcp/vaccine-administration/index.html.*

[762] CDC. Hepatitis B: Hepatitis B vaccine administration. Atlanta, GA: U.S. HHS, CDC; 2024. Retrieved from *https://www.cdc.gov/hepatitis-b/hcp/vaccine-administration/index.html.*

record is not needed. The roster bill claim form contains minimal data and does not require a vaccination record. Such a roster bill claim would be similar to other roster billed vaccines, which include the influenza, pneumococcal, and COVID vaccines.

Comment: Some commenters stated that they look forward to working with CMS to expand the mass immunizer program to include all future preventive Part B vaccines. Some commenters noted that only four preventive vaccines are covered under Medicare Part B which creates barriers to offering in-office administration of newer vaccines, such as shingles and respiratory syncytial virus (RSV) vaccines, to Medicare beneficiaries during an office visit. They also recognized that CMS does not have the authority to add new ACIP-recommended vaccines to Part B coverage, but urged CMS to work with Congress to close this known gap that creates access barriers for patients to much needed vaccines.

Response: We appreciate the suggestions for expanding Medicare coverage under part B for additional vaccines in the future. As some commenters have noted, however, additional legislation would be necessary to expand the scope of coverage under Part B for these additional vaccines. Because those suggestions are outside the scope of our proposed rule, no further response is required.

After considering the public comments, we are finalizing our proposed revisions to § 410.63(a)(2). Specifically, we are adding individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown to the list of intermediate risk groups. Expanding the definition of intermediate risk groups will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States and is in the best interest of the Medicare program and its beneficiaries.

N. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments in § 414.610(c)(5)(i) and three temporary add-on payments in § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

Under the AFS, Medicare Part B covers seven levels of service for ground (including water) ambulance transports and two levels of service for air ambulance transports. The levels of service for ground ambulance transports include basic life support (emergency); basic life support (non-emergency); advanced life support, level 1 (ALS1) (emergency); ALS1 (non-emergency); advanced life support, level 2 (ALS2); paramedic intercept; and specialty care transport (§ 410.40(c)). Definitions for the levels of service can be found at § 414.605 and in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services.

At § 414.605, ALS2 is defined as either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures: (1) Manual defibrillation/cardioversion; (2) Endotracheal intubation; (3) Central venous line; (4) Cardiac pacing; (5) Chest decompression; (6) Surgical airway; (7) Intraosseous line. These procedures must be performed by ALS personnel trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic (§ 414.605).

According to the 2020 National Association of State Emergency Medical Services Organizations Assessment (NASEMSO), there are approximately 11,450 ground EMS agencies that provide 9–1–1 response with transport to an acute care hospital.[763] The administration of low titer O+ whole blood transfusions, otherwise referred to as whole blood transfusion therapy (WBT), began in 2017 when two Emergency Medical Services (EMS) systems in Texas began providing WBT to patients in hemorrhagic shock during ambulance transports. Prior to this, use of blood products in the treatment of hemorrhagic shock in the form of blood component therapy was available only in the hospital setting and by one EMS system. Low titer O+ whole blood contains low levels of antibodies that patients of any blood type can receive, and is provided in EMS settings to significantly increase these patients' chances of survival.

By September 2023, more than 121 EMS systems in the United States were using blood products in the form of either WBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma.[764] Seventy percent of these systems were using WBT.[765] As of March 2024, 147 EMS systems (1.2 percent of the EMS systems in the United States) carry whole blood products, with 200 or more systems anticipated to provide some form of blood product transfusion by the end of 2024.[766] Today, nearly 60 percent of those 147 EMS systems carry low titer O+ whole blood, with the remainder utilizing other blood products.[767]

EMS systems that administer WBT and other blood products (PRBCs and plasma) generally utilize it for patients suffering hemorrhagic shock stemming from traumatic injury, though it may also be indicated in certain non-

[763] National Association of State EMS Officials. 2020 National Emergency Medical Services Assessment 2020. Table 3, p 27. Available from: *www./https://nasemso.org/*. Accessed May 1, 2024.

[764] Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[765] Levy MJ, Garfinkel EM, May R, et al. Implementation of a prehospital whole blood program: Lessons. J Am Coll Emerg Physicians Open. 2024;5: e13142. *https://doi.org/10.1002/emp2.13142*.

[766] Levy MJ, Garfinkel EM, May ER, et al. Implementation of a prehospital whole blood program: Lessons. learned. J Am Coll Emerg Physicians Open. 2024;5: Apr; 5(2): e13142. *https://doi.org/10.1002/emp2.13142*. Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[767] Ibid.

traumatic medical conditions such as hemorrhagic shock from a gastrointestinal bleed.[768] Traditional EMS resuscitation protocol for massive hemorrhage from trauma and other medical conditions such as gastrointestinal bleeding consists of crystalloid fluids and blood component transfusions, which consist of a balanced portion of PBRCs, platelets, and fresh frozen plasma.[769]

During the conflicts in Iraq and Afghanistan, use of this traditional protocol was difficult due to the austere combat environment and limited availability of blood components, which often necessitated the use of fresh whole blood (FWB) in traumatic resuscitation.[770] Data collected related to these conflicts demonstrated improvements in survival rate and reductions in transfusion requirements for military casualties in hemorrhagic shock who received FWB versus those receiving traditional blood component transfusion, and spurred research and interest in the use of WBT in civilian trauma.[771] Additional data demonstrating an improvement in 24-hour and 30-day survival rate among medically evacuated combat casualties in Afghanistan who received prehospital transfusion encouraged research and interest in these techniques for possible deployment by EMS services.[772]

In the treatment of civilian patients with hemorrhagic shock from trauma, studies have demonstrated that WBT provides a substantial survival benefit versus traditional component therapy,[773] especially when provided early in the prehospital and hospital settings.[774] One study found WBT increased the survival of such patients by as much 60 percent and reduced the need for additional blood products in the 24-hour period following the initial transfusion by 7 percent.[775] Another study noted that there was a significant increase in the 24-hour and 30-day survival rate in patients suffering from severe hemorrhage requiring a large transfusion volume.[776]

Patients suffering from hemorrhagic shock require stabilization in the field and rapid transport to an acute care hospital to treat the source of hemorrhage.[777] Individuals who are experiencing hemorrhagic shock primarily due to blood loss may require WBT as their only resuscitative treatment. Each unit of whole blood takes 5–8 minutes to transfuse.[778] Depending on the time needed to transport and clinical need, patients generally receive 1–2 units of WBT during ground transport.[779]

While there may be variance between jurisdictions, the protocols for many EMS systems currently providing WBT are designed for patients who require complex management at the advanced life support level, demonstrating suspicion of blood loss along with evidence of physiologic shock as indicated by parameters such as low blood pressure, an elevated pulse rate, or slow capillary refill.[780] Other relevant factors may include an elevated lactate level, an End-tidal carbon dioxide (EtCO2) waveform capnography reading <25 as surrogate for elevated lactate, a shock index (heart rate/systolic blood pressure) >1, and, where appropriate and consistent with protocol, authorization by online or other medical authority.[781]

We believe that many ground ambulance transports providing WBT already qualify for ALS2 payment, since patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock, and therefore are likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, with endotracheal intubation, chest decompression, and/or placement of a central venous line or an intraosseous line the most probable to be seen in these circumstances. Patients requiring WBT are typically suffering from hemorrhagic shock, for which the usual course of treatment includes airway stabilization, control of the hemorrhagic source, and stabilization of blood pressure using crystalloid infusion and the provision of WBT or other blood product treatments when available, but not necessarily the administration of advanced cardiac life support medications.[782] Consequently, we do not believe it is likely that most patients who may require WBT would trigger the other pathway to qualify as ALS2, that is, the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate).

However, not all ground ambulance transports providing WBT may currently qualify for ALS2 payment. An ambulance transport would not qualify for ALS2 payment where a patient received only WBT during a ground ambulance transport, and not one or more other services that, either by themselves or in combination, presently

[768] Ibid.

[769] Young PP, Cotton BA, Goodnough LT. Massive Transfusion Protocols for Patients with Substantial Hemorrhage. Transfusion Medicine Reviews. 2011, Vol 25(4). 293–303.

Washington State Department of Health Office of Community Health Systems Emergency Medical Services and Trauma Section. Trauma Clinical Guideline: Massive Transfusion for Trauma.

[770] Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. Transfusion. 2013;53: 107S–13S.

[771] Spinella PC, Perkins GJ, Grathwohl KW, Beekley AC, Holcomb J. Warm Fresh Whole Blood is Independently Associated with Improved Survival for Patients with Combat-Related Traumatic Injuries. J Trauma. 2009 April; 66(4 Suppl): S69–S76. *doi:10.1097/TA.0b013e31819d85fb*. Nessen SC, Eastridge BJ, Cronk D, et al. Fresh whole blood use by forward surgical teams in Afghanistan is associated with improved survival compared to component therapy without platelets. Transfusion. 2013;53: 107S–13S.

Gurney J, Staudt A, Cap A, Shackleford A, et al. Improved Survival in Critically Injured Combat Casualties Treated with Fresh Whole Blood by Forward Surgical Teams in Afghanistan. Transfusion. 2020;60; S180–S188.

[772] Shackelford SA, del Junco DJ, Powell-Dunford N, Mazuchowski EL, et al. Association of Prehospital Blood Product Transfusion During Medical Evacuation of Combat Casualties in Afghanistan with Acute and 30-Day Survival. JAMA. 2017; 318(16):1581–1591.

[773] Hazelton JP, Ssentongo AE, Oh JS, et al. Use of Cold-Stored Whole Blood is Associated with Improved Mortality in Hemostatic Resuscitation of Major Bleeding. A Multicenter Study. 2022. Annals of Surgery. Vol 276(4). 579–88.

[774] b. Torres CM, Kent A, Scantling D, et al. Association of Whole Blood With Survival Among Patients Presenting With Severe Hemorrhage in US and Canadian Adult Civilian Trauma Centers. JAMA Surg. 2023;158(5):532–540. doi: *10.1001/jamasurg.2022.6978*.

Brill JB, Tang B, Hatton G, Mueck KM, et al. Impact of incorporating whole blood into hemorrhagic shock resuscitation: Analysis of 1,377 consecutive trauma patients receiving emergency-release uncrossmatched blood products. J Am Coll Surg. 2022;234(4):408–418.

Guyette FX, Sperry JL, Peitzman AB, et al. Prehospital blood product and crystalloid resuscitation in the severely injured patient: a secondary analysis of the prehospital air medical plasma trial. Ann Surg. 2021;273:358–364.

[775] Ibid.

[776] Ibid.

[777] Centers for Disease Control and Prevention. Guidelines for field triage of injured patients. MMWR. 2009;58 (RR–1):1–34.

[778] Vitberg D. Assistant Medical Director. District of Columbia Fire and EMS Department. Zoom meeting. February 20, 2024. Bank EA. Assistant Chief of EMS. Co-Chair of the South East Regional Advisory Council Trauma Committee. Phone conversation, May 10, 2024.

[779] Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[780] Mark H. Yazer, Philip C. Spinella, Eric A. Bank, Jeremy W. Cannon, Nancy M. Dunbar, John B. Holcomb, Bryon P. Jackson, Donald Jenkins, Michael Levy, Paul E. Pepe, Jason L. Sperry, James R. Stubbs & Christopher J. Winckler (2022) THOR–AABB Working Party Recommendations for a Prehospital Blood Product Transfusion Program, Prehospital Emergency Care, 26:6, 863–875.

Ibid., *https://miemss.org/home/Clinicians/Whole-Blood*.

[781] Ibid.

[782] Prehospital Hemorrhage Control and Treatment by Clinicians: A Joint Position Statement. Ann Emerg Med. 2023;82:e1–e8.

qualify as ALS2. We believe WBT should independently qualify as an ALS2 procedure because the administration of WBT and handling of low titer O+ whole blood requires a complex level of care beyond ALS1 for which EMS providers and suppliers at the EMT-Intermediate or paramedic level require additional training. In addition, WBT requires specialized equipment such as a blood warmer and rapid infuser.[783] While there is no established national training protocol, many systems follow the guidelines of the Association for the Advancement of Blood and Biotherapies (AABB), which require additional training that is 4 hours in length for paramedics and 6 hours in length for EMS supervisory staff.[784] Medicare's requirements for ambulance staffing at § 410.41(b) include compliance with state and local laws; those laws would establish appropriate training requirements with respect to WBT administration.

Therefore, we believe it is appropriate to modify the definition of ALS2 to account for the instances where patients are administered WBT but do not otherwise qualify for ALS2 payment. Of note, we do not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT under the AFS.

We proposed in the CY 2025 PFS proposed rule (89 FR 62002 through 62004) to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion to the current list of seven ALS2 procedures as a new number 8. We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides WBT would itself constitute an ALS2-level transport.

We are aware that some established EMS systems may already provide WBT to treat patients in hemorrhagic shock, while other jurisdictions, particularly including those in rural areas, often will rely on alternative blood product treatments such as PRBCs and plasma. The availability of WBT in rural areas is a complex and multifactorial issue. Fluctuating stock of the ''raw product'' (blood donations) along with local healthcare demands for blood products (PRBCs, platelets, plasma, etc.) affect the availability of WBT. Other issues in rural areas include the logistical challenges and the costs involved in acquiring fresh units of WBT and returning any unused units to a supplier.[785]

The training, administration, and monitoring is the same for these alternative blood product treatments as it is for WBT. While we did not include alternative blood product treatments in our proposal, we solicited comment on whether we should add them to the list of ALS2 procedures. We invited comments on this proposal to add the administration of low titer O+ whole blood transfusion as an ALS2 procedure and on whether we should add alternative blood product treatments such as the administration of PRBCs or plasma.

We received public comments on our proposal and solicitation of comments. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that whole blood is not the current standard of care in pre-hospital transfusions, is very expensive, and is more difficult to source than individual blood components.

Response: As previously discussed, many ground ambulance transports providing WBT already qualify for ALS2 payment. WBT is a therapy that is currently being used and is considered to be medically appropriate in certain circumstances by the medical community. Our proposal aimed to ensure that payments for ground ambulance transports better reflect the complexity of the services provided. We are aware that WBT can be difficult to source, and access can be based on factors such as: donor availability, local manufacturing capabilities, demand and usage. We are also aware that geographic locale may be a factor as well.

Comment: Some commenters supported our proposal to add low titer O+ whole blood transfusion to the list of ALS2 procedures. Some commenters stated that the administration of low titer O– whole blood transfusion should also be added to the list of ALS2 procedures.

Response: We appreciate the commenters' support for our proposal and for bringing to our attention that the administration of O– whole blood transfusions, like the administration of O+ whole blood transfusions, should independently qualify as an ALS2 procedure. Low-titer O– blood has the same hemostatic composition and resuscitative benefits as low titer O+ blood but can only be obtained from 3 percent of blood donations because of the rarity of this blood type. Because of its rarity, hospitals and blood banks tend to hold this product in reserve for use in certain patient populations (pediatric, women of childbearing age, sickle cell patients) or clinical conditions such as obstetric hemorrhage.[786]

For that reason—its rarity and general unavailability to ground ambulance providers and suppliers—we had refrained from adding low titer O– whole blood transfusion to our original proposal. After further discussion with EMS officials, we were made aware that some agencies may occasionally receive and use a unit of low titer O– whole blood as part of their transfusion program. Transfusion of low titer O– whole blood requires the same handling and level of training as low titer O+ whole blood. We are therefore adding low titer O– whole blood transfusion to the list of ALS2 procedures at § 414.605.

Comment: Several commenters provided feedback on whether we should add alternative blood product treatments in addition to low titer O+ WBT to the list of ALS2 procedures. Several commenters stated that, given the complexity involved in administering alternative blood products and their expense, the administration of all FDA-approved blood and blood components products (whole blood, plasma, PRBCs, platelets, and clotting fractions such as cryoprecipitate) should be included in the list of ALS2 procedures.

A commenter stated that HHS' Agency for Healthcare Research and Quality (AHRQ) is currently conducting a systematic review on the feasibility, effectiveness, and safety of blood and blood product transfusions in the prehospital setting and will be comparing the benefits and harms of

[783] Pokorny DM, Braverman MA, Edmundson PM, et al. The use of prehospital blood products in the resuscitation of trauma patients; a review of prehospital transfusion practices and a description of our regional whole blood program in San Antionio, TX. ISBT science series, 2018–08, Vol, 14(3), p 332–42.

Floccare D. Air Medical Director, State of Maryland. Email communication. May 14,2024

Krohmer J. Chairman, steering committee of the Prehospital Blood Transfusion Initiative Coalition. Virtual Meeting April 23, 2024.

[784] Bank EA. Assistant Chief of EMS. Co-Chair of the South East Regional Advisory Council Trauma Committee. Email correspondence and phone conversation, May 10, 2024.

[785] Apelseth TO, Strandenes G. Kristofferson K, Hagen KG. How do I implement a whole blood-based blood preparedness program in a small rural hospital? Transfusion. 2020. Vol 60(12) 2793–2800.

Schaefer RM, Bank E, Krohmer JR., Haskell A, et al. Removing the Barriers to Prehospital Blood: A Roadmap to Success. Journal of Trauma and Acute Care Surgery. 2024. 97(2S): S138–S144. doi: 10.1097/TA.0000000000004378.

[786] Transfusion. 2021 Jun;61(6):1966–1971. doi: 10.1111/trf.16380. Epub 2021 Mar 29. PMID: 33780020; PMCID: PMC8251973.

low-titer O+ and O– whole blood transfusion, component blood therapy transfusion, and fluid resuscitation. The commenter stated that AHRQ indicates that the results of the systematic review will inform future prehospital care evidence-based guidelines, protocols, and state and local EMS agency decision-making.

In addition to the ongoing studies and systematic review, the commenter stated that more research and comprehensive data are needed to evaluate these critical interventions, including the risks and benefits of the therapy options to different patient populations and to the continued availability of the blood supply. The commenter stated that a comprehensive gap analysis is also needed to: (1) identify research questions; (2) assess EMS capabilities and operational limitations; (3) define the scope of training needed for EMS personnel to safely administer blood in pre-hospital settings; (4) understand blood collectors' operational limitations that may impact the availability of different interventions; (5) evaluate the potential impact of pre-hospital transfusion programs on the hospitals' inventories, which are essential to patient care; and (6) study blood wastage and methods to limit it.

Response: We appreciate the commenter bringing to our attention the ongoing studies and systematic reviews. CMS looks forward to the results of the study, but we note that current research, guidelines, and EMS protocols indicate that the administration of these services is sufficiently complex that, upon our review, they each should independently qualify as an ALS2 procedure. Many ground ambulance transports already provide blood and blood product transfusions. Based on our review and feedback received from interested parties, we are not aware of any evidence indicating issues with safety or efficacy that may lead CMS to consider not paying for these services furnished as part of a ground ambulance transport.

Upon further review and feedback from interested parties, we have determined that all prehospital blood transfusions (PHBTs), which refer to the administration of low titer O+ and O– WBT, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, should independently qualify as an ALS2 procedures; the administration of low titer O+ whole blood transfusion should not be the only PHBT that independently qualifies as an ALS2 procedure, as we had proposed in the CY 2025 PFS proposed rule (89 FR 62004). The administration, handling, training, specialized equipment, and medical criteria of low titer O– whole blood, PRBCs, and plasma are the same as previously described with respect to low titer O+ whole blood; they require a complex level of care beyond ALS1 for which EMS providers and suppliers at the EMT-Intermediate or paramedic level require additional training.

Use of PHBT is currently considered to be the best practice recommendation by the Trauma, Hemostasis and Oxygenation Research Network and the American Association of Blood Banks Working Party.[787] An early study found that using PRBCs during transport improved the prehospital mortality rate for patients in hemorrhagic shock.[788] A recent study of penetrating injuries in an urban setting found an in-hospital mortality benefit of 22 percent if a PHBT was performed within 15 minutes of the initial patient-EMS encounter.[789] The study also found that the mortality rate increased by 11% for every minute a blood transfusion was delayed after that initial 15 minute period.[790] Another recent study in which the use of two units of PRBCs were central to its initial resuscitation of massively hemorrhaging patients found that this PHBT reduced both prehospital and overall mortality.[791]

The American College of Surgeons Committee on Trauma, the American College of Emergency Physicians, the National Association of EMS Physicians and the U.S. Military's Tactical Combat Casualty Care (TCCC) guidelines recommend WBT as the first line of resuscitative therapy for trauma patients in hemorrhagic shock, followed by PRBCs, and plasma in lieu of crystalloids. To clarify our earlier TCCC statement, traditional resuscitation protocols for massive hemorrhage from trauma and other medical conditions such as gastrointestinal bleeding consisted of crystalloids alone in the field and followed in the hospital with blood component transfusions, which consists of a balanced portion of PRBCs, platelets and fresh frozen plasma. Studies cited previously and noted below have demonstrated a mortality benefit in the use of these products for patients in hemorrhagic over traditional crystalloid therapy especially when provided earlier in the resuscitative process. One early study evaluated patients receiving four different prehospital resuscitation methods: crystalloid only; PRBCs; plasma; and PRBCs and plasma.[792] Data showed that any blood product resuscitation was associated with a lower mortality than crystalloid alone. PRBCs and plasma have similar reductions in mortality; however, PRBCs and plasma had a much greater reduction in mortality than either PRBCs or plasma alone. When used alone, crystalloid fluids in this study demonstrated the greatest mortality.[793]

Other blood products such as platelets and cryoprecipitate are used as part of the resuscitative process after the patient arrives in the hospital. At this time there is little data of their use in the field by EMS providers for patients in hemorrhagic shock. Furthermore, at this time, the use of these products in the field is limited by factors such as their expiration dates and storage requirements. Platelets have a 5 day expiration date and require continuous agitation while in storage at room temperature. Cryoprecipitate requires storage at negative 18 degrees Celsius and thawing before delivery.

Comment: Several commenters stated that the WBT proposal will not have any positive effect on actual reimbursement of the cost associated with keeping and administering blood products because patients sick enough for blood administration already meet the ALS2 criteria. Several commenters stated that the current rate for ALS2 is far too low to accommodate the cost of providing pre-hospital blood transfusions. One commenter stated that they do not support including whole blood or blood products within the AFS unless there are appropriate increases in payment.

Some of these commenters recommended that CMS create a new level of service, ALS3. One commenter recommended a new ALS3 level for critical care that would include, but would not be limited to, the following procedures: blood transfusions, ventilator administration, rapid sequence intubation, chest tube

[787] Weykamp MB, Stern KE Brakenridge SC, Robinson BRH, et al. Pre-Hospital Crystalloid Resuscitation: Practice Variation & Associations with Clinical Outcomes. Shock. 2023. January; 59(1): 28–33.

Ibid.

[788] Rehn M, Weaver A, Brohl K, Eshelb S. Effect of Prehospital Red Blood Cell Transfusion on Mortality and Time of Death in Civilian Trauma Patients. Shock. 2019; Vol. 51, No. 3: 284–288.

[789] Duschesne J, McLafferty BJ, Broome JM, Caputao S, et al. Every minute matters: Improving outcomes for penetrating trauma through prehospital advanced resuscitative care. J Trauma Acute Care Surg. 2024 May 1 doi: 10.1097/TA.0000000000004363. Online ahead of print.

[790] Ibid.

[791] Ritondale J, Piehl M, Caputo S, Broome J, et al. Impact of Prehospital Airway-Breathing-Circulation Resusitation Sequence on Patients with Severe Hemorrhage. J Am Coll Surg. 2024, Vol. 238(4). 367–72.

[792] Guyette FX, Sperry JL, Peitzman AB, Billiar TR, et al. Prehospital Blood Product and Crystalloid Resuscitation in the Severely Injured Patient. A Secondary Analysis of the Prehospital Air Medical Plasma Trial. Ann Surg. 2021;273:358–364.

[793] Ibid.

placement, surgical airway placement, heparinization of patients suffering from an acute myocardial infarction, and placement of umbilical vein catheters in newborns. Other commenters suggested a new level of service for prehospital blood programs.

Several commenters recommended additional funding to fully support adding the administration of low titer O+ WBT as an ALS2 procedure. One commenter recommended a CMMI payment and service delivery model that would incorporate pre-hospital blood transfusions into EMS, where the model should include a pre-hospital blood product add-on payment that incorporates the costs associated with procuring, storing, and administering blood transfusions. The commenter offered that model activities may include, but should not be limited to, procuring blood products from entities such as blood collection establishments and hospitals, storing blood products in accordance with safety standards, and transfusing the blood safely and effectively.

Response: We noted in the CY 2025 PFS proposed rule (89 FR 62004) that we do not have the authority to provide an additional payment, such as an add-on payment for the administration of WBT under the AFS. We may consider the other commenter suggestions for future rulemaking.

Comment: One commenter was concerned about budget neutrality with this proposal, expressing concern that it ought not potentially reduce reimbursement for other appropriate ambulance services.

Response: AFS payment for the other levels of ground ambulance services will not be reduced by virtue of the policies we finalize here.

Comment: Several commenters recommended that payment for WBT and alternative blood product treatments should also be included in air ambulance transport payment.

Response: We appreciate the commenters' input, but comments relating to air ambulance transport are out of scope for this rule.

Comment: One commenter requested clarification that the administration of WBT also meets the requirements for specialty care transport (SCT) if all other requirements are met. The commenter noted that the phrase ''critically injured or ill'' appears in the definition of SCT and in the rationale for including the administration of low titer O+ WBT as an ALS2 procedure.

Response: At § 414.605, SCT means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training. We define interfacility transport in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, Chapter 30.1.1, Definition of Ground Ambulance Services, as: for purposes of SCT payment, an interfacility transportation is one in which the origin and destination are one of the following: a hospital or skilled nursing facility that participates in the Medicare program or a hospital-based facility that meets Medicare's requirements for provider-based status.

An interfacility transport of a critically injured or ill beneficiary by a ground ambulance vehicle does not meet the definition of SCT if the only service provided to the patient during the transport is the administration of low titer O+ whole blood transfusion. The administration of low titer O+ whole blood transfusion requires an individual trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic. It does not require a level of service beyond the scope of the EMT-Paramedic, as required under § 414.605 although CMS notes that requirements may vary by state. We also note that it may be possible, during a transport that otherwise meets the definition of SCT, that the administration of low titer O+ whole blood transfusion may be provided as a medically necessary service, and that the service would therefore be payable as part of a SCT.

Comment: A commenter requested clarification as to whether the medical monitoring of WBT qualifies for ALS2 as it does for endotracheal intubation. The commenter stated that in certain situations, primarily interfacility transports, another healthcare provider may initiate WBT, which an ALS provider or supplier will monitor and maintain during transport. The commenter believes that the transport should qualify as an ALS2 based on the monitoring and maintenance of WBT.

Response: In the Medicare Benefit Policy Manual, Chapter 10, Section 30.1.1, under Application for ALS 2, we state: Endotracheal (ET) intubation (which includes intubating and/or monitoring/maintaining an ET tube inserted prior to transport) is a service that qualifies for the ALS2 level of payment. Medical monitoring of WBT by an EMT-Intermediate or paramedic with additional training to administer WBT during a ground ambulance transport would qualify for ALS2 payment.

After consideration of public comments and upon further review, we are modifying our proposed policy to add the administration of low titer O+ whole blood to the list of procedures that independently qualify as an ALS2 procedure and finalizing a policy to change the definition of ALS2 at § 414.605 by including all PHBTs in the list of procedures that independently qualify as an ALS2 procedure. Specifically, we are modifying the definition of ALS2 at § 414.605 so that the list of ALS2 procedures now includes, as a new number 8, prehospital blood transfusion, which includes the administration of low titer O+ and O– whole blood; the administration of packed red blood cells; the administration of plasma; or the administration of a combination of packed red blood cells and plasma.

O. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (§ 401.305(a)(2), 401.305(b)(1), (2), and (3))

1. Executive Summary

In the proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' which appeared in the December 27, 2022 **Federal Register**, we proposed to amend our regulations regarding the standard for an ''identified overpayment'' under Medicare Parts A, B, C, and D to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the Federal False Claims Act (the False Claims Act) at 31 U.S.C. 3729(b)(1)(A) (87 FR 79452). We refer to that rule as the ''December 2022 Overpayment Proposed Rule.'' In the December 2022 Overpayment Proposed Rule, we proposed to remove the existing ''reasonable diligence'' standard and adopt by reference the False Claims Act definition of ''knowing'' and ''knowingly'' as set forth at 31 U.S.C. 3729(b)(1)(A).

After considering the public comments we received in connection with the December 2022 Overpayments Proposed Rule, we issued a statement in the proposed rule, titled ''Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments'' (CY 2025 PFS), stating that we would retain the Parts A and B proposals published in the December 2022 Overpayment Proposed Rule. In the CY 2025 PFS, we also made additional proposals to revise existing regulations at § 401.305(b) regarding the deadline for reporting and returning overpayments. We are finalizing both the December 2022 Overpayment Proposed Rule proposals and the CY 2025 PFS proposals in this final rule.

2. Provisions of the Regulation (Preamble)

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act), established section 1128J(d) of the Act. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to which the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(4)(B) of the Act defines the term ''overpayment'' as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. For purposes of Medicare Parts A and B, section 1128J(d)(4)(C) of the Act defines the term ''person'' to include providers and suppliers as those terms are defined in the Act.

Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

Section 1128J(d)(4)(A) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). The False Claims Act (31 U.S.C. 3729(b)(1)(A)) defines the terms ''knowing'' and ''knowingly'' to include information about which a person ''has actual knowledge,'' ''acts in deliberate ignorance of the truth or falsity of the information,'' or ''acts in reckless disregard of the truth or falsity of the information.''

a. Regulations Issued Under Section 1128J(d) of the Act

On May 23, 2014, we published a final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844) (hereinafter referred to as the ''Parts C and D Overpayment Final Rule''), which provided, among other things, that an MAO or PDP sponsor has identified an overpayment when the MAO or PDP sponsor has determined, or should have determined through the exercise of reasonable diligence, that the MAO or PDP sponsor has received an overpayment.

On February 12, 2016, we published a final rule titled ''Medicare Program; Reporting and Returning of Overpayments'' (81 FR 7654) (hereinafter referred to as the ''Parts A and B Overpayment Final Rule''), which provided, among other things, that a provider or supplier has identified an overpayment when the provider or supplier has determined, or should have determined through the exercise of reasonable diligence, that the provider or supplier has received an overpayment and quantified the amount of the overpayment.

In the December 2022 Overpayment Proposed Rule, we proposed to amend the existing regulations for Medicare Parts A and B, as well as Parts C and D, regarding the standard for an ''identified overpayment'' to align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act. These proposed regulations would assign the meaning of the terms ''knowing'' and ''knowingly'' in the False Claims Act at 31 U.S.C. 3729(b)(1)(A) to our regulations for purposes of Medicare overpayments. Specifically, in the December 2022 Overpayment Proposed Rule, we proposed to remove the existing ''reasonable diligence'' standard and adopt by reference the False Claims Act definition of ''knowing'' and ''knowingly'' as set forth at 31 U.S.C. 3729(b)(1)(A). We reviewed the comments on the December 2022 Overpayment Proposed Rule and will respond to them in this final rule. We elected not to finalize those provisions in the earlier-published corresponding final rule because we believed that regulatory revisions to address certain issues commenters raised regarding Parts A and B necessitated additional notice-and-comment rulemaking. The additional proposals were published in the CY 2025 PFS proposed rule.

Specifically, in the CY 2025 PFS, we proposed new regulations that specify circumstances under which the deadline for reporting and returning overpayments in Parts A and B would be suspended to allow time for providers and suppliers to investigate and calculate overpayments.

b. Relevant Litigation

In *UnitedHealthcare Insurance Co.* v. *Azar,* a group of MAOs challenged the 2014 Parts C and D Overpayment Final Rule, and the District Court held, in relevant part, that by requiring MAOs to use ''reasonable diligence'' in searching for and identifying overpayments, the final rule impermissibly established False Claims Act liability for mere negligence. *UnitedHealthcare Ins. Co.* v. *Azar,* 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (2022). The District Court noted that ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a-7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' '' *Id.* at 190.

Although the court's ruling applied only to Medicare Part C, to provide for consistency in Medicare regulations related to reporting and returning overpayments, in the December 2022 Overpayment Proposed Rule, we proposed to amend the regulations at current § 401.305(a)(2) to remove the reference to ''reasonable diligence'' and replace it with language incorporating the terminology of section 1128J(d)(4)(A) of the Act by ascribing the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C.

3729(b)(1)(A). *See UnitedHealthcare,* 330 F. Supp. 3d at 191 (finding that CMS adopting the False Claims Act standard would be consistent with a 2000 agency rule, the False Claims Act, and the Affordable Care Act's reference to the False Claims Act).

c. Provisions of Regulations

(1) Medicare Part A and Part B—Amending the Standard for When an Overpayment Is Identified (§ 401.305(a)(2))

Proposals from the December 2022 proposed rule sought to amend § 401.305(a)(2) by changing the standard for an ''identified overpayment.'' We are finalizing the knowledge standard derived from the False Claims Act standard, as proposed. This finalized provision states that a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

We solicited comments on these proposals and received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested clarification on the regulatory text, pointing to language contained in the February 16, 2012 proposed rule (77 FR 9179) that preceded the Parts A and B Overpayment Final Rule, that a person identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. The commenter stated that it is not clear if CMS means something different by using the terms ''received or retained'' rather than ''existence'' as used in the 2012 proposed rule.

Response: The referenced language from the 2012 proposed rule was not finalized in the 2016 overpayment rule, and comments on its proposals are outside the scope of this regulation. However, we note that the section 1128J(d)(4)(B) of the Act defines an overpayment as funds that a person ''receives or retains,'' and the finalized regulatory language mirrors the statutory construction. We recognize the language in the 2012 proposed rule and the language in this final rule differ; however, we believe the language in this final rule is more consistent with the statutory text, which uses the phrase ''receives or retains.''

Comment: One commenter opposed the proposed changes stating that it increases the risk on well-meaning hospice providers of unwarranted False Claims Act liability based on allegations that they knowingly failed to identify, report and refund an overpayment within some unclear timeframe based on a ''reckless disregard or deliberate indifference'' standard that is prone to a high degree of subjectivity. The commenter submits that deleting the practical standards of ''reasonable diligence'' and quantification to align with an unclear, constantly evolving False Claims Act definition and interpretation of ''knowingly'' is unwise.

Response: We thank the commenter for the perspective but disagree with the conclusions drawn by the commenter. We note that ''deliberate indifference'' is not a term included in the definition of ''knowing'' or ''knowingly,'' as defined in section 3729(b)(1)(A) of the Act. The language in this final rule is consistent with the statutory language. We have provided clarification on timeframes in our responses to other comments and hope this addresses the commenter's concerns.

Comment: Some commenters stated that the proposal to define when a person has identified an overpayment is ambiguous and will result in confusion and inconsistent interpretations, and the proposal is silent about what it actually means to be in ''reckless disregard or deliberate ignorance'' of an overpayment. The commenters stated that if CMS adopts the ''knowing'' standard, it must also adopt clear and practical guidance and examples concerning what it means to act in reckless disregard or deliberate ignorance regarding a potential overpayment and when such a state of mind is attributed to a provider. Another commenter requested that CMS clarify the threshold for ''reckless disregard or deliberate ignorance'' that the provider or supplier received or retained an overpayment.

Response: We appreciate the commenters' concerns. We note that the False Claims Act (FCA), from which the language of the ''knowledge'' standard adopted by CMS with this rule originates, is supported by an existing body of False Claims Act caselaw and examples. Importantly, we further note that FCA case law may be broadly illustrative and remind stakeholders that inquiries into whether a person has the requisite knowledge to have identified an overpayment for purposes of § 401.305(a)(2) is a fact-specific inquiry.

Comment: We received numerous comments from providers and suppliers objecting to the change in knowledge standard from ''reasonable diligence'' to ''knowing'' out of concern that the 6-month investigatory timeframe mentioned in a response to comments in the Parts A and B Overpayment Final Rule would be removed. One commenter stated that CMS should reinstate and extend the guidance that (at least) an 8-month diligence period is reasonable and expected, absent particularly complicated or challenging overpayment assessments, which standard was established in the preamble to the Parts A and B Overpayment Final Rule, and that CMS should consider acknowledging that a longer period of time may be necessary in some cases. Other commenters sought clarification on the timeframes for investigation. One commenter stated that CMS does not address the inherent ambiguities and practical problems presented by the proposed definition. For example, the proposed rule does not explain how a provider or supplier would return an overpayment within 60 days if the existence of the overpayment is known but the amount of the overpayment remains unknown.

Response: We understand that providers and suppliers need time to investigate, calculate, and report and return certain overpayments. To address this concern, we are finalizing § 401.305(b)(3), a suspension of the applicable requirements for 180 days, to conduct a timely, good faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment.

Comment: Some commenters questioned if the knowledge standard derived from the False Claims Act requires proactive compliance activities and also requested a more definitive and useful guideline to the knowledge standard. Other commenters inquired if CMS still expects suppliers and providers to undertake reasonable and professional efforts to identify an overpayment before disclosing refunds.

Response: Using the False Claims Act knowledge standard provides an illustrative body of case law with examples that can be used for case-specific queries and analogous fact-patterns about compliance efforts and the required efforts to identify an overpayment. We note also that providers and suppliers may also have proactive compliance obligations under other laws and regulations.

Comment: Many commenters were supportive of the rule.

Response: We appreciate the commenters' support.

Comment: One commenter recommended that CMS expressly include certain concepts in the final rule, such as clarifying that a provider

or supplier that incurs a duty and diligently conducts an investigation, and either (1) reasonably concludes that an overpayment does not exist (even if that conclusion is in error) or (2) reports and returns any resulting overpayments within 60-days after concluding an investigation, will have satisfied its obligation under the proposed rule. The commenter suggested that if the provider then fails to make any reasonable inquiry into the credible information, the provider may be found to have acted in reckless disregard or deliberate ignorance of an overpayment.

Response: We believe the rule is sufficiently clear as written and additional examples or instructions are not necessary. Identified overpayments must be reported and returned in accordance with the statutory and regulatory requirements. We appreciate the commenter's suggestion; however, the scenarios for investigations are varied and fact-specific. While we are not able to address each and every scenario in which a provider conducts an investigation, we refer the commenter to the body of False Claims Act case law and examples that can be used for case-specific queries and analogous fact-patterns.

Comment: One commenter suggested that CMS should explicitly state that the 60-day period to report and return cannot be triggered unless and until a provider or supplier has engaged in reasonable and professional efforts to determine whether an overpayment occurred and has quantified any such overpayment and to which payors it is owed. The commenter also believes that CMS should expressly clarify that providers and suppliers who identify an overpayment should not report in a piecemeal fashion. Rather, they should refrain from reporting, including through an HHS–OIG self-disclosure protocol, until the entire overpayment is identified.

Response: We understand that providers and suppliers need time to investigate, calculate, and report and return certain overpayments. To address this concern, we are finalizing § 401.305(b)(3), which allows a person who has identified an overpayment up to 180 days to conduct a timely, good faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment.

Comment: One commenter stated that ''receive'' and ''retain'' should be defined in a manner that contemplates a provider or supplier must quantify an overpayment to determine whether an overpayment, in fact, exists.

Response: Providers and suppliers should follow the plain meaning of the terms ''receive'' and ''retain.'' The need to quantify overpayments is discussed in the § 401.305(b) discussion later in response to comments.

Comment: One commenter suggested that CMS adopt a definition of ''identified'' that does not impose impractical deadlines on hospitals and health systems before exposing them to False Claims Act liability.

Response: The suspension of the deadline for reporting and returning of overpayments in newly-established § 401.305(a)(3), in addition to the 60 days required by section 1128J of the Act, provides sufficient time providers and suppliers to comply with these requirements before being exposed to False Claims Act liability. However, providers and suppliers that fail to timely report and return overpayments expose themselves to False Claims Act liability.

Comment: One commenter suggested that CMS create safe-harbor provisions such as adding regulatory language to allow for a 6-month investigatory period and a provision that providers should not be considered to have received or retained an overpayment if it is identical or similar to an overpayment that is subject to an administrative appeal.

Response: We appreciate the commenter's suggestion and believe that new § 401.305(b)(3) addresses some of the commenter's concerns with regard to providing additional time to investigate and calculate overpayments. With regard to the suggestion for overpayments subject to an administrative appeal, we refer the commenter to the now-finalized standards for knowingly receiving or retaining an overpayment: when a person has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. We encourage the commenter to evaluate their obligation to report and return based upon this standard and the body of False Claims Act case law.

Comment: One commenter stated that the proposed rule language would inadvertently create confusion as to when the 60-day period to report and return an overpayment begins. Another commenter explained that the proposed language could put providers and suppliers in a position of being accused of having reverse False Claims Act liability for retaining overpayments that cannot be quantified within 60 days. According to the commenter, providers and suppliers may also risk being accused of having constructive knowledge that an overpayment was received or retained without any guidance as to what that means. The commenter recommends that CMS either expressly add quantification to the regulatory text or at least clarify that quantification remains part of the definition of ''identified'' in that a person would not be considered to have actual or constructive knowledge of an overpayment prior to quantifying the amount of the overpayment.

Other commenters were also concerned about our expectations with regard to quantifying overpayments and the amount of time needed to calculate overpayments. One commenter urged CMS to finalize amended regulatory text that includes the ''knowledge'' standard, just as CMS has proposed, but that also adds clarification that identification must include the amount of excess funds received. Another commenter suggested that CMS consider revising proposed § 401.305(a)(2) to read as follows: ''A person has identified an overpayment when the person knowingly receives or retains a quantified overpayment. The term 'knowingly' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).'' Alternatively, the commenter adds, this sentence could be revised to specify that a person ''has identified an overpayment when the person knowingly receives or retains an overpayment and quantifies the amount of the overpayment.

Response: In response to comments, we are clarifying that, for purposes of section 1128J of the Act, a person has identified an overpayment, as the term is defined at section 1128J(d)(4)(B) of the Act, when the person: (1) has actual knowledge of an overpayment; (2) acts in deliberate ignorance of the truth or falsity of information regarding the overpayment; or (3) acts in reckless disregard of the truth or falsity of information regarding the overpayment. In cases where a provider or supplier is actively investigating a potential overpayment, the 60-day period for reporting and returning the overpayment begins when the provider or supplier has actual knowledge of the overpayment. (As explained in greater detail below, the 60-day deadline may be suspended for up to 180 days under § 401.305(b)(3)). On the other hand, in cases where a provider or supplier acts in deliberate ignorance or reckless disregard of the existence of the overpayment, the 60-day period begins on the date that the provider or supplier acted in deliberate ignorance or reckless disregard of the truth or falsity of information regarding the overpayment.

With respect to quantification of the overpayment, once a person has identified an overpayment, as the term is defined at § 401.305(a)(2), the person has 60 days to report and return the overpayment under § 401.305(b)(1)(i), even if the person has not yet calculated the precise amount of the overpayment at the time of identification. Because a person cannot return an indefinite sum, as a practical matter the overpayment amount must be calculated within 60 days of identification to meet the 60-day deadline. However, if the person believes that there may be other related overpayments, the 60-day deadline for reporting and returning the initially identified overpayment may be suspended under § 401.305(b)(3) for up to 180 days, to allow a person to conduct a timely, good faith investigation to determine the existence of related overpayments, if any, that may arise from the same or similar cause or reason as the initially identified overpayment. As noted at § 401.305(b)(3)(ii)(A), the investigatory timeframe under § 401.305(b)(3) includes time to calculate the aggregate amount of *both* the initially identified overpayment and related overpayments, if any, uncovered by the investigation.

Comment: One commenter inquired about a situation where a provider or supplier has found a single overpaid claim, but suspects that the underlying issue may impact additional claims. The commenter questioned whether it would be appropriate to inquire further before reporting and returning the single claim previously determined to be overpaid. The commenter interprets the 60-day period to report and return that overpayment to start on the date that total overpayment was first quantified.

Response: We agree with the commenter that where a single overpayment is found and other related overpayments are suspected, the provider or supplier should investigate and calculate the aggregate overpayment prior to its return. We are finalizing § 401.305(b)(3), which suspends the 60-day report and return obligation for up to 180 days, to allow persons time to complete a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment. As explained in greater detail below, the 60-day clock begins when the initial overpayment is identified, but may be suspended under § 401.305(b)(3) for up to 180 days to conduct a timely, good faith investigation into the existence of other related overpayments.

After consideration of the comments received, we are finalizing the provisions, as proposed.

(2) Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (§§ 401.305(b)(1), (b)(2), (b)(3))

As noted above, after considering the public comments we received in connection with the December 2022 Overpayments Proposed Rule, we published additional proposals in the CY 2025 PFS. We proposed to revise existing regulations at § 401.305(b) regarding the deadline for reporting and returning overpayments.

Existing § 401.305(b)(1) specifies when a person who has received an overpayment must report and return an overpayment. We proposed to amend this paragraph to reference revised § 401.305(b)(2), as well as to reference newly-proposed § 401.305(b)(3).

Existing § 401.305(b)(2) specifies the circumstances under which the deadline for returning overpayments will be suspended. Overpayments must be reported no later than the date which is 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. However, the deadline for returning a reported overpayment will be suspended under specified circumstances, including the acknowledgement of receipt of a submission to the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol, or under specified conditions if a person requests an extended repayment schedule as defined in § 401.603. We proposed a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this section may be applicable after the suspension described in new § 401.305(b)(3) is complete.

Proposed § 401.305(b)(3) specifies the circumstances under which the deadline for reporting and returning overpayments may be suspended to allow time for providers and suppliers to investigate and calculate overpayments. Proposed § 401.305(b)(3)(i) provides that the deadline to report and return an overpayment is suspended if: (1) a person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and (2) the person conducts a timely, good-faith investigation to determine whether related overpayments exist. Proposed § 401.305(b)(3)(ii) provides that, if the conditions for proposed § 401.305(b)(3)(i) are met, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of the date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated, *or* the date that is 180 days after the date on which the initial identified overpayment was identified.

In the proposed rule, we provided an example elucidating a hypothetical circumstance. We are repeating the example here, with certain modifications to further clarify when the 60-day report and return obligation begins. Assume that, on day 1, a person identifies an overpayment (as the term is defined at § 401.305(a)(2)) arising from a physician's failure to properly document the medical record to support the coding of a specific claim, and the person has reason to believe that this may be a common practice of the physician, so there could be more affected claims. Once the overpayment has been identified on day 1, the report and return obligation at § 401.305(b)(1) applies, and the person has 60 days to report and return the overpayment. However, the 60-day deadline may be suspended for up to 180 days to conduct and conclude a good faith investigation to determine whether related overpayments that arise from the same or similar cause or reason as the initially identified overpayment exist. If the person does NOT conduct an investigation, or the investigation is not timely or not conducted in good faith, the identified overpayment must be reported and returned by day 60. If the person does conduct a timely, good faith investigation, suspension of the report and return obligation under § 401.305(b)(3) begins when the person begins the investigation. The suspension of the 60-day deadline ends when the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. Once the suspension of the 60-day deadline ends, the person has the remainder of the 60-day period to report and return the overpayment. For example, assuming the investigation to determine the existence of related overpayments was begun on day 10 (that is, the tenth day after the initial overpayment was identified), the overpayment must be reported and

returned within 50 days after either (1) completion of the investigation or (2) day 180, whichever is earlier. However, the suspension described in § 401.305(b)(2) may also be applicable. For example, if the person is reporting the overpayment to the OIG Self-Disclosure Protocol, as provided for in § 401.305(b)(2) the overpayment return requirement may be further suspended in accordance with that provision.

We received many comments on the December 2022 Overpayment Proposed Rule expressing concern that we proposed to remove the term ''quantified'' from the original regulatory text. We believe § 401.305(b)(3)(ii)(A) addresses these concerns. Other commenters expressed concern that the December 2022 Overpayment Proposed Rule proposals removed a perceived 6-month time period to investigate all overpayments that was referenced in an example in the preamble to the original 2016 Parts A and B Overpayment Rule. The December 2022 Overpayment Proposed Rule was silent on this point. We understand the importance of allowing time to investigate and calculate overpayments. We believe § 401.305(b)(3)(ii) addresses these concerns.

We solicited and received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters requested that CMS provide additional guidance to assist interested parties in complying with these requirements. Some stated there may be confusion on timeframes. Other commenters stated that these requirements lack clear definitions for terms such as ''timely'' or ''good faith.'' Without more precise definitions, commenters stated these terms remain open to interpretation, which could lead to inconsistencies in enforcement and confusion among providers and suppliers. Some commenters stated that education materials would be helpful to assist providers in understanding how they may need to adapt their overpayment policies to remain in compliance.

Response: We appreciate the commenters' concerns; however, we maintain the commenters can rely upon the plain meaning of the terms ''timely'' and ''good faith.'' Further, we also refer the commenters to the body of False Claims Act case law for information about the term knowingly.

Comment: A commenter requested confirmation that the beginning of the 60-day deadline does not commence until after a provider has conducted their investigation. Another commenter stated that since 180-day period is described as an investigation period, it may lead a provider to inaccurately believe that the 60-day period report and repay only begins after the 180-day period has concluded.

Response: The 60-day deadline at § 401.305(b)(1) for reporting and returning an overpayment begins once an overpayment is identified, as the term is defined at § 401.305(a)(2), even if the person has not yet calculated the precise amount of the overpayment at the time of identification. Under § 401.305(b)(3), the 60-day deadline at § 401.305(b)(1) may be *suspended* for up to 180 days to allow a person time to conduct a timely, good faith investigation to determine whether related overpayments exist. If a person does not conduct such an investigation, or the investigation is not timely or not conducted in good faith, the 60-day deadline is not suspended, and the initially identified overpayment must be reported and returned within 60 days of its identification. If the person does conduct a timely, good faith investigation, the 60-day deadline is suspended until the investigation is concluded and the initially identified overpayment and related overpayments, if any, are calculated, or by day 180, whichever is earlier. Once the suspension of the 60-day deadline ends, the person has the remainder of the 60-day period to report and return the overpayment. For example, if a person began a timely, good faith investigation of related overpayments 20 days after identifying the initial overpayment, the suspension of the deadline would apply on day 20, and there would be 40 days remaining in the 60-day period to report and return the overpayment after the suspension at § 401.305(b)(3)(ii) ends.

Comment: Some commenters requested specificity for terms such as ''good-faith investigations'' and for us to provide additional information on CMS' expectations for a reasonable timeline for conducting such an investigation.

Response: We appreciate the commenters' concerns; however, we maintain the commenters can rely upon the plain meaning of those terms.

Comment: Some commenters opposed what they called a strict, bright-line, or arbitrary timeframe for investigating and reporting overpayments, stating that the current standard allows an indefinite period of time for providers to identify, investigate, and, if an overpayment exists, report to Medicare for corrective action. These commenters recommended that CMS consider one modification to the policy—to create a process to request an extension beyond 180 days for complex investigations. Some commenters stated that 8 months is a more appropriate period of time for providers to investigate, report, and return overpayments under normal circumstances.

Response: We heard from many interested parties that advocated for us to codify a specific period of time to investigate, calculate, report and return overpayments, which is the policy we are finalizing in this rule. Most commenters were supportive of our proposal; however, we appreciate that investigations are often complex and require the devotion of resources. We believe we have appropriately balanced the needs of providers and suppliers with the required statutory mandates.

Comment: One commenter requested that the time required for advisors or for governmental agencies to clarify applicable rules would not count for the 180 days because the overpayment identification is not possible without the conclusions from these deliberations. Another commenter requested that we delay requirements to allow for time for compliance office, legal services, clinical providers, and other governmental authorities to provide input.

Response: We heard from many commenters on the issue of time needed for investigations and calculations of overpayments. We believe that the newly-established 180-day suspension for providers and suppliers that have situations that qualify, in addition to the 60 days to report and return overpayments, provides enough time. We, therefore, decline to delay implementation or provide additional time to comply with these requirements.

Comment: One commenter, submitting a comment more than 60 days after the December 2022 Overpayments Proposed Rule was displayed, emphasized that this proposal, which would remove the ''reasonable diligence'' standard and replace it with a ''knowing/knowingly'' standard is ill-advised, in that, it would accelerate the 60- day clock and place unnecessary stress on those conducting important compliance activities.

Response: While we appreciate the commenters' concerns and we disagree with this conclusion, comments on the December 2022 Overpayments Proposed Rule proposal were due within the 60 days comment period after that proposal was displayed. It is, therefore, outside of the scope of this proposal.

Comment: One commenter requested that CMS revise proposed § 401.305(b)(3)(ii) to provide that the deadline is suspended for the entirety of a timely, good-faith investigation to

minimize the piecemeal report and return of overpayments.

Response: We understand the commenter's concern; however, we heard from many interested parties that advocated for us to codify a specific period of time to investigate, calculate, report and return overpayments, which is the policy we are finalizing in this rule. We believe we have appropriately balanced providers' and suppliers' needs with the required statutory mandates. These requirements provide additional time so that providers and suppliers do not need to piecemeal report and return overpayments.

Comment: Many commenters supported our proposals and thanked CMS for providing defined timeframes for providers making a good-faith effort in complex situations. Some commenters requested that CMS formalize this policy as soon as possible.

Response: We appreciate the commenters' support.

Comment: One commenter encouraged CMS to describe the criteria it would apply to determine whether an investigation has been undertaken in ''good faith'' and therefore the deadline may be suspended.

Response: We encourage the commenter to use the plain meaning of the term ''good faith''.

Comment: A commenter disagreed with CMS' reliance on UnitedHealthcare Insurance Co. v. Azar to remove the ''reasonable diligence'' standard because the commenter does not believe the case requires CMS to alter its policy for Medicare Parts A and B. Another commenter stated similarly that UnitedHealthcare Insurance Co. v. Azar does not dictate a wholesale redefinition of the legal standard for identifying overpayments in Parts A and B.

Response: While we agree that Medicare Parts A and B were not directly at issue in UnitedHealthcare Insurance Co. v. Azar, the underlying statutory provision (section 1128J(d) of the Act) is applicable to Medicare Parts A, B, C, and D. The agency, therefore, proposed to align its knowledge standard for the policies that are subject to that shared statutory provision.

Comment: One commenter urged CMS to clarify that physician practices will have adequate time to organize funds and make payment once an aggregate repayment amount is determined.

Response: The governing statutory provisions, in section 1128J(d)(4)(A) of the Act, provide clear requirements and allows 60 days for providers to report and return overpayments.

Comment: One commenter expressed concern that CMS is proposing changes on top of other proposed changes that are not final, leaving providers in a difficult position of having to interpret different requirements that may not align.

Response: In the CY 2025 PFS proposal we stated that we were retaining the Parts A and B proposals published in the December 2022 Overpayment Proposed Rule and we did not alter them in that proposed rule. We did supplement that language in response to the comments we received on the December 2022 Overpayment Proposed Rule. We are not aware of any misalignment in the two proposals and thus do not agree that there is any need to clarify them in this final rule.

Comment: A commenter requested that CMS confirm that the proposed amendments to § 401.305 would not impose any 6-month or other regulatory clock on the first investigation that results in the identification of an initial overpayment.

Response: With respect to the initial identification of an overpayment, the general 60-day rule at § 401.305(b)(1), coupled with the definition of ''identified'' at § 401.305(a)(2), determines the deadline for reporting and returning the overpayment. In cases where a provider or supplier is actively investigating a potential overpayment, the 60-day period for reporting and returning the overpayment begins when the provider or supplier has actual knowledge of the overpayment. The suspension under § 401.305(b)(3) is available *after* a person has identified an overpayment, as the term is defined at § 401.305(a)(2). As explained in final § 401.305(b)(3)(i)(A), the suspension for reporting and returning overpayments under § 401.305(b)(3) applies when a person *has* identified an overpayment but has *not yet* completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment. If, after identifying the overpayment, the person conducts a timely, good faith investigation to determine the existence of related overpayments in accordance with § 401.305(b)(3), the 60-day deadline for reporting and returning the initially identified overpayment will be suspended for up to 180 days, as provided for under § 401.305(b)(3)(ii). On the other hand, in cases where a provider or supplier acts in deliberate ignorance or reckless disregard, the 60-day period begins on the date that the provider or supplier acts in deliberate ignorance or reckless disregard of the truth or falsity of information regarding the overpayment.

Comment: Commenters had several comments and questions regarding related overpayments. One commenter stated that the proposed text would appear to consider a related overpayment to be unlawfully retained—therefore exposing the organization to False Claims Act liability—even before the organization actually identifies the related overpayment. Some were concerned that this introduces ambiguity and believe that the timeframe does not take into the account the true complexity of these overpayment investigations. Another commenter stated the 6 month benchmark did not encompass such a duty to investigate ''related'' overpayments and the proposed change effectively shortens the timeline for providers and suppliers to carry out their investigations. Another commenter stated that the proposal also appears to create obligations that are contrary to the governing statute and CMS lacks authority to effectively require investigation of ''related'' overpayments. One commenter stated that CMS should revise its proposal to make clear that there is no requirement to report and return related overpayments. Finally, another commenter requested that CMS adopt language to allow providers up to 180 days to identify and quantify an overpayment, regardless of whether an investigation into related overpayments is required.

Response: We disagree with the suggestion that we are requiring providers and suppliers to report and return overpayments that have not been identified or that we are creating new requirements not authorized by the statute. Our proposal in the CY 2025 PFS only addressed circumstances when the 60-day deadline to report and return identified overpayments will be suspended for up to 180 days.

Final § 401.305(b)(3) does not impose an independent obligation to investigate related overpayments when a person has actual knowledge of an overpayment. However, other laws, such as the federal False Claims Act, may impact whether a person must investigate overpayments. If a person believes related overpayments may exist, § 401.305(b)(3) permits the person up to 180 days to conduct an investigation into the existence of related overpayments, provided that the person conducts a timely, good-faith investigation. Without this provision, persons conducting such investigations might face a rolling series of relatively short-term deadlines as the investigation advances and uncovers additional

overpayments, each with its own 60-day deadline. On the other hand, if a person has actual knowledge of an overpayment and has no reason to believe that there are other related overpayments (that is, the person is not acting in deliberate ignorance or reckless disregard to the truth or falsity of information about other related overpayments), then there is no obligation to investigate, calculate, and report and return such other overpayments. In such cases, the person would have 60 days after identifying the isolated overpayment to report and return it, as specified at § 401.305(b)(1).

Comment: One commenter stated that we should not deviate from the current practice and impose an a two-tiered timeframe and unnecessary disclosure requirements on hospitals and health systems to identify, investigate, disclose to agencies, and return overpayments.

Response: We appreciate the commenter's opinion; however, we believe this change better aligns with the statutory language.

Comment: Some commenters opined that we should not deviate from this current practice by imposing the False Claims Act definition of ''identified'' overpayments rather than the current ''reasonable diligence'' standard.

Response: We appreciate the commenters' opinion; however, we believe this change better aligns with the statutory language.

Comment: One commenter stated that Medicare hospice claims have been improperly denied or quality providers without outlier data have been repeatedly subjected to pervasive and costly audits. To this end, they urged CMS to perform an evaluation of hospice denials overturned on appeal and conduct training with audit contractors to ensure the appropriate review of medical claims.

Response: This comment is outside the scope of this proposal.

Comment: One commenter requested that CMS consider requiring Medicare Advantage companies to issue overpayment notices in a specified timeframe. This would allow providers to address potential overpayments in a timely manner.

Response: This proposal was specific to Medicare Parts A and B; therefore, this comment is outside of the scope of this rule.

After consideration of the public comments received, we are finalizing the provisions at § 401.305(a)(2) and (b)(1), (2), and (3) as proposed.

P. Medicare Parts C and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c))

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act) established section 1128J(d) of the Act. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(4)(B) of the Act defines the term ''overpayment'' as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. Section 1128J(d)(4)(C) of the Act defines the term ''person'' for purposes of Medicare Part C and Part D to include a Medicare Advantage organization (''MAO'') (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D–41(a)(13) of the Act).

Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

Section 1128J(d)(4)(A) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). The False Claims Act (31 U.S.C. 3729(b)(1)(A)) defines the terms ''knowing'' and ''knowingly'' to include information about which a person ''has actual knowledge,'' ''acts in deliberate ignorance of the truth or falsity of the information,'' or ''acts in reckless disregard of the truth or falsity of the information.''

1. Parts C & D Regulation Promulgated Under Section 1128J(d) of the Act

On May 23, 2014, CMS published a final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844) (hereinafter referred to as the ''Parts C & D Final Overpayment Rule''), which provided, among other things, that an MAO or Part D sponsor has identified an overpayment when the MAO or Part D sponsor has determined, or should have determined through the exercise of reasonable diligence, that the MAO or Part D sponsor has received an overpayment.

2. Relevant Litigation

In *UnitedHealthcare Insurance Co.* v. *Azar,* a group of MAOs challenged the final Parts C & D Overpayment Rule, and the District Court held, in relevant part, that by requiring MAOs to use ''reasonable diligence'' in searching for and identifying overpayments, the final rule impermissibly created False Claims Act liability for mere negligence.[794] The District Court noted that ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a–7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' ''.[795] On December 27, 2022, CMS published in the **Federal Register** the proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' (the December 2022 proposed rule).[796] CMS proposed to amend the final Parts C & D Overpayment Rule at §§ 422.326(c) and 423.360(c) to remove the reference to ''reasonable diligence'' and replace it with language at section 1128J(d)(4)(A) that gives the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A).[797]

[794] *UnitedHealthcare Ins. Co.* v. *Azar,* 330 F. Supp. 3d 173, 191 (D.D.C. 2018), *rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. 2021), *cert. denied,* 142 S. Ct. 2851 (2022).

[795] *UnitedHealthcare,* 330 F. Supp. 3d at 190.

[796] (87 FR 79452).

[797] *See UnitedHealthcare,* 330 F. Supp. 3d at 191 (finding that CMS adopting the False Claims Act

3. Provisions of Final Regulations: Medicare Advantage Program and Part D—Amending the Standard for When an Overpayment Is Identified (§§ 422.326(c) and 423.360(c))

In the December 2022 proposed rule, CMS proposed to remove the existing standard for when an overpayment is identified in the Medicare Advantage and Part D programs and adopt, by reference, the False Claims Act definition of ''knowing'' and ''knowingly.'' This section of the final rule amends §§ 422.326(c) and 423.360(c) to change the standard for an ''identified overpayment'' in the Medicare Advantage and Part D programs to align with the statutory obligation provided by Congress in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). Under the proposed rule, an MAO or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal to amend the standard for identification of an overpayment.

Response: We appreciate the support.

Comment: A commenter recommended that CMS follow the plain language of the statute and adopt an actual knowledge standard. The commenter suggested the following language: ''an MA plan or Part D sponsor has 'identified' an overpayment once it has determined that the overpayment exists.'' They stated that reckless disregard and deliberate ignorance go beyond the plain language reading intended by Congress and cited to opinions from the U.S. Court of Appeals for the District of Columbia and the U.S. District Court for the District of Columbia, as well as to legislative history.

Response: We respectfully disagree with the commenter. Our proposal to adopt, by reference, the False Claims Act definition of ''knowing'' and ''knowingly,'' that an MAO or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment, comes directly from the statute. Section 1128J(d)(4)(A) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given to those terms in the False Claims Act. We acknowledge that commenters have stated that the defined terms are not used in the statute, but we see nothing in the statute indicating that this provision is mere surplusage or that Congress intended to create a lower knowledge standard for Medicare overpayments than otherwise exists under the False Claims Act. Such an interpretation would effectively allow MAOs and Part D sponsors to ''bury their heads in the sand'' and deliberately ignore or recklessly disregard overpayments. As the District Court in *UnitedHealthcare* noted, ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a–7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' '' [798]

Comment: Some commenters noted concerns that the new knowledge standard for the identification of an overpayment would eliminate the 6-month investigatory period discussed in the 2016 Parts A & B Overpayment Final Rule (81 FR 7654) and that, by failing to comply with what they see as a reduced timeframe, they could violate the False Claims Act. Some commenters noted that they provide services under Medicare Parts A, B, C, and D, and that maintaining a broad array of payment rules is complex and requires more than 60-days to ensure payment accuracy across various payors. A commenter asked if there is an acceptable period of investigation, such as six months, allowed for MAOs to quantify the overpayment before they have actually identified it.

Response: We note that unlike the 2016 Parts A and B Overpayment Final Rule, the 2014 Parts C & D Overpayment Final Rule did not mention an allowance of 180 days for investigation.

The Parts C & D Final Overpayment Rule applies to MAOs and Part D sponsors and provides that the 60-day period is the time period for MAOs and Part D sponsors to report and return an identified overpayment, after the organization has conducted the activities needed to identify that it has received an overpayment. The 60-day requirement to report and return overpayments is statutorily required in section 1128J(d)(2) of the Act.

Additionally, risk adjusted payment for Medicare Parts C and D differs from Fee-For-Service payment in traditional Medicare. Risk adjustment payment is based on diagnoses data that MAOs submit to CMS. Diagnoses eligible for risk adjustment are those that have been documented in the beneficiaries' medical record as the result of a face-to-face visit from an acceptable provider type and source, and coded using ICD coding guidelines. MAOs submit and delete diagnoses from CMS systems (Risk Adjustment Processing System (RAPS) and/or Encounter Data Processing System (EDPS)) on an ongoing basis based on individual encounters (see § 422.310(d)). Pursuant to § 422.310(g), under this longstanding process MAOss have from the beginning of the data collection period through the final risk adjustment data submission deadline, which is a minimum of 13 months, to investigate any issues with their data submissions and submit corrections.

CMS recalculates risk scores and adjusts payments through the final reconciliation payment process in accordance with § 422.310(g)(2). CMS also periodically reruns risk score calculations and adjusts payments after it makes final reconciliation payments to MAOs to account for instances in which MAOs delete diagnosis data or otherwise report overpayments as prescribed by CMS from a period for which the deadline for final reconciliation payments has closed (for example, when they make ''closed-period deletes'' in RAPS and EDPS).

Likewise, Part D sponsors report and return Part D overpayments related to prescription drug event (PDE) and direct and indirect remuneration (DIR) data through the submission of corrected data.[799] PDE/DIR-related overpayments for a given contract year can occur after data is due for the annual Part D payment reconciliation for that year. Section 423.360(a), Data for the annual Part D payment reconciliation, is due within 6 months of the end of the contract year.[800] CMS recoups PDE/DIR-

standard would be consistent with a 2000 agency rule, the FCA, and the Affordable Care Act's reference to the False Claims Act).

[798] *UnitedHealthcare,* 330 F. Supp. 3d at 190; *see also id.* at 191 (finding that CMS adopting the False Claims Act standard would be consistent with a 2000 agency rule, the FCA, and the Affordable Care Act's reference to the False Claims Act).

[799] See HPMS memorandum, Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting, April 6, 2028 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms%2520memo_reopen%2520and%2520overpay_04-06-2018_90.pdf*).

[800] *See* §§ 423.336(c)(1), 423.434(c)(1) and (d)(1).

related overpayments through the global reopening process described at § 423.346(a)(2), which is consistent with the 6-year overpayment look-back period described at § 423.360(f).[801] As a result of this process, it is not necessary for a Part D sponsor to calculate the amount of the overpayment, as entities are required to do under the Medicare Parts A and B overpayment regulation at § 401.305. The PDE/DIR-related overpayment reporting and returning process is operationally less complex, and therefore, an extensive investigation period prior to submitting corrected data is not necessary.

Comment: A commenter asked if an MAO receives a recoupment payment from a provider, does that equate to ''knowing'' under the new standard, and would the MAO then need to report and return this to CMS since they ''know'' of an overpayment.

Response: We appreciate the concern for the appropriate repayment of overpayments. The payment system for MAOs is distinct from that for Part A and Part B. Rather than payments being based on services provided, payments to MAOs are based on a capitated rate that is risk-adjusted to reflect each enrolled beneficiary's demographic and health characteristics. Due to the nature of how MAOs are paid, recouped payments an MAO receives from a provider do not necessarily equate to that MAO having been overpaid by CMS. However, as a condition of payment, MAOs are obligated to submit risk adjustment data that is accurate, complete, and truthful based on their best knowledge, information, and belief as part of the annual risk adjustment data certification (§ 422.504(l)). MAOs are thereby required to delete any risk adjustment data submitted to CMS that they know to be incorrect.

We received a number of comments to the proposal made in the Parts C & D Overpayment provision in the December 2022 proposed rule that were out of scope. While these comments are out of scope for this final rule because they are not about the specific proposal that the standard for identification of an overpayment be amended, we appreciate the feedback.

After consideration of the public comments received, we are finalizing the provisions at §§ 422.326(c), 423.360(c), as proposed. We do not expect the proposed change to result in additional costs or savings and are not scoring this provision in the Regulatory Impact Analysis section of this rule. Further, as we are not imposing any new reporting requirements, we do not believe that our proposal will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

IV. Updates to the Quality Payment Program

A. CY 2025 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of this final rule outlines changes to the Quality Payment Program starting January 1, 2025, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on alignment and new options for clinicians to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2025 performance period/2027 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which the Medicare program rewards clinicians who provide high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined at § 414.1305) [802] are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight under these exceptions, for CY 2025 performance period/2027 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for a MIPS eligible clinician, CMS accounts for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. CMS then applies the MIPS payment adjustment factor to amounts otherwise paid under Part B with respect to covered professional services for the MIPS eligible clinician for the applicable MIPS payment year such that their payments for such covered professional services are increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

[801] For additional information on reopenings and the recoupment of PDE/DIR-related overpayments see *Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE),* 89 FR 30448 (April 23, 2024).

[802] We note that the term MIPS eligible clinician is defined at § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

For the Advanced APM track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the CY 2024 performance year receive a 1.88 percent APM Incentive Payment in the 2026 payment year. Beginning with the CY 2024 performance year (payment year 2026), QPs will also receive a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

Participation in the Quality Payment Program's MIPS track (defined as MIPS eligible clinicians with a final score greater than 0, including both those who submitted data and those who did not submit data) increased slightly to 98.98 percent in the seventh year (CY 2023 performance period/2025 MIPS payment year) with 679,634 MIPS eligible clinicians receiving a final score other than zero out of 686,645 MIPS total eligible clinicians. In the CY 2022 performance period/2024 MIPS payment year, 97.59 percent of the 624,209 MIPS eligible clinicians received a final score other than zero. Therefore, participation rates in MIPS increased slightly between the CY 2022 and CY 2023 performance periods.

In addition, 76.81 percent of MIPS eligible clinicians received a positive payment adjustment for the 2025 MIPS payment year based on their performance in the CY 2023 performance period. Please note that results for the CY 2023 performance period/2025 MIPS payment year described herein are subject to change as a result of the targeted review process, which began on August 12, 2024, and concluded on October 11, 2024. For more information on the targeted review process for the CY 2023 performance period/2025 MIPS payment year, please see our targeted review guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2961/2023-Targeted-Review-Guide.pdf.*

Regarding performance in Advanced APMs, for the CY 2023 QP Performance Period, 508,876 eligible clinicians (TIN–NPIs) earned Qualifying APM Participant (QP) status while another 1,521 eligible clinicians earned partial QP status.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with implementing MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are continuing to develop new MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the eighth year of the Quality Payment Program, we will be implementing the updates set forth in this section of this final rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

Our National Quality Strategy (*https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy*) addresses the urgent need to advance towards a more equitable, safe, and outcomes-based health care system for all individuals. We have a corresponding cohesive value-based care strategy for Medicare along three main pillars: Alignment, Growth, and Equity.[803] We continue to focus on transforming health care delivery [804] and our 2030 goal to have all traditional Medicare beneficiaries in an accountable care relationship with their health care provider. In pursuit of this vision, we are driving higher value care, supporting Advanced APM participation, increasing alignment to reduce burden, and promoting health equity. We are exploring new care delivery and payment models; for example, we are considering an ambulatory care model that would connect payment to performance for specialists in the ambulatory setting to increase the number of specialists who deliver longitudinal care in an accountable manner and to support greater integration between specialty and primary care. This potential model would utilize MVPs as a foundation for assessing specialist performance (refer to section III.J of this final rule). We are finalizing as proposed in section II.G.2 of this final rule to make payment for advanced primary care management (APCM) services furnished by a physician or other qualified health care professional who is responsible for all primary care (for example, physicians and non-physician practitioners, including nurse practitioners, physician assistants, certified nurse-midwives and clinical nurse specialists), and serve as the continuing focal point for all needed health care services during a calendar month. This proposed payment would incorporate several specific, existing care management and communication technology-based services into a bundle and include a performance measurements requirement that could be met by reporting the Value in Primary Care MVP by clinicians billing for APCM services. We are finalizing as proposed that billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) will not have to report the MVP in order to furnish and bill for APCM services.

Separately, we continue to implement MVPs and subgroup reporting option to allow clinicians to report on a cohesive set of measures and activities that more directly reflect their clinical practice. MVPs allow for more clinically relevant performance measurement, engage more specialists in performance measurement, and help reduce barriers to APM participation. While traditional MIPS continues to be a reporting option, we intend to move to full MVP adoption and to sunset traditional MIPS in the future. That future date has not been determined and will be established through the official notice and comment rulemaking process.

(a) MIPS Value Pathways Development and Maintenance

In an effort to promote high-quality, safe, and equitable care and to implement the vision outlined in the CMS National Quality Strategy, we are finalizing as proposed six new MVPs around the following topics: Complete Ophthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal

[803] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity, Health Affairs Forefront, March 14, 2024. *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

[804] Quality in Motion, Acting on the CMS National Quality Strategy, April 2024. *https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf.*

Care for Patients with Urologic Conditions, Pulmonology Care and Surgical Care. Complete Ophthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal Care for Patients with Urologic Conditions, Pulmonology Care, and Surgical Care.

We are also finalizing our proposal to modify the MVP maintenance webinar process as proposed, to provide more flexibility on how we communicate submitted maintenance recommendations prior to proposing them formally in rulemaking (refer to section IV.A.4.a of this final rule).

Lastly, we are finalizing as proposed MVP maintenance updates to our MVP inventory that are in alignment with the MVP development criteria, and in consideration of the feedback from interested parties we have received through the maintenance process.

(b) MVP Requirements and Scoring

We are finalizing our proposal to update the scoring of population health measures in MVPs by using the highest score of all available population health measures, and we are finalizing our proposal to remove the requirement for MVP Participants to select a population health measure at the time of MVP registration. We are also finalizing our proposal to modify the MVP scoring policies at § 414.1365(d)(3)(ii) with respect to the cost performance category to refer to, and therefore align with, our methodology for scoring cost measures at § 414.1380(b)(2) under our traditional MIPS policies. Additionally, we are finalizing our proposal to align MVP scoring with traditional MIPS policies by removing references to high- and medium-weighted improvement activities in MVPs. We are finalizing our proposal to update MVP scoring to assign 40 points for each improvement activity to provide full credit for the improvement activities performance category for MVP Participants who report one improvement activity. For the MVP Promoting Interoperability performance category, we are finalizing our proposal to modify our policy at § 414.1365(c)(4)(i)(A), requiring a subgroup to submit the affiliated group's data for this performance category, by removing references to specific performance periods/MIPS payment years, thereby permitting subgroups to report data for this category in this manner for the CY 2025 performance period/2027 MIPS payment year and beyond.

(c) APM Performance Pathway

We are finalizing our proposal to create within the APM Performance Pathway (APP) the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year to align with the Universal Foundation measures under the CMS National Quality Strategy. We are not modifying the existing APP quality measure set, which already includes five of the ten Universal Foundation measures. Instead, we are establishing the APP Plus quality measure set as a second measure set distinct from the existing APP quality measure set. The APP Plus quality measure set will be an optional measure set that will incrementally add the six measures from the existing APP quality measure set and the remaining five Universal Foundation measures not already included in the APP quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. Under this proposal, a MIPS eligible clinician, group, or APM Entity that reports the APP may choose to report either the APP quality measure set or the APP Plus quality measure set.

(d) Data Submission for the Performance Categories

We are finalizing our proposal to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality, improvement activities, and Promoting Interoperability performance categories, which we proposed to codify at § 414.1325(a)(1)(i) through (iii). Specifically, we are finalizing our proposals that a qualifying data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures for the quality performance category and include a response of ''yes'' for at least one activity in the MIPS improvement activities Inventory for the improvement activities performance category. For the Promoting Interoperability performance category, we are finalizing our proposal that a qualifying data submission must include: (1) performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS; (2) required attestation statements, as specified by CMS; (3) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and (4) the start date and end date for the applicable performance period as set forth at § 414.1320.

We are also finalizing our proposal to codify our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories at § 414.1325(f)(1). We are also finalizing our proposal to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category, which we proposed to codify at § 414.1325(f)(2). Specifically, for the quality and improvement activities performance categories, we are finalizing our proposal that for multiple data submissions received from submitters in multiple organizations, we will calculate a score for each submission received and assign the highest of the scores. For multiple data submissions received from a submitter in the same organization, we will score the most recent submission. For the Promoting Interoperability performance category, we are finalizing our proposal to modify our policy so that, for multiple data submissions received, we will calculate a score for each data submission received and assign the highest of the scores.

(e) MIPS Performance Category Measures and Activities

(i) Quality Performance Category

We are finalizing, the proposal to establish the data submission criteria for the Alternative Payment Model (APM) Performance Pathway (APP) quality measure set; finalizing, as proposed, our proposal to maintain the data completeness criteria threshold to at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years; finalizing, with modification, our proposal to establish a measure set inventory of 195 (instead of 196 as proposed) MIPS quality measures, of which 192 (instead of 193 as proposed) are available in traditional MIPS and 3 are available only for utilization in MVPs; and codifying previously established criteria pertaining to the removal of MIPS quality measures.

(ii) Cost Performance Category

We are finalizing our proposal to add 6 new episode-based measures to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year, as proposed: Chronic Kidney Disease, End-Stage Renal Disease, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis, and Respiratory Infection Hospitalization. We are also finalizing as proposed modifications to 2 existing episode-based cost measures so that their specifications reflect re-evaluated versions: Cataract Removal with Intraocular Lens (IOL) Implantation (currently titled Routine Cataract Removal with IOL

Implantation) and Inpatient (IP) Percutaneous Coronary Intervention (PCI) (currently titled ST-Elevation Myocardial Infarction (STEMI) PCI). We are finalizing our proposal to adopt a 20-episode case minimum for each of the six new episode-based cost measures, as proposed. We are also finalizing our proposal to maintain the case minima for the 2 existing measures as proposed, which are a 20-episode case minimum for the IP PCI measure and a 10-episode case minimum for the Cataract Removal with IOL Implantation measure. Additionally, we are finalizing our proposal to update the operational list of care episode and patient condition groups and codes to reflect these new and modified measures that we proposed. Lastly, we are finalizing our proposal to adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category, which we are also codifying at § 414.1350(e), as proposed.

(iii) Improvement Activities Performance Category

As part of our regular maintenance of the improvement activities Inventory, we are finalizing our proposals to add two new, modify two existing, and remove four existing improvement activities for the CY 2025 performance period/2027 MIPS payment year. We are finalizing a delayed implementation of the modification of one existing improvement activity and the removal of four existing improvement activities until the CY 2026 performance period/2028 MIPS payment year. The new activities help fill gaps we have identified in the Inventory while the modified and removed activities will ensure that it includes only the most meaningful activities that have a clear path to clinical practice improvement. In addition, we are finalizing our proposals for two changes to the traditional MIPS improvement activities reporting and scoring policies for the CY 2025 performance period/2027 MIPS payment year: to eliminate the weighting of activities and to reduce the number of activities to which clinicians are required to attest to achieve a score in the improvement activities performance category. Lastly, we are finalizing our proposal to codify seven improvement activity removal factors to establish criteria used to identify activities for potential removal or modification.

(iv) Promoting Interoperability Performance Category

We do not have any proposals for the Promoting Interoperability performance category.

(f) MIPS Final Scoring Methodology

(i) Scoring the Quality Performance Category

We are finalizing with modifications our proposal to implement defined topped out benchmarks for topped out measures in specialty sets affected by limited measure choice and the list of measures that would use the defined topped out measure benchmark for CY 2025 performance period/2027 MIPS payment year. We are updating the defined topped out measure benchmark to include all deciles from 1 to 10 measure achievement points. We are finalizing our proposal to apply a Complex Organization Adjustment for virtual groups and APM Entities (including SSP ACOs) reporting eCQMs. We are finalizing our proposal to score Medicare CQMs using flat benchmarks for their first 2 years in the program consistent with the Shared Saving Program's policies.

(ii) Scoring the Cost Performance Category

We are finalizing our proposal to modify our methodology for scoring measures for the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year. Additionally, we are finalizing our proposal to adopt a new cost measure exclusion policy beginning with the CY 2024 performance period/2026 MIPS payment year.

(g) MIPS Payment Adjustments

We are finalizing our proposal to establish the mean as the methodology for determining the performance threshold for the CY 2025 performance period/2027 MIPS payment year through the CY 2027 performance period/2029 MIPS payment year. To determine the performance threshold for the CY 2025 performance period/2027 MIPS payment year, we are finalizing our proposal that we will use the mean of the final scores from the CY 2017 performance period/2019 MIPS payment year. Based on the mean final score from that prior period, we are finalizing our proposal to establish a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year.

(h) Calculating the Final Score

We are finalizing our proposal to adopt a new reweighting policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*), as proposed. Specifically, we are finalizing that, beginning with the CY 2024 performance period/2026 MIPS payment year, we may reweight one or more of the performance categories (specifically, quality, improvement activities, or Promoting Interoperability) where we determine, based on information submitted to us on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We note that, to determine whether to apply reweighting to the affected performance category(ies), we will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

(i) Third Party Intermediaries

We are finalizing our proposal to add a requirement that CMS-approved survey vendors must provide information on the cost of their services beginning with the CY 2026 performance period/2028 MIPS payment year. This requirement will only be applicable to the cost of services for the CAHPS for MIPS Survey measure. The CAHPS for MIPS Survey Vendor Participation Form and the CAHPS for MIPS Survey Minimum Business Requirements in the QPP Resource Library will be updated to detail the required survey vendor cost information.

(2) Advanced APM Proposals

(a) Overview of the APM Incentive

An eligible clinician who meet or exceed threshold levels of participation in one or more Advanced APMs to become a Qualifying APM Participant

(QP) (or partial QP) is excluded from MIPS reporting requirements and payment adjustments. We assess an eligible clinician's level of participation in Advanced APMs based on whether either the payment amount or patient count Threshold Score as provided at § 414.1425 meets or exceeds the threshold percentages specified at § 414.1430. Threshold scores are calculated using the ratio of attributed beneficiaries to attribution-eligible beneficiaries. A beneficiary is considered attribution-eligible and included in the calculation of threshold scores if they meet the six criteria specified in the definition of ''attribution-eligible beneficiary'' at § 414.1305. We proposed to modify the sixth criterion under the definition of ''attribution-eligible beneficiary.'' Specifically, we proposed to include as attribution-eligible any beneficiary who has a minimum of one claim for covered professional service furnished by an eligible clinician for purposes of making QP determinations. We also proposed to amend § 414.1430 to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count methods under the Medicare Option and the All-Payer Option with respect to payment year 2026 (performance year 2024) in accordance with amendments made by the CAA, 2024. Relatedly, we also proposed to amend § 414.1450 to reflect the statutory APM Incentive Payment amount for the 2026 payment year (performance year 2024) of 1.88 percent of the eligible clinician's estimated aggregate payments for covered professional services in accordance with amendments made by the CAA, 2024.

2. Definitions

At § 414.1305, we are not finalizing our proposal to revise the definition of the following term:

- Attribution-eligible beneficiary

This term and definition are discussed in detail in section IV.A.4.k. of this final rule.

We solicited comments on this proposal. Our response to comments can be found in detail in the section IV.A.4.k.(2) of this final rule.

We are finalizing the proposed changes to the APM Incentive Payment as proposed.

3. Transforming the Quality Payment Program

Medicare plays a lead role in transitioning the health care system away from fee-for-service payment, which incentivizes the quantity of care, toward value-based payment, which incentivizes higher-quality care and smarter spending. We continue to focus on transforming health care delivery and our 2030 goal to have all traditional Medicare beneficiaries in an accountable care relationship with their health care provider. We also continue to pursue driving higher value care, supporting Advanced APM participation, increasing alignment to reduce burden, and promoting health equity.

We intend to continue our efforts to align the Quality Payment Program with the value-based strategy Alignment, Growth and Equity pillars,[805] the National Quality Strategy,[806] [807] [808] and broader CMS initiatives. We also intend to transform MIPS and obtain more meaningful comparable performance data, drive higher value care through MVPs and to provide as much transparency as possible about the timing for sunsetting traditional MIPS (86 FR 39356). As stated previously (86 FR 65394 through 65396), we envision a full transition to MVP reporting to support movement towards value-based payment.

In the CY 2025 PFS proposed rule (89 FR 62010 through 62016), we addressed how we can achieve full MVP adoption and subgroup participation as we move toward the sunsetting of traditional MIPS and advancing the three pillars and the National Quality Strategy. Specifically, in a request for information (RFI), we solicited feedback on MIPS eligible clinicians' readiness to report MVPs, how we should ensure there are applicable MVPs for all MIPS eligible clinicians, and what guidance/parameters are needed for multispecialty groups to place MIPS eligible clinicians into subgroups for reporting an MVP relevant to the scope of care provided (89 FR 62016). Please note, this was an RFI only.

We received many comments on this RFI and we thank commenters for their responses. Although we will not be addressing in this final rule the comments received in response to this RFI, we value the input received and will take the comments into consideration to help us consider potential future policies for MVPs for MIPS. We will consider the feedback received for future rulemaking.

4. QPP Reporting and Data Submission

a. CY 2025 MVP Development and Maintenance

(1) Development of New MVPs

In the CY 2023 PFS final rule (87 FR 70035 through 70037), we finalized modifications to the MVP development process to broaden opportunities for the general public to provide feedback on new candidate MVPs prior to the notice and comment rulemaking process. We refer readers to the Quality Payment Program website to review the public feedback we received for each 2025 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

Through our development processes for new MVPs (85 FR 84849 through 84856, 87 FR 70035 through 70037), we aim to gradually develop new MVPs that are relevant and meaningful for MIPS eligible clinicians. We proposed the inclusion of six new MVPs (89 FR 62582 through 62606):

- Complete Ophthalmologic Care;
- Dermatological Care;
- Gastroenterology Care;
- Optimal Care for Patients with Urologic Conditions;
- Pulmonology Care; and
- Surgical Care.

With the proposed addition of the 6 new MVPs, we estimated approximately 80 percent of MIPS eligible clinicians will have applicable MVPs available for reporting. We are finalizing all six new MVPs, three as proposed and three with modifications. We refer readers to Appendix 3: MVP Inventory, of this final rule for discussion of the proposed new MVPs, the public comments received, and our responses.

Although our intended goal has been to offer MVPs for all specialties and subspecialties during the transition from traditional MIPS to full MVP implementation (84 FR 40732 through 40740), we acknowledge our existing portfolio of quality and cost measures may not be applicable to all specialties and subspecialties. For quality measures, while most specialties and subspecialties can report on broadly applicable quality measures to meet the reporting requirements for the quality performance category within an MVP, some specialties and subspecialties do not have sufficient robust quality measures that are specific to their scope

[805] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity, Health Affairs Forefront, March 14, 2024. *https://www.healthaffairs.org/content/forefront/update-medicare-value-based-care-strategy-alignment-growth-equity.*

[806] CMS National Quality Strategy. (Centers for Medicare & Medicaid Services, April 2022). *https://www.cms.gov/files/document/cms-national-quality-strategy-fact-sheet-april-2022.pdf.*

[807] The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Centers for Medicare & Medicaid Services, June 2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality | CMS (*https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality#_ftn4*).

[808] Quality in Motion, Acting on the CMS National Quality Strategy, April 2024. *https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf.*

of care. Thus, we continue to explore options for overcoming challenges to develop MVPs for those specialties and subspecialties with limited quality measures.

For cost measures, while most specialties have at least one applicable episode-based cost measure or population-based cost measure, these measures may not encompass the full array of care that could be covered by a given specialty and, in some instances, some specialties and subspecialties may not have an applicable cost measure. For example, the following specialties have limited cost measures available and applicable based on the current MIPS cost measure inventory:

- Diagnostic Radiology;
- Interventional Radiology;
- Optometry;
- Pathology;
- Radiation Oncology; and
- Speech Language Pathology.

Additionally, some specialties have one or more applicable cost measures, but subspecialists may not be captured under these measures. In the case of the Melanoma Resection measure, it applies to individual MIPS eligible clinicians, groups, and subgroups that perform a sufficient number of melanoma excision procedures to meet the measure's case minimum. Although this measure is applicable to many dermatologists, whether a dermatologist is scored on this measure depends on multiple factors, including whether they submit claims on, and are attributed a sufficient number of qualifying melanoma excision procedures (minimum of 10 cases as specified under § 414.1350(c)(4)) to receive a score on this cost measure as set forth in § 414.1380(b)(2). While there are existing policies to reweight the cost performance category for individual, groups, and subgroups of MIPS eligible clinicians that cannot be scored on cost measures in accordance with § 414.1380(b)(2), an MVP cannot be developed for a specialty or subspecialty if there is not at least one applicable cost measure, as finalized in the CY 2021 PFS final rule (85 FR 84472). The intent of MVPs is to assess MIPS eligible clinicians, groups, and subgroups across all performance categories, and additional cost measures would support this intent.

We use prioritization criteria that we established in the CY 2022 PFS final rule (86 FR 65456) to determine which cost measures to develop:

- Clinical coherence of measure concept (to ensure valid comparisons across clinicians).
- Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).
- Opportunity for performance improvement.
- Alignment with quality measures and improvement activities to ensure meaningful assessments of value.

In the CY 2022 PFS final rule (86 FR 65457), we also established the following standards for cost measure construction:

- Measures must assign services that accurately capture the role of attributed clinicians.
- Measures must have clear, ex ante attribution to clinicians.
- Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.
- Measures' construction methodology must be readily understandable to clinicians.
- Measures must hold clinicians accountable for only the costs they can reasonably influence.
- Measures must convey clear information on how clinicians can alter their practice to improve measured performance.
- Measures must demonstrate variation to help distinguish quality of care across individual clinicians.
- Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.

As of the CY 2024 performance period/2026 MIPS payment year, we have developed and implemented 29 MIPS cost measures, which reflect the prioritization criteria and input from interested parties about potential clinical topics, measure scope, clinically related services, and potential challenges or barriers to measurement. This is a substantial achievement in building out the cost measure portfolio since MIPS began with only two population-based cost measures, the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) measure.

However, there are still MIPS eligible clinicians who do not have cost measures that apply to the major aspects of their care practice. For example, there are specialties or clinical topics where clinically coherent measure concepts have not yet been identified, plus there are impacts of cost, clinician, or patient coverage being lower than other measure concepts that were prioritized for development. Therefore, we continue to encourage interested parties to utilize our established pre-rulemaking processes, such as the Call for Measures (*https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview*), to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*).

We refer readers to section IV.A.3. of this final rule for a discussion of our request for information on Transforming the Quality Payment Program, challenges to adopting MVPs, and a potential path forward for developing MVPs for MIPS eligible clinicians with limited measures.

(2) MVP Maintenance Process

In the CY 2023 PFS final rule (87 FR 70037), we finalized a modification to the annual maintenance process for MVPs previously finalized in the CY 2022 PFS final rule (86 FR 65410). We communicated that if we identified any potentially feasible and appropriate submitted maintenance recommendations, we would host a public facing webinar open to interested parties and the general public through which they could offer their feedback on the potential maintenance updates we have identified.

Because we have had a low volume of submitted maintenance recommendations in past years, we proposed to modify the MVP maintenance webinar process to provide us more flexibility in how we communicate submitted maintenance recommendations prior to proposing them formally in rulemaking. Allowing flexibility in communicating recommendations through alternative webinar formats or other public communication channels would offer similar opportunities for public review and feedback as a live public webinar. For example, in lieu of a live webinar, we could choose to communicate submitted maintenance recommendations via a pre-recorded webinar, which will encourage interested parties to submit their feedback on the submitted recommendations in writing by email before maintenance updates are formally proposed in rulemaking. It is important to reiterate this public webinar process supports our commitment to consider interested parties' feedback when determining which maintenance updates are appropriate for inclusion in formal notice and comment rulemaking.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to replace the live webinar with alternative approaches for the MVP maintenance process. The commenters shared their belief that alternative approaches could provide additional opportunities for interested parties to offer feedback on potential MVPs. One commenter recommended that we retain the current length of the public comment period to provide feedback on MVP candidates.

Response: We thank the commenters for their support. We intend to retain the 45-day public comment period to provide feedback on MVP candidates.

Comment: One commenter did not support the proposed modification to the MVP maintenance webinar process and recommended we continue offering the live webinar as it allows interested parties to engage directly with us.

Response: Interested parties will continue to have the opportunity to directly engage with us on MVP development. For example, they may submit suggestions to our mailbox at *PIMMSMVPSupport@gdit.com*. These suggestions are accepted on a rolling basis throughout the year. Recommendations we identify as potentially feasible and appropriate are communicated to interested parties and the general public as an additional opportunity to provide feedback on potential MVP maintenance updates prior to formal notice and comment rulemaking. We will also consider providing a live webinar if the feedback warrants discussion or dialogue with interested parties.

After consideration of public comments, we are finalizing our proposal as proposed to publicize any potentially feasible and appropriate submitted maintenance recommendations through various platforms, including but not limited to a live webinar, alternative webinar formats, and other public communication channels as we deem appropriate. Interested parties may offer their feedback on the potential maintenance updates we have identified directly, when the selected communication channel permits and otherwise through the mailbox noted.

(3) MVP Maintenance Updates to Previously Finalized MVPs

Between the CY 2022 PFS final rule (86 FR 65998 through 66031) and the CY 2023 PFS final rule (87 FR 70037), we finalized 12 MVPs available for reporting beginning with the CY 2023 performance period/2025 MIPS payment year:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Improving Care for Lower Extremity Joint Repair;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Optimal Care for Neurological Conditions;
- Patient Safety and Support of Positive Experiences with Anesthesia;
- Promoting Wellness; and
- Supportive Care for Cognitive-Based Neurological Conditions.

In the CY 2024 PFS final rule (88 FR 79978 through 80047), we consolidated Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single primary care MVP titled ''Value in Primary Care MVP'' as well as finalized five additional MVPs available for reporting beginning with the CY 2024 performance period/2026 MIPS payment year:

- Focusing on Women's Health;
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and Human Immunodeficiency Virus (HIV);
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care.

In the CY 2025 PFS proposed rule (89 FR 62607 through 62648), we proposed modifications to all 16 MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). Through these modifications, we can expand upon the clinical concepts, advance health equity, address maintenance requests from the public, and remove measures and activities that would either be finalized for removal from their respective MIPS Inventory or replaced by more robust measures. In addition, through the MVP maintenance process, we proposed to consolidate the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP and the Supportive Care for Neurodegenerative Conditions MVP into a single consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions MVP.

Comment: One commenter expressed opposition to organizing MVPs at the broad specialty level and urged us to propose MVPs that are more clinically relevant by focusing on a discrete condition or clinical episode, even if they are only provided by a subset of the specialty's members or by a particular subspecialty. Alternatively, the commenter requested we consider updates to the proposed framework, which would continue to allow for broad specialty MVPs, but broken out by sub-clinical conditions.

Response: We will address refinements to the general MVP framework in future rulemaking, and we will take these suggestions into consideration.

In addition, we received public comments on the proposed maintenance updates to previously finalized MVPs. We refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications to the previously finalized MVPs, the public comments received, and our responses.

b. MVP Requirements and Scoring

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized policies for MVP reporting requirements, including subgroup requirements, which took effect beginning in the CY 2023 performance period/2025 MIPS payment year, at § 414.1365(c)(1) through (4). We noted that MVP reporting requirements are based on the reporting requirements of traditional MIPS but have some differences, such as reporting fewer measures, to reduce MVP reporting burden and allow for measurement that is more meaningful by requiring clinicians to report on measures and activities that comprehensively reflect an episode of care or clinical condition (86 FR 65411).

In the CY 2022 PFS final rule, we finalized policies for MVP scoring that took effect beginning in the CY 2023 performance period/2025 MIPS payment year. We refer readers to 86 FR 65419 through 65427 for the details of those finalized policies. We previously finalized at § 414.1365(d)(2) that, unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP (86 FR 65419 through 65421). We noted that in general, we have adopted the scoring policies from traditional MIPS for MVP Participants unless there is a compelling reason to adopt a different policy to further the goals of the MVP framework (86 FR 65419). In the CY 2025 PFS proposed rule (89 FR 62018 through 62021), we

proposed to update the registration process and scoring policies for population health measures in the quality performance category, clarify the alignment between scoring cost measures in MVPs and traditional MIPS, update requirements and scoring policies for improvement activities in the improvement activities performance category, and update the requirements for subgroup reporting in the Promoting Interoperability performance category.

We refer readers to section IV.A.4.d. of this final rule for policies on data submission requirements; section IV.A.4.e.(1)(c)(i) of this final rule for policies on the data completeness threshold; section IV.A.4.f.(1)(b) of this final rule for policies on scoring of topped out measures, and scoring virtual groups and APM Entities (including SSP ACOs) in the quality performance category; section IV.A.4.f.(1)(d)(ii)(B) of this final rule for benchmarking policies for scoring the cost performance category; section IV.A.4.e.(3)(b)(iv) of this final rule for policies for requirements and scoring that remove medium- and high-weighting from improvement activities in the improvement activities performance category; and section IV.A.4.e.(4) of this final rule for current requirements and the Request for Information (RFI) for the Promoting Interoperability performance category.

(1) Quality Performance Category in MVPs

(a) Background on Population Health Administrative Claims-Based Measures

In the CY 2021 PFS final rule, we discussed the inclusion of population health measures as a part of the foundational layer of MVPs, to improve patient outcomes, reduce reporting burden and costs, and better align with clinician quality improvement efforts (85 FR 84856 and 84857). In the CY 2022 PFS final rule we defined a population health measure as a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services (86 FR 65408 and 65409). We also discussed in the CY 2022 PFS final rule the importance of currently adopted population health measures, noting that they capture outcomes important to patients and thus provide meaningful information to clinicians so they can improve their practice, and discussed the use of population health measures as the foundational layer in MVPs to ensure that important areas of measurement are reflected within all MVPs (86 FR 65408).

We finalized in the CY 2022 PFS final rule (86 FR 65414) at § 414.1365(c)(4)(ii) that an MVP Participant is scored on one population health measure in accordance with § 414.1365(d)(1). Since the MVP population health measures are administrative claims-based, they do not require data submission from clinicians and do not contribute to reporting burden. To track which population health measure an MVP Participant intends to report, we finalized in the CY 2022 PFS final rule (86 FR 65417) at § 414.1365(b)(2)(i) that MVP Participants are required to select one population health measure at the time of MVP registration.

(b) Proposal To Use the Highest Score of All Available Population Health Measures

In the CY 2022 PFS final rule (86 FR 65421 and 65422) we finalized scoring rules for population health measures in MVPs. We finalized at § 414.1365(d)(3)(i)(A) that, except as provided in paragraph (d)(3)(i)(A)(*1*), each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. In cases where an MVP Participant selects a population health measure that cannot be scored because it does not have a benchmark or meet the case minimum requirement, we do not score any other population health measures that may be applicable and available.

Population health measures are included in the MVP foundational layer because they capture outcomes important to patients and thus provide meaningful information to clinicians so they can improve their practice (86 FR 65408). Under the current policy, we cannot score an MVP Participant on a population health measure if the MVP Participant selects a measure at registration that lacks a benchmark or if their case volume does not meet the case minimum requirement for the selected measure, even if another measure is applicable and available. In the CY 2022 PFS final rule (86 FR 65414) we discussed calculating each population health measure and applying the higher score to the quality score; however, we ultimately proposed and finalized the current policy to score only one selected population health measure to mitigate concerns from interested parties that not all population health measures are applicable to all specialties (86 FR 65414). We now realize that at the time of registration, an MVP Participant will not be able to determine if they will have enough cases to meet the case minimum required for scoring the selected population health measure and may not be able to reliably predict how the measure will score compared to a benchmark, given that benchmarks for administrative claims measures are set using data from the same performance year. Requiring an MVP participant to select the population health measure to be scored at the time of registration may unfairly penalize an MVP Participant.

To increase the likelihood that a population health measure can be scored, we had considered several options, including calculating the population health measure score by using an average score of all population health measures that have a benchmark and meet the case minimum requirement and using the score of the population health measure with the highest number of cases in order to score the population health measure that represents the most care provided by an MVP Participant. However, we determined these approaches could result in a lower score for an MVP Participant that did not correlate to the MVP Participant's performance. We also considered whether an MVP Participant could select a population health measure at the time of data submission when all other measures are reported. However, population health measures are calculated by CMS using administrative claims-based data and therefore do not require data submission from clinicians, and administrative claims-based data is not available for CMS calculation until at least 60 days after the end of the reporting period. Therefore, the MVP Participant would not know whether they would meet the case minimum requirement for the selected population health measure at the time of data submission.

Because population health measures in the MVP capture outcomes important to patients (that is, for example, hospitalizations for acute illness) and thus, provide meaningful information to clinicians so they can improve their practice, we want to avoid scenarios where MVP Participants may inadvertently select a measure that cannot be scored. As described for traditional MIPS at § 414.1380(b)(1)(i), we calculate all administrative claims-based quality measures and score the clinician on each measure for which there is a benchmark and the clinician meets the case minimum requirement. Calculating all population health

measures in MVPs would more closely align with the policy to calculate all administrative claims-based quality measures. Additionally, we have developed MVPs with a smaller, more cohesive set of measures and streamlined reporting requirements. A policy to take the highest population health score would increase the likelihood that an MVP Participant is scored on a population health measure and would ensure that MVP Participants receive the highest possible population health score that correlates to their performance.

We proposed in the CY 2025 PFS proposed rule (89 FR 62018 through 62020) to revise § 414.1365(d)(3)(i)(A) to state that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MVP Participants would be scored on the selected population health measure and beginning in the CY 2025 performance period/2027 MIPS payment year, we would use the highest score of all available population health measures. If no population health measure has a benchmark or meets the case minimum requirement, then the population health measure is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. To apply this policy to subgroups reporting an MVP, we also proposed in the CY 2025 PFS proposed rule (89 FR 62019) to update § 414.1365(d)(3)(i)(A)(*1*) to provide that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, subgroups will be scored on the selected population health measure based on its affiliated group score, if available, and beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

We also proposed in the CY 2025 PFS proposed rule (89 FR 62019 and 62020) to remove the requirement for an MVP Participant to select a population health measure at the time of MVP registration. By implementing our proposal to calculate each population health measure for an MVP Participant and use the participant's highest score for population health measures in MVPs, there would be no need for the MVP Participant to select a measure during registration. We proposed in the CY 2025 PFS proposed rule (89 FR 62019 and 62020) to revise § 414.1365(b)(2)(i) to provide that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received on the proposed revisions to (1) score MVP Participants on their highest scoring of all population health measures; (2) score subgroups on the highest scoring of all available population health measures based on its affiliated group score, if available; and (3) remove the requirement for an MVP Participant to select a population health measure at the time of MVP registration and our responses.

Comment: Many commenters supported the proposal to use the highest score of all available population health measures. A few commenters expressed their belief that this proposal will reduce clinician burden, reduce the likelihood that a clinician selects a measure that cannot be scored, and will more accurately reflect the quality of care provided in the population health measure score.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposal to use the highest score of all available population health measures and recommended that we apply the proposal retroactively for the CY 2024 performance period/2026 MIPS payment year.

Response: We clarify that the proposal, with respect to years prior to the CY 2025 performance period/2027 MIPS payment year was not a proposal to retroactively modify current policy. Instead, it principally specified that the CY 2024 performance period would be the last performance period to operate under existing policy and the newly proposed policy would begin with the CY 2025 performance period. While the agency may adopt rules retroactively under certain circumstances, it declines to do so here.

Comment: A few commenters, who appear to be MIPS eligible clinicians, requested that we provide data on their performance for all population health measures, including those not scored.

Response: We agree that it would be beneficial to provide feedback on all population health measures in an MVP. We will explore whether it is technically feasible to provide each MIPS eligible clinician with patient-level reports to MVP Participants for any population health measure that meets case minimum, and not just the one that contributes to the final score.

After consideration of public comments, we are finalizing, as proposed, to revise § 414.1365(d)(3)(i)(A) to state that, except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. Beginning in the CY 2025 performance period/2027 MIPS payment year, except as provided in paragraph (d)(3)(i)(A)(*1*), the highest score of all applicable and available population health measures will be used. If no population health measure has a benchmark or meets the case minimum requirement, each such measure is excluded from the MVP Participant's total measure achievement points and total available measure achievement points. We are also finalizing as proposed to revise § 414.1365(d)(3)(i)(A)(*1*) to state for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, a subgroup is scored on the selected population health measure based on its affiliated group score, if available, and beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. We are also finalizing as proposed to revise § 414.1365(b)(2)(i) to provide that for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant

must select an MVP and any outcomes-based administrative claims-based measure on which the MVP Participant intends to be scored.

(2) Cost Performance Category in MVPs

In the CY 2022 PFS final rule, we finalized at § 414.1365(d)(3)(ii) to use the methodology established at § 414.1380(b)(2)(i) through (v) to score the cost performance category for MVPs using the cost measures included in the MVP that MVP Participants select and report. The finalized policies at § 414.1380(b)(2) score cost measures based on achievement and improvement when the case minimum specified under § 414.1350(c) is met or exceeded and CMS has determined a benchmark (86 FR 65422 and 65423). We discussed in the CY 2022 PFS final rule that aligning MVP scoring policies with existing traditional MIPS scoring policies balances the statutory requirements and goals of the program with ease of use, stability, and meaningfulness to MIPS eligible clinicians (86 FR 65419). We refer readers to section IV.A.4.f.(1)(d)(ii)(B) of this final rule for discussion of our proposals to modify the cost performance category's scoring methodology at § 414.1380(b)(2), which we are finalizing.

To ensure alignment between MVP and traditional MIPS scoring policies, it is important that MVP cost performance category scoring policies refer to the traditional MIPS policy on how cost measures are scored. We remind readers that cost measures are scored based on the MIPS eligible clinician's performance on the measure during the performance period compared to the measure's benchmark, as set forth in § 414.1380(b)(2). Currently, § 414.1365(d)(3)(ii) provides that the cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report. To ensure continued alignment, we proposed in the CY 2025 PFS proposed rule (89 FR 62020) to modify § 414.1365(d)(3)(ii) to replace the reference to § 414.1380(b)(2)(i) through (v) with a broader reference to the cost performance category scoring policies at § 414.1380(b)(2).

We also proposed in the CY 2025 PFS proposed rule (89 FR 62020) to similarly revise § 414.1365(d)(3)(ii)(A). This regulation currently provides that a subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. In addition, § 414.1365(d)(3)(ii)(A) provides that, if the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2)(i) through (v). We proposed in the CY 2025 PFS proposed rule (89 FR 62020) to modify § 414.1365(d)(3)(ii)(A) to replace the reference to § 414.1380(b)(2)(i) through (v) with a broader reference to the cost performance category scoring policies at § 414.1380(b)(2).

We received public comments on these proposals. The following is a summary of the comments we received on the proposed revision to the MVP cost performance category scoring policy regulation text to reference the traditional MIPS policy on how cost measures are scored and our responses.

Comment: A few commenters supported the proposal to modify the regulation text governing MVP cost performance category scoring to more broadly reference the traditional MIPS cost performance category scoring methodology. One commenter requested clarification as to whether the proposed modification to the cost performance category's scoring methodology in section IV.A.4.f.(1)(d)(ii)(B) of the CY 2025 PFS proposed rule (89 FR 62083 through 62087) will apply to cost measures in MVPs.

Response: We thank commenters for their support. We clarify that the proposed modifications to the cost performance category's scoring methodology, as described in the CY 2025 PFS proposed rule (89 FR 62083 through 62087) and finalized in section IV.A.4.f.(1)(d)(ii)(B) of this final rule, will apply to our scoring of cost measures in MVPs.

After consideration of public comments, we are finalizing as proposed modifications to the MVP cost performance category scoring policies at § 414.1365(d)(3)(ii) and § 414.1365(d)(3)(ii)(A). Specifically, we are finalizing replacing references to § 414.1380(b)(2)(i) through (v) in each provision with a broader reference to the cost performance category's scoring policies at § 414.1380(b)(2). We are finalizing our proposed modification at § 414.1365(d)(3)(ii) to state the cost performance category is calculated for an MVP Participant using the methodology at § 414.1380(b)(2). We also are finalizing our proposed modification to § 414.1365(d)(3)(ii)(A) to state that, if the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2).

(3) Improvement Activities Performance Category in MVPs

The improvement activities performance category should provide clinicians with an opportunity to select from a subset of improvement activities within an MVP that are relevant to the clinical topic. In the CY 2022 PFS final rule (86 FR 65412 and 64513) we finalized at § 414.1365(c)(3), that an MVP Participant who reports an MVP must report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at § 414.1380(b)(3)(ii). We established in the CY 2022 PFS final rule (86 FR 65412 and 64514) that MVP Participants submitting MVPs would report fewer improvement activities than eligible clinicians reporting traditional MIPS to support MVP adoption.

Additionally, in the CY 2022 final PFS rule (86 FR 65423 and 65424) we finalized at § 414.1365(d)(3)(iii) that the improvement activities performance category score for MVP Participants is calculated based on the submission of high- and medium-weighted improvement activities. We finalized that MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Therefore, MVP Participants who do not participate in a certified or recognized PCMH or comparable specialty practice must submit one high-weighted improvement activity or two medium-weighted improvement activities included in the MVP to receive a full credit score of 40 points. We stated that these requirements will provide an incentive for reporting MVPs, since fewer improvement activities are required to receive a full score for the improvement activities category in an MVP compared to traditional MIPS (86 FR 65423).

We refer readers to section IV.A.4.e.(3)(b)(iv) of this final rule for finalized policies that remove the medium- and high-weighting for improvement activities in traditional MIPS starting in the CY 2025

performance period/2027 MIPS payment year. In the CY 2025 PFS proposed rule (89 FR 62020 and 62021), we proposed to align MVP policies with the traditional MIPS proposal regarding the weighting of improvement activities and to reduce the number of improvement activities an MVP Participant must submit for an MVP. In the CY 2022 PFS final rule, we discuss that maintaining a lower reporting burden will encourage MVP participation (86 FR 65412). We discussed in the CY 2022 PFS final rule that incentives for reporting MVPs, including reduced reporting requirements, allow MVP Participants to report on a smaller, more cohesive subset of measures and activities that are relevant to a given clinical topic, condition, or episode of care (86 FR 65419 and 65420). Therefore, we proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) that starting in the CY 2025 performance period/2027 MIPS payment year, MVP Participants would be required to submit one improvement activity to achieve 40 points, or full credit, whereas in traditional MIPS clinicians will be required to submit two improvement activities to achieve full credit for the improvement activities performance category. We also proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) to update reporting requirements and scoring rules related to the improvement activities performance category for MVPs accordingly.

We proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) to revise § 414.1365(c)(3) to reflect reporting requirements for the CY 2023 and 2024 performance periods/2025 and 2026 MIPS payment years and the reporting requirements beginning in the CY 2025 performance period/2027 MIPS payment year. The revisions proposed in the CY 2025 PFS proposed rule (89 FR 62020 through 62021) at § 414.1365(c)(3)(i) introductory text and additions proposed at paragraphs (c)(3)(i)(A) through (C) would require that an MVP Participant who reports an MVP, in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized PCMH or comparable specialty practice as described at § 414.1380(b)(3)(ii). Additionally, we proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) at § 414.1365(c)(3)(ii) introductory text and (c)(3)(ii)(A) and (B), beginning in the CY 2025 performance period/2027 MIPS payment year an MVP Participant who reports an MVP must report either one improvement activity or participation in a certified or recognized PCMH, or comparable specialty practice as described at § 414.1380(b)(3)(ii). We sought comment on the proposals.

We received public comments on these proposals. The following is a summary of the comments we received on the proposed revisions to MVP reporting requirements for the improvement activities performance category and our responses.

Comment: Many commenters supported the proposal to reduce the MVP reporting requirement for improvement activities.

Response: We thank commenters for their support.

Comment: One commenter expressed a concern that the policy will reduce requirements of the improvement activities performance category and may inadvertently lower the bar for improving quality. The commenter recommended increasing the number of improvement activities required for MVPs.

Response: We aim for MVPs to promote high value care by connecting the MIPS performance categories, standardizing performance measurement of a specialty, medical condition, or episode of care, and providing patients and clinicians with robust and meaningful healthcare data (86 FR 65391).

We are finalizing our policy that an MVP Participant who reports an MVP must report either one improvement activity or participation in a certified or recognized PCMH or comparable specialty practice in order to better focus on the highest impact improvement activities and to encourage quality improvement. MVP scoring policies are intended to reduce reporting requirements in MVPs to incentivize MVP participation and allow MVP Participants to report on a smaller, more cohesive subset of measures and activities that are relevant to a given clinical topic, condition, or episode of care, while still driving quality (86 FR 65419 and 65420). The new policy supports our goal of encouraging improvement while lowering the reporting burden.

After consideration of public comments, we are finalizing as proposed to update § 414.1365(c)(3)(i) introductory text and additions at paragraphs (c)(3)(i)(A) through (C) to require that an MVP Participant who reports an MVP in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized PCMH or comparable specialty practice as described at § 414.1380(b)(3)(ii). We are also finalizing as proposed to update § 414.1365(c)(3)(ii) introductory text and (c)(3)(ii)(A) and (B), that beginning in the CY 2025 performance period/2027 MIPS payment year an MVP Participant who reports an MVP must report either one improvement activity or participation in a certified or recognized PCMH, or comparable specialty practice as described at § 414.1380(b)(3)(ii).

We also proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) to align MVP scoring with proposed modifications to traditional MIPS scoring that will remove the reference to high- and medium-weighted improvement activities for scoring and assign 40 points for each improvement activity submitted by MVP Participants. We proposed in the CY 2025 PFS proposed rule (89 FR 62020 and 62021) at § 414.1365(d)(3)(iii) that in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants submitting MVPs in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years would receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants would receive 40 points for each improvement activity that is submitted or participation in a certified or recognized PCMH or comparable specialty practice. We sought comment on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received on the proposal to update MVP scoring policies for the improvement activities performance category and our responses.

Comment: Many commenters supported the improvement activities scoring policy in MVPs, stating that this scoring policy will simplify scoring,

reduce complications, and support efficient participation in MVPs.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing as proposed to update at § 414.1365(d)(3)(iii) that in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants submitting MVPs in the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants will receive 40 points for each improvement activity that is submitted or participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(4) Promoting Interoperability Performance Category in MVPs

In the CY 2022 PFS final rule, we finalized at § 414.1365(c)(4)(i) that an MVP Participant is required to meet the Promoting Interoperability performance category's reporting requirements. We also finalized at § 414.1365(c)(4)(i)(A) the Promoting Interoperability performance category's requirements for a subgroup participating in MVP reporting (86 FR 65413 and 65414). Specifically, at § 414.1365(c)(4)(i)(A), we stated that, for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. Under this policy, the submission of the affiliated group's data will be on the subgroup's behalf. If the affiliated group chooses to report as a group for the Promoting Interoperability performance category, the group will still be required to submit its own data separately and in accordance with the reporting rules for groups. We refer readers to the CY 2022 PFS final rule for additional details (86 FR 65413 and 65414).

We acknowledge the existing language under § 414.1365(c)(4)(i)(A) establishes the requirement for a subgroup to submit its affiliated group's data for the Promoting Interoperability performance category in the foundational layer of an MVP for only the CY 2023 performance period/2025 MIPS payment year and CY 2024 performance period/2026 MIPS payment year.[809] In the CY 2022 PFS final rule, we stated our intent to assess the performance of clinicians participating in subgroups in the Promoting Interoperability performance category using subgroup level data to the extent that it is operationally feasible (86 FR 39371 and 39372). However, as discussed in the CY 2022 PFS final rule (86 FR 39371), we heard from interested parties through the MVP Town Hall (85 FR 84846), that some clinicians will need additional time to resolve operational challenges, including challenges related to configuration of EHR systems for reporting Promoting Interoperability data at the subgroup level. We recognize that clinicians and interested parties may need additional time to resolve the technical challenges related to configuration of EHR systems for capturing and submitting data at the subgroup level.

We proposed in the CY 2025 PFS proposed rule (89 FR 62021) that this subgroup reporting policy to use the affiliate group's data for the Promoting Interoperability performance category in the MVP they select apply beyond the CY 2023 performance period/2025 MIPS payment year and CY 2024 performance period/2026 MIPS payment year currently specified at § 414.1365(c)(4)(i)(A). Specifically, we proposed in the CY 2025 PFS proposed rule (89 FR 62021) to modify § 414.1365(c)(4)(i)(A) by removing the references to the specific performance periods/MIPS payment years and provide instead that an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category. This change would allow a subgroup to continue to submit the affiliated group's data for the MVP Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and subsequent years. We note that we will continue to monitor the operational challenges with the EHR systems and reassess whether subgroups should be required to submit performance data at the subgroup level for the Promoting Interoperability performance category.

We received public comments on this proposal. The following is a summary of the comments we received on the proposal to allow subgroups to continue to submit affiliated group's data for the Promoting Interoperability performance category and our responses.

Comment: A few commenters supported the proposal for subgroups to continue to use the affiliate group's data for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and subsequent years.

Response: We thank commenters for their support for continuing the policy beyond the CY 2025 performance period/2027 MIPS payment year.

Comment: One commenter supported the proposal and recommended that we evaluate if subgroups are disincentivized to submit MVPs because of the policy.

Response: We thank the commenter for their support and believe the policy enables MVP participation for subgroups without the infrastructure to report data for the Promoting Interoperability performance category measures at the subgroup level. We will monitor subgroup participation in future years.

After consideration of public comments, we are finalizing as proposed modification to § 414.1365(c)(4)(i)(A) to allow subgroups to continue to submit affiliated group's data for the Promoting Interoperability performance category. As finalized, § 414.1365(c)(4)(i)(A) will state that an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

c. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning in CY 2021 performance period/2023 MIPS payment year. The APP was designed as a reporting and scoring pathway available only to MIPS APM participants in order to provide a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation by, these clinicians. We also established in the APM Performance Pathway for Shared Savings Program ACOs section of that same rule that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/

[809] In the CY 2025 PFS proposed rule (89 FR 62021), we inadvertently stated in error that the existing language under § 414.1365(c)(4)(i)(A) applied the requirement to the 2027 MIPS payment year. We have corrected this typographical error here in this final rule.

2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861). The complete existing APP quality measure set is shown in Table 66. As indicated in Table 66, the current APP quality measure set includes six quality measures, of which five also are Universal Foundation measures. Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

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TABLE 66: Existing APM Performance Pathway Quality Measure Set

Quality ID #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type	Universal Foundation Measure
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	APM Entity/ Third Party Intermediary	Chronic Conditions	Intermediate Outcome	Yes
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	APM Entity/ Third Party Intermediary	Behavioral Health	Process	Yes
236	Controlling High Blood Pressure	eCQM/MIPS CQM (all APP reporters) Web Interface/ Medicare CQM (SSP ACOs only)	APM Entity/ Third Party Intermediary	Chronic Conditions	Intermediate Outcome	Yes
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/ Experience	Yes
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome	Yes
484	Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome	No

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We stated when finalizing the APP that the goal of the APP quality measure set is not necessarily to reflect the specific quality goals of clinicians within their respective APMs, but rather to reduce the burden of reporting on quality measures twice: once to MIPS and once to their APMs. We believed that by using this broadly applicable population-health-based measure set, we would enable MIPS APM participants to focus more of their energy and attention on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from one year to the next (85 FR 84862).

We also finalized the Web Interface measure set for the CY 2021 MIPS performance period within the APP for Shared Savings Program ACOs only (85 FR 84720 through 84723), and in the CY 2022 PFS final rule, extended this collection type through CY 2024 (86 FR 65429). In the CY 2024 PFS final rule, we established the Medicare Clinical Quality Measure for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM) collection type in the APP quality measure set and finalized that the Medicare CQM collection type would be available to only ACOs participating in the Shared Savings Program. Beginning with the 2024 performance year, ACOs in the Shared Savings Program have the option to report the Medicare CQM under the APP on only ''beneficiaries eligible for Medicare CQMs as defined at § 425.20, instead of their all payer/all patient population'' (88 FR 79329).

(2) Establishment of the APP Plus Quality Measure Set To Align With the Universal Foundation

We explained in the CY 2025 PFS proposed rule that under the goals of the CMS National Quality Strategy to improve the quality and safety of healthcare for everyone,[810] CMS is implementing a building-block approach to streamline quality measures across CMS quality programs for measuring primary care clinician performance in the adult and pediatric populations by leveraging the Universal Foundation of quality measures (89 FR 61854). The Universal Foundation of quality measures focuses clinicians' attention on measures that are meaningful for the health of broad segments of the population; reduces provider burden by streamlining and aligning measures; advances equity with the use of measures that will help CMS recognize and track disparities in care among and within populations; aids the transition from manual reporting of quality measures to seamless, automatic digital reporting; and permits comparisons among various quality and value-based care programs to help the Agency better understand what drives quality improvement and what does not.[811] The Universal Foundation, which identifies a set of key quality measures for use where relevant throughout CMS programs, is already reflected in the Medicaid Core Sets and the Marketplace Quality Rating System.[812] In addition, in the CY 2024 PFS final rule (88 FR 79321 and 80043), CMS consolidated the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MIPS Value Pathways (MVPs) into a single consolidated primary care MVP (Value in Primary Care MVP) that aligns with the adult Universal Foundation quality measures. In the Announcement of CY 2024 Medicare Advantage (MA) Capitation Rates and Part C and D Payment Policies, we also solicited comment on adding the Universal Foundation measures to Medicare Advantage and the Part D Star Ratings Program. We noted that we would take these comments into consideration in the future, and that any additional measures added to the Star Ratings Program would need to be added through rulemaking.[813] Alignment of quality measures across CMS programs allows practitioners to better focus their quality efforts, reduces administrative burden, and drives digital transformation and stratification of a focused quality measure set to assess impact on disparities.[814]

To further advance Medicare's overall value-based care strategy, which emphasizes preventive care and primary care and to promote greater alignment within and across CMS' quality programs, we proposed in the CY 2025 PFS proposed rule (89 FR 62023) to create the APP Plus quality measure set within the APP specifically to incorporate all of the Adult Universal Foundation measures. Five of the ten adult Universal Foundation measures already are represented in the existing APP quality measure set for the CY 2025 performance period/2027 MIPS payment year under policies finalized in the CY 2024 PFS final rule (88 FR 79113). The Universal Foundation measures included in the APP quality measure set are listed in Table 66. The inclusion of half of the measures in the Universal Foundation in the existing APP quality measure set and the recognition that a significant number of current and potential users of the APP—those clinicians participating in MIPS APMs—practice in primary and preventive care areas that are relevant to the Universal Foundation make the APP a meaningful addition to CMS' efforts at quality alignment by bringing in MIPS reporting by MIPS APM participants and in turn by providing feedback in the form of their MIPS quality score to those participants as they also continue to work towards advancing the care they provide within the context of their respective MIPS APMs.

We noted that we did not propose to modify the existing APP quality measure set or the overall framework for the APP as a reporting and scoring pathway (89 FR 62023). For example, under this proposal, the APP would continue to be available to MIPS eligible clinicians, groups, and APM Entities participating in MIPS APMs, meaning that only these clinician types would be able to report and be scored on the APP Plus quality measure set. We proposed that, within the APP, the APP Plus quality measure set will be a second measure set distinct from the existing APP quality measure set that MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM may optionally choose to report. Under the proposal, when an applicable MIPS eligible clinician, group, or APM Entity chooses to report the APP beginning in the CY 2025 performance period/2027 MIPS payment year, they will also choose whether to report the APP quality measure set or the APP Plus quality measure set. We proposed for the CY 2025 performance period/2027 MIPS payment year, the APP Plus quality measure set would include the current APP quality measures and two

[810] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[811] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS—The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

[812] ''Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546.*

[813] Centers for Medicare and Medicaid Services (2023). Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Retrieved March 22, 2024 from Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (*https://www.cms.gov/files/document/2024-announcement-pdf.pdf*).

[814] ''Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546.*

additional quality measures from the Adult Universal Foundation measure set. The measure set would incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. Specifically, we proposed to adopt one new quality measure beginning with the CY 2026 performance period/2028 MIPS payment year, and two new quality measures beginning with the CY 2028 performance period/2030 MIPS payment year.

We requested public comment on this proposal.

The following is a summary of the public comments we received on this proposal and our responses. Because the Shared Savings Program proposed to require reporting of the APP Plus quality measure set to meet its quality performance standard (89 FR 61853 through 61858), many of the comments we received on the establishment of the APP Plus quality measure set were submitted by Shared Savings Program ACOs. While we have included those comments in this section, we refer readers to section III.G.4.b.(2)(a) of this final rule for comments related to the APP Plus quality measure set that are specific to the Shared Savings Program's proposal to require that ACOs report and be scored on the APP Plus quality measure set for purposes of meeting the Shared Savings Program's quality performance standard.

Comment: Several commenters expressed support for the incorporation of specific measures into the APP Plus quality measure set, including the Breast Cancer Screening (Quality ID #112) measure, Colorectal Cancer Screening measure (Quality ID #113), Substance Use Disorder Treatment measure (Quality ID #305), Screening for Social Drivers of Health (Quality ID #487) measure, and the Adult Immunization Status (Quality ID #493) measure.

Response: We thank commenters for their support.

Comment: Many commenters requested a delay in incorporation of the new quality measures into the APP Plus quality measure set. Some commenters suggested that CMS delay incorporation of the APP Plus quality measure set from one to three years. Other commenters suggested a one or two-year delay to the measure phase-in schedule as it relates to each measure due to the complexity and administrative burden associated with reporting these new measures.

A few commenters stated that the proposed timeline for incorporating measures with eCQM collection types into the APP Plus quality measure set is appropriate provided that the measure specification for each measure is available at least 12 to 24 months prior to the respective measure incorporation date. These commenters stated this lead time is necessary for vendors and clinicians to prepare to report new measures. Other commenters encouraged CMS to consider an alternative timeline for incorporating measures with eCQM collection type into the APP plus quality measure set.

Response: We have heard from APM Entities, including Shared Savings Program ACOs, and other interested parties about the need for additional time to report the APP Plus quality measure set due to administrative burdens and/or technical complexities associated with reporting quality measures using the eCQM collection type. We appreciate that it takes time to integrate new quality measures into workflows and eCQMs into EHR systems. This is especially so for APM Entities whose constituent groups and eligible clinicians are spread across different practice locations and may use different EHR systems from each other, necessitating the additional steps of data aggregation, deduplication, and validation.

After consideration of public comment, we are finalizing our proposal to establish the APP Plus quality measure set with modification. We are revising the timeline for incorporating various measures into this measure set. Because CMS identified no other programs or MIPS APMs outside of the Shared Savings Program that will explicitly require participants to report the APP Plus quality measure set in the 2025 PFS proposed rule, our plan to modify the timeline for incorporating various measures into APP Plus quality measure set is predominantly to allow Shared Savings Program ACOs additional time to become familiar with new quality measures and their specifications, and to implement workflows necessary to support the reporting of new measures, as discussed in the comments above. For more information about Shared Savings Program proposals and finalized policies to require ACOs to report and be scored on the APP Plus quality measure set for purposes of meeting the Shared Savings Program's quality performance standard and the measure collection types available to Shared Savings Program ACOs, please see the discussion at sections III.G.4.b.(2)(a) and III.G.4.b.(2)(b) of this final rule, respectively.

As modified, the APP Plus quality measure set will now add one new measure per year from the Adult Universal Foundation measure set for the first three years and will delay the incorporation of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure by one year.

Specifically, for the CY 2025 performance period/2027 MIPS payment year, the APP Plus quality measure set will now include the measures in the existing APP quality measure set that are also Universal Foundation measures as described in Table 68 and the following quality measure from the Universal Foundation of measures: The Breast Cancer Screening (Quality ID #112) measure. It will no longer include the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure nor the Colorectal Cancer Screening (Quality ID #113) measure as originally proposed in the CY 2025 PFS proposed rule. As a result of these modifications, there will be a total of six measures in the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year.

Beginning with the CY 2026 performance period/2028 MIPS payment year, and as described in Table 69 the APP Plus quality measure set will incorporate the Colorectal Cancer Screening (Quality ID #113) measure and add back the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure for a total of eight measures. The Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure will be added to the APP Plus quality measure set in the CY 2026 performance period/2028 MIPS payment year instead of the CY 2025 performance period/2027 MIPS payment year to, as further discussed below, allow CMS time to assess whether and how the measure can be respecified to allow more ACOs to be scored on the measure.

Beginning with the CY 2027 performance period/2029 MIPS payment year, and as described in Table 70, the APP Plus quality measure set will incorporate the Initiation and Engagement of Substance Use Disorder Treatment (Quality ID #305) measure for a total of nine measures. As further discussed below, this measure will be added to the APP Plus quality measure set in the CY 2027 performance period/2029 MIPS payment year instead of the

CY 2026 performance period/2028 MIPS payment year to allow APM Entities time to create new workflows and processes to help track referrals and follow-ups related to SUD treatment.

The APP Plus quality measure set will add the final two measures from the Adult Universal Foundation measure set, the Screening for Social Drivers of Health (Quality ID #487) and Adult Immunization Status (Quality ID #493) measures, for a total of 11 measures, beginning with the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specification becomes available for each respective measure, whichever is later, as described in Table 71. As discussed below, each of these two measures may be added after the CY 2028 performance period/2030 MIPS payment year as originally proposed to ensure that the eCQM specification for a measure is made available in advance of its incorporation into the APP Plus quality measure set so that APM Entities, including ACOs, can establish the necessary cross-practice workflows to implement the measures.

Expanding the APP Plus quality measure set on this modified schedule will allow APM Entities, groups, and clinicians the necessary time to become familiar with new measure specifications and incorporate each new measure into electronic health records so that they can successfully report the APP Plus quality measure set.

We also proposed in the CY 2025 PFS proposed rule to revise § 414.1367(c)(1) such that each MIPS eligible clinician, group, or APM Entity APM that elects to report the APP would choose to report either the APP quality measure set or the APP Plus quality measure set. We proposed that a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set for a performance period would be required to report all available measures in the APP Plus quality measure set for that performance period and will be scored on all such measures. For example, with respect to the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set would be required to report nine MIPS quality measures (to the extent applicable and available): the nine measures are the six measures incorporated from the existing APP quality measure set and the three additional Universal Foundation measures we proposed to incrementally adopt in the APP Plus quality measure set in the CY 2025, 2026, and 2027 performance periods/2027, 2028, and 2029 MIPS payment years. The clinician would also be scored on all nine of these measures.

The proposal would incrementally incorporate into the APP Plus quality measure set the Universal Foundation measures that are not already included in the existing APP quality measure set beginning in the CY 2025 performance period/2027 MIPS payment year. The Universal Foundation measure set aligns quality measures used across CMS programs and initiatives and is relevant to a significant subset of the clinicians who are eligible to report the APP. The APP Plus quality measure set will allow MIPS eligible clinicians, groups, and APM Entities eligible to report the APP to report Universal Foundation quality measures, which are used across CMS programs and initiatives.

We described the APP Plus quality measure set as separate from the APP quality measure set and optional for a MIPS eligible clinician, group, or APM Entity to report (89 FR 62024).[815] Although we want to promote greater familiarity with the Universal Foundation measures and to encourage clinicians to use the Universal Foundation measures through their MIPS participation, it is important to continue to allow the APP to serve its original purpose of offering a streamlined, stable reporting and scoring pathway for MIPS APM participants, who are already performing practice transformation and are reporting and being scored on quality measures within their APMs. Further, we recognize that while the Adult Universal Foundation quality measures are relevant to a significant portion of clinicians who are eligible to report the APP, they are not relevant for all such clinicians. For example, there are specialists for whom few, if any, of these measures may be relevant, and we do not wish to effectively exclude these clinicians from accessing the benefits of the APP when they otherwise are eligible. Moreover, we recognize that as CMS continues to evolve APM offerings for specialists, there may be more clinicians in the future who are participating in MIPS APMs and will therefore be eligible for the APP, which could shift the proportion of clinicians for whom the Universal Foundation measures are relevant as compared to today. For these reasons, we believe it is important to maintain the existing APP quality measure set and to continue to offer it as an option alongside the APP Plus quality measure set. We also are continuing to explore ways in which we may be able to offer specialists participating in MIPS APMs opportunities to report more relevant measures within the APP.

For the reasons specified previously, we proposed to amend § 414.1367(c)(1) to establish the APP Plus quality measure set and provide MIPS eligible clinicians, groups, and APM Entities the option to report the APP quality measure set or the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. We requested comment on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to create the APP Plus quality measure set as an optional measure set within the APP at § 414.1367(c)(1). These commenters noted that the proposal offers several potential benefits. Numerous commenters appreciated that the APP Plus quality measure set will incrementally incorporate all of the existing Adult Universal Foundation measures, thereby promoting alignment and streamlining quality measure reporting across CMS quality programs and, as one commenter stated, with the private sector. Many commenters stated that our proposal to incrementally incorporate the Adult Universal Foundation measures and eCQM collection type into the APP Plus quality measure set is appropriate. Several commenters suggested that alignment of quality measures may drive improvements in care quality and outcomes. A few commenters noted the APP Plus quality measure set can help to encourage APM participation.

Response: We thank the commenters for their support.

Comment: One commenter questioned the necessity of creating the APP Plus quality measure set, instead of expanding the existing APP quality measure set. Several commenters expressed concern that reporting the APP Plus quality measure set will increase complexity and reporting burden for APM Entities that report the APP, particularly for Shared Savings Program Accountable Care Organizations (ACOs).

Response: We established the APP Plus quality measure set as a second measure set distinct from the existing APP quality measure set because we recognize that reporting the APP Plus

[815] That said, we note that the Shared Savings Program proposed to require that ACOs report the APP Plus quality measure set starting with PY 2025 (89 FR 61853).

quality measure set with its additional quality measures may require additional investments in infrastructure, skill development, and knowledge. However, because the APP Plus quality measure set is optional, a MIPS eligible clinician, group, or APM Entity that chooses to report the APP can assess the feasibility and benefits of reporting the APP Plus quality measure set as compared to the existing APP quality measure set and decide which measure set to report. We refer readers to section III.G.4.b.(2)(a) of this final rule for discussion regarding the separate but related proposal to require Shared Savings Program ACOs to report and be scored on the APP Plus quality measure set for purposes of meeting the Shared Savings Program's quality performance standard.

Comment: Many commenters provided feedback on specific measures proposed for inclusion in the APP Plus quality measure set. Specifically, we received comment on Quality ID #112 Breast Cancer Screening; Quality ID #113 Colorectal Cancer Screening; Quality ID #305 Initiation and Engagement of Substance Use Disorder Treatment; Quality ID #479 Hospital-Wide, 30-day All-Cause Unplanned Readmission (HWR) Rate for MIPS Clinician Groups; Quality ID #484 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions; Quality ID #487 Screening for Social Drivers of Health; and Quality ID #493 Adult Immunization Status. Commenters expressed support for some measures and concern for other measures. Many commenters also commented on our proposed schedule for incorporating various measures into the APP Plus quality measure set. While some commenters suggested our incorporation schedule is appropriate, numerous other commenters had concerns with the timeline for incorporating the five additional Universal Foundation measures with the eCQM collection type into the APP Plus quality measure set and requested that we delay incorporation of each measure by one year or more to allow more time to prepare to report these measures.

Response: We appreciate the commenters' careful consideration of our proposal to establish the APP Plus quality measure set, inclusive of the individual measures that will comprise it and our proposed schedule for incorporation of quality measures into the APP Plus quality measure set. The incremental incorporation of the five Universal Foundation measures not already included in the APP quality measure set into the APP Plus quality measure set will give eligible clinicians, groups and APM Entities that report the APP Plus quality measure set time to become familiar with new measure specifications and implement workflows necessary to support reporting of each additional measure. This phase-in approach will permit vendors to adequately prepare for eCQM implementation. However, we recognize that there may be increased burden with increased reporting requirements, and while the APP Plus quality measure set is optional for MIPS APM participants, we acknowledge that the reporting of all measures within the set is a requirement that follows on to the choice to use it, and further we recognize that the use of the APP Plus quality measure set will be required for Shared Savings Program ACOs. Therefore, to allow APM Entities, including Shared Savings Program ACOs, more time to build capacity to report the complete set of measures, we are finalizing our proposal with modification to incorporate the Universal Foundation measures more gradually than the schedule that we proposed for incorporation into the APP Plus quality measure set.

For a few measures, we received comments on neither the incorporation of the measure into the APP Plus quality measure set nor on the proposed timeline for doing so, and therefore are finalizing the incorporation and phase-in schedule as proposed. Specifically, we are finalizing as proposed the incorporation of the following quality measures into the APP Plus quality measure set in the CY 2025 performance period/2027 MIPS payment year: Quality ID #001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control; Quality ID #134 Preventive Care and Screening: Screening for Depression and Follow-up Plan; Quality ID #236 Controlling High Blood Pressure; and Quality ID #321 CAHPS for MIPS.

We address comments we received on specific quality measures in the responses below.

Comment: Several commenters expressed support for incorporating Quality ID #112 Breast Cancer Screening and Quality ID #113 Colorectal Cancer Screening into the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year.

Response: We thank the commenters for their support.

Comment: One commenter stated that Quality ID #112 Breast Cancer Screening and Quality ID #113 Colorectal Cancer Screening were retired from MIPS in 2024, while another commenter stated they believed vendors are no longer supporting these measures; these commenters suggested that incorporation of the measures into the APP Plus quality measure set should be delayed. Another commenter stated that adding these measures to the APP Plus quality measure set would increase administrative burden specifically for Shared Savings Program ACOs beginning in 2025 since they would be required to report all measures in the APP Plus quality measure set.

Response: We want to correct an apparent misunderstanding regarding the Status of Quality ID #112 Breast Cancer Screening and Quality ID #113 Colorectal Cancer Screening in MIPS. Beginning with the CY 2024 performance period/2026 payment year, these measures (in addition to one other) were removed from the traditional MIPS reporting option but otherwise retained for MVP development (88 FR 79897 through 79900). The clinical concepts represented by these quality measures support some specialties in a more targeted approach rather than the broader clinical concept of preventive screenings represented within the Quality #497: Preventive Care and Wellness (composite) measure. We also note that the measures are also being maintained for the CMS Web Interface collection type for Shared Savings Program ACOs reporting under the APP through the 2024 performance period, after which time the Web Interface will sunset. Nevertheless, we understand that reporting new quality measures may require an APM Entity, group, and/or clinician to update their workflows and processes. At the same time, we believe that it may take more effort to prepare to report quality measures with greater complexity and that there is a marked difference in complexity between the two cancer screening measures. Specifically, we believe the Colorectal Cancer Screening measure to be a more complex measure because five different screening tests can be used to build the numerator with look-back periods ranging from the current performance period to nine years prior as compared to the Breast Cancer Screening measure that has only one way to build the numerator (mammography) and a shorter look-back period of 27-months. In recognition of the difference in complexity between these two measures, we are finalizing without modification our proposal to incorporate Quality ID #112 Breast Cancer Screening into the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year but are finalizing with modification our proposal to

incorporate Quality ID #113 Colorectal Cancer Screening into the APP Plus quality measure set with a one-year delay from the CY 2025 performance period/2027 MIPS payment year to the CY 2026 performance period/2028 MIPS payment year. The incorporation dates of these measures are reflected in Table 67. We refer readers to section III.G.4.b.(2)(a) of this final rule for discussion regarding the separate but related proposal to require Shared Savings Program ACOs to report and be scored on the APP Plus quality measure set beginning in the CY 2025 performance period.

Comment: With respect to Quality ID #305 Initiation and Engagement of Substance Use Disorder Treatment, several commenters expressed support for the inclusion of a behavioral health measure in the APP Plus quality measure set. These commenters believe the measure promotes whole person care. One commenter stated: ''given that overdose rates continue to be unacceptably high, it is critical to get upstream and employ preventive measures that help initiate and engage with substance use treatment.''

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern with incorporating Quality ID #305 Initiation and Engagement of Substance Use Disorder Treatment into the APP Plus quality measure set. Two commenters stated that the measure is not endorsed at the clinician level. One commenter stated ''clinicians cannot force a patient to accept treatment for SUD'' and that the measure is ''difficult, if not impossible, for clinicians to track in the current health care landscape with a lack of interoperability across care settings and providers.'' A few commenters noted that some communities lack the resources necessary to assist patients with SUD. For the above reasons, commenters stated that reporting the measure would be complex and requested that the measure either not be incorporated into the APP Plus quality measure set or its incorporation be delayed.

Response: We acknowledge that clinicians cannot force patients to initiate SUD treatment. However, we note that alcohol use disorder and SUD are prevalent, undertreated, and sources of significant morbidity and mortality with the majority of patients affected not receiving evidence-based care. For these reasons, we believe that initiation of treatment is important to measure. While our proposal to incorporate Quality ID #305 Initiation and Engagement of Substance Use Disorder Treatment into the APP Plus quality measure set did not provide distinct factors for commenters to address with respect to timing of incorporation into the APP Plus quality measure set, we are receptive to commenters' concerns about the behavioral health landscape and the challenges that lack of interoperability in health care present to accurately capturing and reporting the measure's numerator. We understand that reporting the Initiation and Engagement of Substance Use Disorder Treatment measure may be complex for APM Entities, groups, and clinicians, especially because not all APM Entities, groups and clinicians have the capability to furnish SUD treatment and must therefore refer patients out for such treatment. We recognize that outside referrals might be difficult for some clinicians to track for a variety of reasons, such as when a patient cannot be reached or otherwise declines to schedule an appointment. Therefore, to allow APM Entities time to create new workflows and processes that potentially rely on more than one source of data for documenting and tracking referrals and follow-up, we are finalizing with modification our proposal to incorporate Quality ID #305 Initiation and Engagement of Substance Use Disorder Treatment with a one-year delay from the CY 2026 performance period/2028 MIPS payment year to the CY 2027 performance period/2029 MIPS payment year. The incorporation date of this measure is reflected in Table 67.

Comment: With respect to Quality ID #479 Hospital-Wide, 30-Day, All Cause Unplanned Readmission (HWR) Rate, one commenter questioned whether hospital readmissions rates accurately reflect the quality of care for all patient populations and asked whether incentivizing lower readmissions could exacerbate disparities in care. This commenter opposed incorporation of the HWR measure into the APP Plus quality measure set.

Response: We acknowledge the commenter's concerns. However, Quality ID #479 HWR Rate is not a new measure and we expect that APP reporters are familiar with it. The HWR Rate measure is a Universal Foundation measure and already included in the existing APP quality measure set. As we indicated throughout the proposed rule, our principal aim in the establishment of the APP Plus quality measure set is aligning with the Universal Foundation, which would not be fully accomplished if we permanently left out one of its included measures. Further, like all measures in the existing APP quality measure set, we believe inclusion of this measure in the APP Plus quality measure set meaningfully contributes to our stated goal to align quality measures across CMS programs. We also note that the measure uses administrative claims data to evaluate readmission rates and requires no additional data submission from APM Entities, groups, or eligible clinicians, which means there is no reporting burden associated with this measure. Therefore, we are finalizing as proposed our proposal to incorporate Quality ID #479 HWR Rate into the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year.

Comment: A few commenters noted that the measure specification for Quality ID #484 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MIPS MCC) as used in the APP quality measure set excludes patients assigned to a clinician who achieves qualifying APM participant (QP) status from the denominator. These commenters pointed out that in the 2023 performance period, the denominator exclusion caused Shared Savings Program ACOs whose eligible clinicians were determined to be QPs to not be scored on the measure, resulting in greater weight being placed on the remaining measures within the APP quality measure set for such ACOs. These commenters are opposed to incorporating the MIPS MCC measure into the new APP Plus quality measure set out of concern that weight redistribution will continue to occur with potentially negative effects on ACOs' performance category scores.

Response: We thank the commenters for bringing this to our attention. CMS understands that the exclusion of patients of QPs from the denominator of the MIPS MCC measure disparately impacts certain Shared Savings Program ACOs. This is so because of our QP determination rule for participation in an Advanced APM as specified at 42 CFR 414.1425(b)(1) provides that eligible clinicians are assessed at the APM Entity level when a Participation List is used to identify eligible clinicians that participate with the APM Entity, as is the case with the Shared Savings Program and because the Shared Savings Program requires all participating ACOs to report and be scored on the quality measures in the APP quality measure set at the APM Entity level to evaluate quality performance, regardless of whether an ACO's eligible clinicians otherwise achieve QP status for a year through a track that qualifies as an Advanced APM.

When a Shared Savings Program ACO's eligible clinicians achieve QP status together at the APM Entity level and the ACO reports the MCC measure, the denominator will be reduced to zero because the measure specification excludes patients of QPs. As the commenters noted, for the 2023 performance year, this resulted in some Shared Savings Program ACOs effectively not being scored on the MCC measure and having greater weight placed on the remaining measures in the APP quality measure set because when the denominator for a quality measure is reduced to zero, the measure is removed from the performance category score. Non-Shared Savings Program APM Entities that participated in an Advanced APM in 2023, and whose clinicians achieved QP status for the year, did not experience the same weight redistribution with the APP quality measure set since QPs are ordinarily excluded from MIPS reporting and scoring. However, we note that these effects are seen when the measure is being used for purposes of the quality program of the Shared Savings Program, which requires its participant ACOs to report the APP. The APP is designed as a reporting and scoring pathway within MIPS for participants of MIPS APMs, and regulations governing the APP sit with other MIPS regulations. We recognize that at times, the interrelationship between the APP as a MIPS pathway and the Shared Savings Program may lead to intended consequences in one program and unintended consequences in the other. In this case, the exclusion of QPs from the measure is appropriate in the context of MIPS, from which QPs are statutorily excluded from participating, whereas for purposes of the Shared Savings Program, the exclusion of QPs leads to the aforementioned scoring quirk.

It is concerning to us that the MIPS MCC measure specification may result in disparate impacts on the quality performance category scores between Shared Savings Program ACOs that participate in an advanced track of the program and APM Entities that participate in other APMs. However, as we stated in the CY 2025 proposed rule, we continue to believe that hospital admission rates are an effective marker of ambulatory care quality (89 FR 62026). We also believe that a MCC measure can help incentivize clinicians to develop and implement efficient and coordinated chronic disease management strategies to limit unplanned hospital admissions. This is consistent with the rationale we provided when we first proposed an MCC measure for inclusion in MIPS, at which time we stated that such measure ''promotes improved MCC management and coordinated care by assessing the unplanned hospital admissions for this high-risk population.'' (84 FR 40939). Therefore, we are finalizing with modification our proposal to incorporate Quality ID #484 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions into the APP Plus quality measure set. We are delaying the incorporation of the measure by one year from the CY 2025 performance period/2027 MIPS payment year to the CY 2026 performance period/2028 MIPS payment year to allow CMS time to assess whether and how the measure can be respecified to allow more ACOs to be scored on the measure. The new incorporation date of this measure is reflected in Table 67. We will examine the use of this measure within MIPS for MIPS APM participants via the APP and by the Shared Savings Program as specified to exclude QPs from the calculation of the measure.

Notwithstanding the incorporation delay of the MIPS MCC measure into the APP Plus quality measure set, the MIPS MCC measure will remain a part of the original APP quality measure set for the CY 2025 performance period/2027 MIPS payment year such that MIPS APM participants who choose to report the APP quality measure set will be scored on the measure as it is currently specified.

Comment: Several commenters expressed support for incorporating Quality ID #487 Screening for Social Drivers of Health (SDOH) into the APP Plus quality measure set. These commenters believe that assessing social needs can improve mental and physical health outcomes and advance health equity.

Response: We thank the commenters for their support.

Comment: Several commenters opposed to the incorporation of Quality ID #487 Screening for Social Drivers of Health (SDOH) measure into the APP Plus quality measure set. A few commenters noted that CMS requires collection of Health-Related Social Need (HRSN) data across multiple setting-specific programs and stated that repeated screenings could result in duplicative efforts and be counter-productive to building trust with patients. A few commenters highlighted research that suggests screening and referral for SDOH does not improve health outcomes. One commenter stated that reporting the measure would increase burden for clinicians because it requires evaluation of patient needs across many domains. Another commenter stated EHR may not reliably capture required data elements in available data fields. A few commenters noted that the eCQM specification is not currently available for the Screening for SDOH measure. Several commenters requested that CMS make available the eCQM specification for this measure in advance of its incorporation into the APP Plus quality measure set while one commenter specifically suggested that the Screening for SDOH measure be incorporated into the APP Plus quality measure set prior to the CY 2028 performance period.

Response: CMS has recognized the importance of screening for SDOH in prior rulemaking. Most recently, in the CY 2024 PFS final rule, we provided an illustrative example of how clinicians that identify unmet HRSNs through screening for SDOH can better understand and help address problem(s) addressed in a medical visit and associated risk factor. In this example, a clinician discovers a patient's living situation does not permit reliable access to electricity by screening the patient for HRSNs and, as a result, considers whether to prescribe an inhaler rather than a power-operated nebulizer to treat asthma (88 FR 78921). Absent SDOH screening, the clinician in this example might inadvertently prescribe a treatment (power-operated nebulizer) that the patient could not consistently self-administer as prescribed, leading to poor symptom control or frequent exacerbation of symptoms. This scenario makes clear that information regarding housing instability and utility difficulties gathered from screening for SDOH has the potential to improve health outcomes. We believe that information collected about HRSNs from other domains when screening for SDOH can be just as valuable when incorporated into clinical decision making. In addition, because HRSNs may change rapidly and identification of unmet needs may be used to improve patient care plans, it is appropriate to require collection of HRSN data across multiple setting-specific programs.

CMS acknowledges that the Screening for SDOH measure requires assessment across multiple domains—specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. However, we note that measure burden is minimized because screening is accomplished through the use of a single, standardized tool and multiple assessments are not required within the same performance period. Further, clinicians have the

flexibility to choose which standardized tool to use to build the measure's numerator. The measure specification does not prescribe a tool that must be used but rather provides examples of standardized screening tools that may be used. These tools include: Accountable Health Communities Health-Related Social Needs Screening Tool (2017);[816] Accountable Health Communities Health-Related Social Needs Screening Tool (2021);[817] The Protocol for Responding to and Assessing Patients' Risks and Experiences (PRAPARE) Tool (2016);[818] WellRx Questionnaire (2014);[819] and American Academy of Family Physicians (AAFP) Screening Tool (2018).[820] This flexibility allows APM Entities, groups, and eligible clinicians to choose the tool that can best be integrated into clinical workflows and practice-specific EHR. MIPS eligible clinicians, groups, and APM Entities are encouraged to work with their EHR vendors to ensure that screening for HRSNs across domains can be captured in practice-specific EHR.

In response to comments received that noted an eCQM is not presently available for the Screening for SDOH measure, we are finalizing with modification our proposal to incorporate Quality ID #487 Screening for Social Drivers of Health (SDOH) into the APP Plus quality measure set with a delay until the CY 2028 performance period, or the performance period that is one year after the eCQM specification becomes available for this measure, whichever is later. The incorporation date of this measure is reflected in Table 67. This delay is necessary due to variables related to the development and testing of new measures. In addition, we understand that it can take a substantial amount of time for a new measure specification to be supported by vendors and incorporated into electronic health records. We also believe a delay will allow APM Entities time to create new workflows and processes to screen for HRSNs. For these reasons, we are declining to incorporate the Screening for SDOH measure into the APP Plus quality measure set prior to the CY 2028 performance period.

As stated above, we recognize that there are factors in the process of developing quality measure specifications beyond CMS' control, which may in turn delay the publication of the Screening for SDOH eCQM specification on the eCQI resource center and, ultimately, availability of the collection type for MIPS quality measures. We want to clarify that for the Adult Immunization Status measure to be incorporated into the APP Plus quality measure set in the CY 2028 performance period, the eCQM specification must be published on the eCQI resource center by May 2027. If, however, the eCQM specification is published later, for example in May 2028, then the Screening for SDOH measure will be incorporated into the APP Plus quality measure set in the CY 2029 performance period. Similarly, if the eCQM specification is published in May 2029, then the Screening for SDOH measure will be incorporated into the APP Plus quality measure set in the CY 2030 performance period, and so on.

Comment: Several commenters expressed support for incorporating Quality ID #493 Adult Immunization Status into the APP Plus quality measure set. A few commenters stated that vaccinations can improve health equity given the disparate impact of infectious diseases on marginalized populations. One commenter stated that ''measure is perhaps one of the strongest tools to increase rates of adult immunizations.''

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern about incorporation of Quality ID #493 Adult Immunization Status into the APP Plus quality measure set. These commenters stated that the measure would be technically complex to report and noted that the measure requires reporting on four different vaccines. One commenter stated that the vaccines with which the measure is concerned are not routinely administered in office-based settings because they are covered by Medicare Part D. Another commenter pointed out that patients may receive vaccines outside of office-based settings such as at retail pharmacies, local health departments, and in the workplace, creating difficulties tracking patient vaccinations. This commenter also stated that immunization registry challenges create administrative burden for clinicians that report vaccine measures. As with the SDOH measure, a few commenters noted that an eCQM specification is not currently available for the Adult Immunization Status measure and requested that CMS make available the eCQM specification for this measure in advance of its incorporation into the APP Plus quality measure set.

Response: We acknowledge that clinicians may face challenges administering vaccines in office-based settings, including the four vaccines with which the Adult Immunization Status measure is concerned: influenza, Td/Tdap, herpes zoster, and pneumococcal conjugate. However, Medicare Part B covers a limited set of vaccines including both the influenza vaccine and pneumococcal conjugate, two of the four vaccines assessed by the Adult Immunization Status measure. Medicare Part D covers all commercially available vaccines, except those covered by Medicare Part B. With respect to the vaccines measured by the Adult Immunization Status measure, Medicare Part D covers the vaccines not covered by Medicare Part B; namely, Td/Tdap and herpes zoster. Clinicians can bill Medicare Part D for vaccines administered in office if enrolled in Medicare. We also note that under the current MIPS CQM specification, patient reported vaccination, when recorded in the medical record, is acceptable for meeting the numerator of the measure.[821]

Nevertheless, in response to comments received that noted an eCQM specification is not presently available for the Adult Immunization Status measure, we are finalizing with modification our proposal to incorporate Quality ID #493 Adult Immunization Status into the APP Plus quality measure set until the CY 2028 performance period, or the performance period that is one year after the eCQM specification becomes available for this measure, whichever is later. The incorporation date of this measure is reflected in Table 67. This delay is necessary due to variables related to the development and testing of new measures. In addition, we understand that it can take a substantial amount of time for a new measure specification to be supported by vendors and incorporated into electronic health records. We also believe a delay will allow APM Entities time to create new

[816] Centers for Medicare and Medicaid Services (2017). *The Accountable Health Communities Health-Related Social Needs Screening Tool https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf.*

[817] Centers for Medicare and Medicaid Services (2021). *The Accountable Health Communities Health-Related Social Needs Screening Tool https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion#page=55&zoom=100,0,0.*

[818] PREPARE Collaboration (2016). *Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences https://prapare.org/the-prapare-screening-tool/.*

[819] The Journal of the American Board of Family Medicine May 2016, 29 (3) 414–418; *DOI: 10.3122/jabfm.2016.03.150272.* WellRx Questionnaire.

[820] American Academy of Family Physicians (2018). *Social Needs Screening Tool https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/hops19-physician-form-sdoh.pdf.*

[821] Quality ID #493 (CBE 3620): Adult Immunization Status (2024), available at *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQMMeasures/2024_Measure_493_MIPSCQM.pdf.*

workflows and processes to collect data related to vaccinations, particularly those administered outside the APM Entity.

As stated above, we recognize that there are factors in the process of developing quality measure specifications beyond CMS' control, which may in turn delay the publication of the Adult Immunization Status eCQM specification on the eCQI resource center and, ultimately, availability of the collection type for MIPS quality measures. We want to clarify that for the Adult Immunization Status measure to be incorporated into the APP Plus quality measure set in the CY 2028 performance period, the eCQM specification must be published on the eCQI resource center by May 2027. If, however, the eCQM specification is published later, for example in May 2028, then the Adult Immunization measure will be incorporated into the APP Plus quality measure set in the CY 2029 performance period. Similarly, if the eCQM specification is published in May 2029, then the Adult Immunization Status measure will be incorporated into the APP Plus quality measure set in the CY 2030 performance period, and so on.

Comment: A few commenters suggested that we incorporate into the APP Plus quality measure set the measures from Universal Foundation of measures but with modifications. Several commenters suggested substitute or alternate measures for incorporation into the APP Plus quality measure set. Yet a few other commenters suggested that we incorporate additional measures into the APP Plus quality measure set including a cardiac care measure, a kidney health evaluation measure, an HIV screening measure, and any new setting- and population-specific ''add-on'' measures later added to the Universal Foundation of measures.

Response: When we proposed to leverage the Universal Foundation of measures to create the APP Plus quality measure set, we did so with the goal of aligning quality programs across CMS. It was never our intent to create a new or iterative quality measure set as doing so would not streamline quality measure reporting across CMS. While each of the measures suggested may have specific merits, as we stated in the CY 25 PFS proposed rule, ''alignment of quality measures across CMS programs allows practitioners to better focus their quality efforts, reduces administrative burden, and drives digital transformation and stratification of a focused quality measure set to assess impact on disparities'' (89 FR 62023). We believe that incorporating the Universal Foundation of measures into the APP Plus quality measure set as is best supports our goal of alignment.

Comment: Several commenters observed that the APP Plus quality measure set is primary-care focused and stated that it should include more specialty measures.

Response: When we proposed to establish the APP Plus quality measure set in the CY 2025 PFS proposed rule and shared our plans to incorporate the Universal Foundation of measures into the APP Plus quality measure set, we acknowledged that the Universal Foundation emphasizes primary and preventive care. We also recognized that ''while the Adult Universal Foundation quality measures are relevant to a significant portion of clinicians who are eligible to report the APP, they are not relevant for all such clinicians'' and that ''there are specialists for whom few, if any, of these measures may be relevant'' (89 FR 62024). We want to reiterate that the APP's primary goal is to offer an opportunity for MIPS APM participants to align with quality programs across CMS. As CMS continues to develop new and innovative APM offerings for specialists, and the proportion of specialists in APMs increases, we are considering how the MIPS quality performance category as it is reported and scored within the APP might better reflect the practice and needs of specialists. As such, we continue to explore ways in which we may be able to offer specialists participating in MIPS APMs opportunities to report more relevant measures within the APP, including considering methods for collecting input from interested parties on this point.

Comment: One commenter questioned why eligible clinicians, groups, and APM Entities that report the APP Plus quality measure set for a performance period would be required to report all measures in the APP Plus quality measure set instead of selecting six measures, as required for other MIPS reporting pathways.

Response: The APP Plus quality measure set was designed to align with other quality programs across CMS and leverages the Universal Foundation of measures to do that. If APP reporters could each choose from the APP Plus quality measure set a subset of six measures to report for a performance period, many unique combinations of measures could result. Such variability would not allow for meaningful quality comparisons between or among APP reporters, which is essential for many of the APMs, including the Shared Savings Program, that use the APP. True alignment across CMS quality programs cannot be achieved if those reporting the APP Plus quality measure set do not report substantially the same measures as participants of other quality programs. Additionally, because our regulations already establish with respect to the APP that all measures in the original APP quality measure set are required to be reported and scored, if applicable, CMS' operational process for scoring the APP would need to be changed to reflect a top-six approach for the APP Plus quality measure set, increasing operational cost and complexity year after year with the incremental adoption of each measure into the APP Plus quality measure set. Without a strong programmatic benefit for doing so, it would not be prudent to take on the added burden and commensurate cost to the public. Finally, while it may seem counterintuitive that reporting more measures has a burden reduction component, there is administrative simplicity in knowing exactly what to report and which measures will be scored without having to examine and choose individual measures each year, when reporters have incentives to switch measures to maximize scoring. When we proposed to establish the APP for the CY 2021 performance period, we proposed to require that MIPS eligible clinicians who reported the APP would be scored on all measures in the APP quality measure set (85 FR 50285).[822] We finalized this proposal in the CY 2021 final rule (85 FR 84472–85377) so that MIPS APM participants that reported under the APP would know exactly what measures to report and would not have to expend effort poring over measure options and making individual measure choices. Therefore, we are now similarly finalizing the requirement that MIPS eligible clinicians scored under the APP Plus APP Plus quality measure set to report all measures in the measure set.

Comment: One commenter believed our proposal would ''open up the APP (and APP Plus) measure sets'' to MIPS eligible clinicians and groups not in a MIPS APM.

Response: In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APP at § 414.1367 beginning in CY 2021 performance period/2023 MIPS payment year as an optional streamlined reporting and

[822] But note, ''[f]or those MIPS eligible clinicians, groups, or APM Entities for whom a measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we [ ] propos[ed] to remove such measure from the quality performance category score for such MIPS eligible clinician, group or APM Entity.'' 85 FR 50286.

scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity. When we proposed to create the APP Plus quality measure set, we noted that we were not proposing to modify the existing APP framework for the APP as a reporting and scoring pathway and stated ''the APP will continue to be available to MIPS eligible clinicians, groups, and APM Entities participating in MIPS APMs, meaning that only these clinician types will be able to report and be scored on the APP Plus quality measure set'' (89 FR 62023). We regret that this statement may have caused confusion. However, because the APP is only available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity, and the APP is the only reporting pathway that offers the APP Plus quality measure set, it is our intent that only MIPS eligible clinicians, groups, and APM Entities that participate in a MIPS APM and are otherwise eligible to report the APP, and do report the APP, may choose to report the APP Plus quality measure set.

After consideration of public comments, we are finalizing our proposal to amend § 414.1367(c)(1) to establish the APP Plus quality measure set and provide MIPS eligible clinicians, groups, and APM Entities the option to report the APP quality measure set or the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. However, we are finalizing with modification the phase-in schedule for incorporating measures into the APP Plus quality measure set.

(3) Measures for Use in the APP Quality Measure Set and APP Plus Quality Measure Set

In the CY 2021 PFS final rule, we adopted the current APP quality measure set (85 FR 84860 and 84861). Table 66 contains the current APP quality measure set. We did not propose any changes to the existing APP quality measure set for the CY 2025 performance period/2027 MIPS payment year or successive years.

In the CY 2025 PFS propose rule, we proposed a phased approach to establish the APP Plus quality measure set over four years (89 FR 62024). As early as the CY 2028 performance period/2030 MIPS payment year, the APP Plus quality measure set will consist of the measures currently contained in the APP quality measure set and five additional quality measures from the Universal Foundation measure set. We proposed to phase in the new measures over time to allow for both the eCQM and, for Shared Savings ACOs, Medicare CQM collection types to be developed and become available. Specifically, we proposed that the APP Plus quality measure set will consist of the six measures currently contained in the APP quality measure set and the following five new measures described below, which will be added incrementally. However, as described in the comment responses, we are finalizing a modified timeline for incorporating quality measures into the APP Plus quality measure set.

- Beginning with the CY 2025 performance period/2027 MIPS payment year and subsequent performance periods: The Breast Cancer Screening (Quality ID #112) measure. This measure is currently available with the eCQM, MIPS CQM, and Medicare Part B Claims measure collection types. We will make the Medicare CQM collection type available for this measure prior to the start of performance year 2025 only for Shared Savings Program ACOs.
- Beginning with the CY 2026 performance period/2028 MIPS payment year and subsequent performance periods: The Colorectal Cancer Screening (Quality ID #113) measure. This measure is currently available with the eCQM, MIPS CQM, and Medicare Part B Claims measure collection types. We will make the Medicare CQM collection type available for this measure prior to the start of performance year 2026 only for Shared Savings Program ACOs. Beginning with the CY 2026 performance period/2028 MIPS payment year, we will also incorporate the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) measure. The MCC measure is an administrative claims-based measure.
- Beginning with the CY 2027 performance period/MIPS payment year 2029 and subsequent performance periods: The Initiation and Engagement of Substance Use Disorder Treatment (Quality ID #305) measure. This measure is currently available with the eCQM collection type. We will make the Medicare CQM collection type available for this measure prior to the start of performance year 2027 and only for Shared Savings Program ACOs.
- Beginning no earlier than the CY 2028 performance period/2030 MIPS payment year and continuing for subsequent performance periods: The Screening for Social Drivers of Health (Quality ID #487) and Adult Immunization Status (Quality ID #493) measures. These measures are currently available with the MIPS CQM collection type but are not currently available with the eCQM or Medicare CQM collection types. Because developing an eCQM specification typically takes three years, we will add these measures to the APP Plus quality measure set in the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specification becomes available for each respective measure, whichever is later. We will make these measure specifications available prior to the first year that each measure is incorporated into the APP Plus quality measure set.

As discussed earlier, we intend to incorporate the Adult Universal Foundation measures in the APP Plus quality measure set. We note that the additional Universal Foundation measures that we proposed to include in the APP Plus quality measure set align with national condition-specific initiatives and CMS priorities. In this section, we briefly discuss each new Universal Foundation measure that will be added to the APP Plus quality measure set and that is not already included in the APP quality measure set: Breast Cancer Screening and Colorectal Cancer Screening Measures.

(a) Breast Cancer Screening Measure and Colorectal Cancer Screening Measure

Our addition of the Breast Cancer Screening (Quality ID #112) and Colorectal Cancer Screening (Quality ID #113) measures to the APP Plus quality measure set starting with the CY 2025 performance period and the CY 2026 performance period, respectively, aligns with the President and First Lady's Cancer Moonshot initiative, of which a key objective is to ''make sure everyone has access to cancer screenings—so more Americans can catch cancer early, when outcomes are best.'' [823] Breast cancer and colorectal cancer are two of the most common types of cancers, accounting for an estimated 23 percent of all new cancer diagnoses in the United States in 2023.[824] Because the risk of developing these types of cancers increases with age, the Breast Cancer Screening measure focuses on mammogram screening for breast cancer every 24 months starting at age 50 and the Colorectal Cancer Screening measure focuses on appropriate screening for colorectal cancer once per

[823] The White House (n.d.). The President and First Lady's Cancer Moonshot. Accessed March 28, 2024. *https://www.whitehouse.gov/cancermoonshot/.*

[824] Siegel, R.L., Miller, K.D., Wagle, N.S., & Jemal, A. (2023). Cancer statistics, 2023. *CA: a cancer journal for clinicians, 73*(1), 17–48. *https://doi.org/10.3322/caac.21763.*

performance period, also starting at age 50. Additionally, the February 2024 preliminary measure specifications for the eCQM version of Colorectal Cancer Screening lower the starting age for screenings to 45, an update that aligns with United States Preventive Services Task Force recommendation that colorectal cancer screening begin at age 45 to reduce risk of death.[825]

(b) Initiation and Engagement of Substance Use Disorder Treatment Measure

We described in the CY 2025 PFS proposed rule that an estimated 48.7 million Americans aged 12 or older (17.3 percent of the population) were classified as having had a substance use disorder (SUD) in the past year in 2022 (89 FR 62025).[826] These individuals are at an increased risk for having major medical conditions, injury, overdose, and death.[827] Outcomes for individuals with SUDs are improved through early and regular treatment.[828] Initiation and Engagement of Substance Use Disorder Treatment (Quality ID #305) measure ensures patients 13 years of age and older with a new SUD episode have the initiation of intervention or medication within 14 days of the new SUD episode or engage in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication within 34 days of the initiation of treatment. This measure also supports CMS efforts to reduce deaths related to opioid overdoses, which have significantly increased in recent years,[829] and the CMS Behavioral Health Strategy.[830]

(c) Screening for Social Drivers of Health Measure

We described in the CY 2025 PFS proposed rule (89 FR 62025) that in the CY 2023 PFS proposed rule (87 FR 46154 through 46155) we had sought comment on the potential future inclusion of the Screening for Social Drivers of Health (Quality ID #487) measure in the APP quality measure set. While the majority of commenters were generally supportive of adding the Screening for Social Drivers of Health measure, several raised concerns related to the undue burden on collection, cost and resources of implementation, and holding providers accountable for the collection of data which could be beyond their scope or ability. Some supportive commenters appreciated that the Screening for Social Drivers of Health measure could drive the standardization of measures that examine social drivers of health in Federal health care quality and payment systems, and that this would ultimately drive the health of our patients and our Nation, maximize the use of limited Government resources to support vulnerable patients, and achieve quality improvement and equity in health outcomes. Commenters further stated that the Screening for Social Drivers of Health measure is crucial in recognizing the impact of health-related social needs issues on patients and providers, in laying the foundation to invest in those communities, and in avoiding fragmentation and provider/patient burden by supporting alignment across public and private quality and payment programs. Some commenters opposed the addition of the measure and cautioned CMS to test it before it would be required. Other opposed commenters voiced their concern about the undue burden on data collection among patients and providers and the costs and resources associated with implementing new Social Drivers of Health measures, and that gathering health related social needs data would lead to holding providers accountable for addressing social needs of patients that is beyond a provider's scope or ability.

The benefits of adding the Screening for Social Drivers of Health measure to the APP Plus quality measure set outweigh these concerns. For example, while the challenges and concerns noted previously in this section associated with implementing screening for Social Drivers of Health are voiced by family medicine clinicians, social workers, and clinical staff, including the potential negative impact screening could have on the patient-clinician relationship, screening for social drivers of health uncovers patient needs, allows clinicians to provide their patients with resources or referrals, results in appropriately adapting patient care, and prioritizes patient safety.[831] The addition of the Screening for Social Drivers of Health measure also is consistent with our priorities to advance health equity and move toward whole-person care throughout our various programs, including the MIPS and the Hospital Inpatient Quality Reporting (HICR) programs. This measure addresses five social and economic determinants—namely, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety[832]—that are central to the Health Equity strategic plan pillar (*https://www.cms.gov/pillar/health-equity*) and have been identified as both a measurement priority and a performance gap among CMS programs.

The movement to address socioeconomic, environmental, and behavioral health factors (referred to as drivers of health) has gained traction after a study estimated that only 20 percent of a person's health outcomes are linked to their medical care with the remaining 80 percent attributable to drivers of health.[833] Because of the strong relationship between Social Drivers of Health and physical health outcome, screening for Social Drivers of Health will support the goals of improving health outcomes by providing clinicians with a more comprehensive understanding of each patient's circumstances to inform clinical decision making and ensure high-quality care.

In addition, many of these drivers of health are not only linked to poorer health, but disproportionately impact

[825] eCQI Resource Center (2023). Colorectal Cancer Screening. Accessed March 29, 2024. *https://ecqi.healthit.gov/ecqm/ec/2024/cms0130v12?compare=2024to2023*. United States Preventative Task Force (2021). Final Recommendation on Screening for Colorectal Cancer. *https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/colorectal-cancer-screening-final-rec-bulletin.pdf*.

[826] Substance Abuse and Mental Health Services Administration. (2023). Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23–07–01–006, NSDUH Series H–58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. *https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291754/*.

[827] Bahorik, A.L., D.D. Satre, A.H. Kline-Simon, C.M. Weisner, C.L. Campbell. 2017. ''Alcohol, Cannabis, and Opioid Use Disorders, and Disease Burden in an Integrated Health Care System.'' J Addiction Medicine 11(1),3–9. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291754/*.

[828] Kampman, K., K. Freedman. 2020. ''American Society of Addiction Medicine (ASAM) National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update.'' Journal of Addiction Medicine 14, no. 2S: 1–91, *https://doi.org/10.1097/ADM.0000000000000633*.

[829] National Institute on Drug Abuse (2023). Drug Overdose Deaths. Accessed March 28, 2024. *https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates*.

[830] Centers for Medicare and Medicaid Services (2024). CMS Behavioral Health Strategy. Accessed April 19, 2024. *https://www.cms.gov/cms-behavioral-health-strategy*.

[831] Porterfield, L., Jan, Q.H., Jones, F., Cao, T., Davis, L., Guillot-Wright, S., & Walcher, C.M. (2024). Family Medicine Team Perspectives on Screening for Health-Related Social Needs. Journal of the American Board of Family Medicine: JABFM, jabfm.2023.230167R3. Advance online publication. *https://doi.org/10.3122/jabfm.2023.230167R3*.

[832] *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_487_MIPSCQM.pdf*.

[833] Hood, C.M., K.P. Gennuso, G.R. Swain, and B.B. Catlin. 2016. County health rankings: Relationships between determinant factors and health outcomes. *American Journal of Preventive Medicine* 50(2):129–135. *https://doi.org/10.1016/j.amepre.2015.08.024*.

communities of color and underserved populations. Through screening, once per performance period, of patients 18 years and older for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety, screening for Social Drivers of Health and appropriate referrals can potentially improve health outcomes and reduce health disparities. As we indicated when we proposed to adopt Screening for Social Drivers of Health in MIPS in the CY 2023 PFS proposed rule, we believe that consistently addressing drivers of health will have two significant benefits. First, because drivers of health disproportionately impact individuals and communities that are disadvantaged and/or underserved by the healthcare system, the promotion of screening for these factors will support clinician practices and health systems in actualizing an expressed commitment to address disparities in care, implementing associated equity measures to track progress, and improving overall health equity.[834] Second, patient-level driver of health data through screening is essential in the long-term to encourage meaningful collaboration among clinicians and community-based organizations, and implement and evaluate related innovations in healthcare and social service delivery. (87 FR 46280)

(d) Adult Immunization Status Measure

We described in the CY 2025 PFS proposed rule that the Adult Immunization Status measure (Quality ID #493) ensures that adults are up to date with the recommended routine vaccines: influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal (89 FR 62026). We also stated that this robust measure supports the comprehensive evaluation of compliance with recommended adult immunizations that improve quality care and prevent disease (89 FR 62026).

(e) Maintaining the Use of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients With Multiple Chronic Conditions Measure in the APP Quality Measure Set and Including It in the APP Plus Quality Measure Set

We noted in the CY 2025 PFS proposed rule (87 FR 46154 through 46155) that Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) is an administrative claims-based measure that is in the APP quality measure set for the MIPS CY performance period 2025/2027 payment year under policies finalized in the CY 2024 PFS final rule (88 FR 79113 and 79114) but is not one of the ten Adult Universal Foundation measures. Our proposal would continue to maintain this measure in the APP quality measure set, but the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) would be withheld from the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year before being incorporated in the CY 2026 performance period/2028 MIPS payment year and subsequent performance periods. We continue to believe that hospital admission rates are an effective marker of ambulatory care quality. As noted in our rationale for adopting the measure in the measure specifications, ''Hospital admissions from the outpatient setting reflect a deterioration in patients' clinical status and as such reflect an outcome that is meaningful to both patients and providers.[835] Patients receiving optimal, coordinated high-quality care should use fewer inpatient services than patients receiving fragmented, low-quality care. Thus, high population rates of hospitalization may signal poor quality of care or inefficiency in health system performance. Furthermore, these effects may be exacerbated in disadvantaged areas.[836] Patients with multiple chronic conditions are at high risk for hospital admission, often for potentially preventable causes, such as exacerbation of pulmonary disease.'' [837] Maintaining this measure in the APP quality measure set and, as a consequence, including it in the APP Plus quality measure set also is consistent with our previously stated goals in the CY 2021 PFS final rule to align the APP with the Meaningful Measures framework, an initiative to remove lower value quality measures across CMS programs while keeping measures that have less burden and are the most meaningful with the greatest impact on patient outcomes. This measure supports the framework's goals as it is identified among the highest priorities for quality measurement and improvement while also reducing burden, promoting alignment, moving payment toward value, and identifying key quality performance metrics for consumers (85 FR 84726).

(f) The APP and APP Plus Quality Measure Sets Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year

Table 67 identifies the measures in the Adult Universal Foundation measure set, crosswalks them to corresponding MIPS measures, and lists the timeline for their incorporation into the APP Plus quality measure set between the CY 2025 and 2028 performance periods/2027 and 2030 MIPS payment years as they become available for both the eCQM and Medicare CQM collection types. We note that Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID #484) is not one of the ten Adult Universal Foundation measures and is not listed in Table 23; however, we are maintaining reporting of this measure in the APP quality measure set, and, as such, also proposed to include it in the APP Plus quality measure set. We note we are finalizing incorporation Quality ID #484 into the APP Plus quality measure set with a one-year delay to the CY 2026 performance period/2028 MIPS payment year and subsequent performance periods, as discussed above.

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[834] American Hospital Association. (December, 2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. Available at *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf*.

[835] Centers for Medicare and Medicaid Services—Quality Payment Program (2023). Measure information for the Multiple Chronic Care Conditions (MCC) Risk-standardized Hospital Submission Rate for Patients for the Merit-based Incentive Payment System (MIPS) Groups, Performance Year (PY)2023 MCC Measure Code Specifications, Retrieved March 22, 2024 from 2023 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions—QPP. *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2202/2023%20MIPS%20Multiple%20Chronic%20Conditions%20Measure%20Specifications.zip*.

[836] Jencks, S.F., et al. (2019). ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program: An Observational Study.'' Ann Intern Med. *doi: 10.7326/M16-2671*.

[837] Abernathy, K., Zhang, J., Mauldin, P., Moran, W., Abernathy, M., Brownfield, E., & Davis, K. (2016). Acute Care Utilization in Patients With Concurrent Mental Health and Complex Chronic Medical Conditions. *Journal of Primary Care & Community Health, 7*(4), 226–233. *https://doi.org/10.1177/2150131916656155*.

TABLE 67: Alignment of the APP Plus Measure Set with the Adult Universal Foundation Measure Set [a]

Quality #	Identification Number and Name [b]	Measure Title	Domain [c]	Performance Period Measure Added to the APP Plus Measure Set
001	204: Hemoglobin A1c poor control (>9%)	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	Chronic Conditions	2025
134	672: Screening for depression and follow-up plan	Preventive Care and Screening: Screening for Depression and Follow-up Plan	Behavioral Health	2025
236	167: Controlling high blood pressure	Controlling High Blood Pressure	Chronic Conditions	2025
321	(# varies by program) Consumer Assessment of Healthcare Providers and Systems overall rating measures	CAHPS for MIPS	Person-Centered Care	2025
479	44 or 561: All-cause hospital readmissions or readmissions plan all-cause readmissions	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Clinician Groups	Affordability and Efficiency	
112	93: Breast cancer screening	Breast Cancer Screening	Wellness and Prevention	2025
113	139: Colorectal cancer screening	Colorectal Cancer Screening	Wellness and Prevention	2026
305	394: Initiation and engagement of substance use disorder treatment	Initiation and Engagement of Substance Use Disorder Treatment	Behavioral Health	2027
487	Identification number undetermined: Screening for social drivers of health	Screening for Social Drivers of Health	Equity	2028, or the performance period that is one year after the eCQM specification becomes available, whichever is later
493	26: Adult immunization status	Adult Immunization Status	Wellness and Prevention	2028, or the performance period that is one year after the eCQM specification becomes available, whichever is later

[a] Jacobs D, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher L. Aligning Quality Measures across CMS – The Universal Foundation. New England Journal of Medicine, March 2, 2023, available at *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

[b] Identification numbers are CMS Measures Inventory Tool measure family identification numbers; names reflect the descriptions associated with those numbers.

[c] Domains are from Meaningful Measures 2.0.

We refer readers to Table 66 for the APP quality measure set for the CY 2025 performance period/2027 MIPS payment year and subsequent years. The APP Plus quality measures for the CY 2025, 2026, 2027, and 2028 performance period and subsequent performance periods are displayed in Tables 68, 69, 70, and 71 respectively. We are finalizing that there will be six measures in the APP Plus quality measure set in the CY 2025 performance period (Table 68), eight measures in the CY 2026 performance period (Table 69), nine measures in the CY 2027 performance period (Table 70), and eleven measures no sooner than the CY 2028 performance period (Table 71). We refer readers to Appendix 1 of this final rule for additional measure specification information.

TABLE 68: APP Plus Quality Measure Set for the CY 2025 Performance Period

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE 69: APP Plus Quality Measure Set for the CY 2026 Performance Period

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

TABLE 70: APP Plus Quality Measure Set for the CY 2027 Performance Period

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Person-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and Engagement of Substance Use Disorder Treatment	eCQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process

TABLE 71: APP Plus Quality Measure Set for the CY 2028 Performance Period and Subsequent Performance Periods

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Behavioral Health	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Chronic Conditions	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient-Centered Care	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups	Administrative Claims	N/A	Affordability and Efficiency	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Affordability and Efficiency	Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process
305	Initiation and	eCQM (all APP	MIPS Eligible	Behavioral	Process

Quality #	Measure Title	Collection Type	Submitter Type	Meaningful Measures 2.0 Area	Measure Type
	Engagement of Substance Use Disorder Treatment	reporters) Medicare CQM (SSP ACOs only)	Clinician Representative of a Practice APM Entity Third Party Intermediary	Health	
487*	Screening for Social Drivers of Health	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Equity	Process
493*	Adult Immunization Status	eCQM/MIPS CQM (all APP reporters) Medicare CQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Wellness and Prevention	Process

* Indicates this measure will be incorporated into the APP Plus quality measure set in the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specification becomes available, whichever is later.

Scoring for the APP quality performance category scoring methodology at § 414.1367(c)(1) will continue to be performed in accordance with § 414.1380(b)(1). For the APP quality measure set, this means that the scoring methodology will not change. For the APP Plus quality measure set, we proposed to calculate the MIPS quality performance category score for a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set via the APP by summing the scores for all of the measures, as applicable, included in the APP Plus quality measure set for a given year. Scoring clinicians on all measures, as applicable, in the APP Plus quality measure set will promote the best, safest, and most equitable care and provide a comprehensive assessment of the performance of those who choose to report the measure set.

Because we proposed that a MIPS eligible clinician, group, or APM Entity that chooses to report the APP Plus quality measure set will be scored on all of the measures in that set, we also proposed a conforming change to MIPS data submission requirements in § 414.1335(b) to require that a MIPS eligible clinician, group, or APM Entity that reports the APP Plus quality measure set via the APP will be required to report on all measures included in the APP Plus quality measure set, except for administrative claims-based measures, which are calculated using data from claims submissions. We solicited comment on this proposal. For further discussion on the data submission proposal for the APP Plus quality measure set, see section IV.A.4.e.(1)(b) of this final rule.

d. Data Submission for the Performance Categories

(1) Overview

For previously established policies relevant to data submission for the MIPS performance categories, we refer readers to § 414.1325 and the CY 2017 Quality Payment Program final rule (81 FR 77087 through 77097), CY 2018 Quality Payment Program final rule (82 FR 53619 through 53626), CY 2023 PFS final rule (86 FR 65438 through 65441) and CY 2024 PFS final rule (88 FR 79330 through 79332). Specifically, we finalized at § 414.1325(a)(1) that individual MIPS eligible clinicians, groups, virtual groups, subgroups, and Alternative Payment Model (APM) Entities must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with § 414.1325. We note, that under the current policies described at § 414.1325(a)(2), there are no data submission requirements for the cost performance category or administrative claims-based quality measures.

In the CY 2025 PFS proposed rule (89 FR 62031 through 62036), we proposed to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality, improvement activities, and Promoting Interoperability performance categories at § 414.1325(a)(1)(i) through (iii). We also proposed to codify our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories at § 414.1325(f)(1). We also proposed to modify our existing policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category at § 414.1325(f)(2).

Policies in this section of this final rule are intended to eliminate certain issues with the scoring of an unintended data submission affecting payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. We proposed these changes to be effective beginning with the CY 2024 performance period/2026 MIPS payment year for the data submission period in CY 2025.

(2) Minimum Criteria for a Qualifying Data Submission for the MIPS Quality, Improvement Activities, and Promoting Interoperability Performance Categories

(a) Background

CMS uses the data submitted by (or on behalf of) individual MIPS eligible clinicians, groups, virtual groups, subgroups, or APM Entities in the quality, improvement activities, and Promoting Interoperability performance categories to assess their performance on the measures and activities in these three categories and to determine their MIPS payment adjustments. Under the previously established data submission policies at § 414.1325, individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities generally submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with the data submission deadlines at § 414.1325(e)(1). Under our current policies, we consider any submission of data received for a MIPS performance category during the designated data submission period for a MIPS performance period in accordance with § 414.1325(e)(1) to be a data submission for the corresponding MIPS performance period and assign a score for the submission.

For the quality and improvement activities performance categories, under the current reweighting policies at § 414.1380(c)(2)(i)(A)(*6*) through (*8*) for an extreme and uncontrollable circumstance (EUC) or other type of exception based on certain circumstances, we score any data submitted by (or on behalf of) a MIPS eligible clinician with an approved reweighting application. This includes MIPS eligible clinicians with an approved application-based EUC reweighting or an approved reweighting for a clinician identified in a CMS-designated region affected by an automatic EUC event. Under this current policy, in the event that a MIPS eligible clinician submits any data for the quality or improvement activities performance category, such submission overrides the approved reweighting for the applicable performance category and we score the performance categories for which data was submitted, and include the performance category scores in the MIPS eligible clinician's final score as otherwise provided in § 414.1380(c).

Similarly, for the Promoting Interoperability performance category, under the current reweighting policies at § 414.1380(c)(2)(i)(C) for a significant hardship or other type of exception based on certain circumstances, we score any data submitted by (or on behalf of) a MIPS eligible clinician with an approved reweighting application, except as provided in § 414.1380(c)(2)(i)(C)(*10*) and (*11*). Under this current policy, in the event that a MIPS eligible clinician submits any data for the Promoting Interoperability performance category, such submission overrides the approved reweighting for the performance category and we will score the Promoting Interoperability performance category and include the category score in the MIPS eligible clinician's final score as otherwise provided in § 414.1380(c).

We have received inquiries from MIPS eligible clinicians that highlight unintended consequences associated with our current data submission requirements. Several MIPS eligible clinicians have notified us that there have been instances where they unintentionally submitted non-scorable data for a MIPS performance category, which overrode an approved reweighting or a previously scorable data submission for the MIPS quality, improvement activities, or Promoting Interoperability performance categories. Data submissions without any scorable data (non-scorable data submissions) generally only include limited data that cannot be scored, such as a practice ID, date, activity ID, measure ID, or CMS Electronic Health Record (EHR) Certification ID (CEHRT ID). MIPS eligible clinicians have also notified us that, in some instances, the data submission overriding the prior approved reweighting or prior scorable submission was performed by a third-party intermediary or a practice representative.

The MIPS eligible clinician, group, virtual group, subgroup, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, as applicable, that submits data on measures and activities under MIPS is defined at § 414.1305 as the submitter type.

The mechanism by which a submitter type submits data to CMS (including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims, and the CMS Web Interface) is defined at § 414.1305 as the submission type. The direct submission type allows users to transmit data through a computer-to-computer interaction, such as an API. The log in and upload submission type allows users to upload and submit data in the form and manner specified by CMS with a set of authenticated credentials. The log in and attest submission type allows users to manually attest that certain measures and activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We refer readers to § 414.1325(b) and (c) for available data submission types that individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities may utilize to submit data for the quality, improvement activities, and Promoting Interoperability performance categories.

To submit data, a submitter must gain access to the Quality Payment Program website (*https://qpp.cms.gov/login*) for submitting or viewing data for the associated individual MIPS eligible clinician, group, subgroup, virtual group, or APM Entity. We refer readers to the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*) for additional information on the MIPS data submission process and obtaining access to submit data during the designated submission period under § 414.1325(e)(1).

After gaining access to the Quality Payment Program website for the associated individual MIPS eligible clinician, group, subgroup, virtual group, or APM entity, a submitter can navigate to the ''Eligibility and Reporting'' tab and view whether there is any reweighting applied for one or more of the MIPS performance categories for the associated individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. In addition, at the time of submission, the system generates warnings to the submitter (for all the available submission types) if there is an existing approved reweighting for the performance category in which the data is being submitted or an existing data submission for an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. For example, if a group has an approved reweighting for the Promoting Interoperability performance category, the system alerts the submitter prior to completing the data submission with a message stating: ''This Action Will Impact Your Category Weights. Currently, Promoting Interoperability does not count towards your final score. By choosing to report Promoting Interoperability data, your score for this category will be included in your final score. This action cannot be undone.'' The submitter must check the ''Yes, I agree'' box prior to confirming the data submission in the performance category. We refer readers to the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*) for additional details on the process to

submit MIPS data for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities.

Under the current policy and process, we assign a score for any submission received from an individual MIPS eligible clinician, group, virtual group, subgroup or APM Entity for a performance period during the designated MIPS submission period regardless of whether the submission included data on the MIPS measures and activities. We implemented the policy and process to recognize any data submitted as an extension of the policy that submission of any data overrides reweighting of the MIPS performance categories as described at § 414.1380(c)(2). We assign a score for submissions with data on MIPS measures and activities, and also for submissions that only include non-scorable data, such that they do not include any data that allows us to measure a clinician's performance on the applicable measures and activities. For example, if we receive a submission for a MIPS performance category without any measure or activity data (for example, without numerator and denominator data for any quality measures, without a response of ''yes'' for any improvement activities, without a ''yes'' or ''no'' response for an attestation, or responses for the required objectives and associated measures and attestation statements for the Promoting Interoperability performance category), and the data submission includes only non-scorable data (such as the practice ID, measure ID and TIN/NPI information), we assign a zero score for the applicable MIPS performance category in the event we do not receive a subsequent submission with measure or activity data.

Despite implementing these system warnings to alert the submitter of a potential impact of their entry on the reweighting status or existing data submission, we continue to receive non-scorable data submissions, which override an approved reweighting or a previously scored data submission, for the MIPS quality, improvement activities, or Promoting Interoperability performance categories. To help address the unintentional overriding of an existing scorable data submission or an approved reweighting for the MIPS performance categories, we proposed a narrower set of minimum criteria of what would qualify as a data submission under our existing policies. We note that we did not propose to change our existing policies to assign a score for a data submission (meeting the proposed narrower minimum criteria) for the applicable MIPS performance categories, including our policy governing data submissions from a third-party intermediary, even if the submission overrides an approved reweighting or a prior scorable submission for the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity.

We have identified that we could potentially avoid submissions without any scorable data on MIPS measures or activities from overriding previously approved reweighting or a prior submission for the MIPS performance categories if we require a submission to include certain data on measures or activities in the MIPS quality, improvement activities, or Promoting Interoperability performance categories to assign a score. Therefore, we proposed to adopt minimum criteria for what we would consider to be a qualifying data submission for which CMS can assign a score.

Specifically, we proposed to consider a submission valid and scorable (including, potentially, a score of zero) for the applicable MIPS performance category only if the data submission includes: numerator and denominator data for at least one MIPS quality measure in the quality performance category; a response of ''yes'' for at least one improvement activity in the improvement activities performance category; and all required elements to report objectives and associated measures and attestation statements for the Promoting Interoperability performance category.[838] We describe the details of these data submission criteria for each performance category in sections IV.A.4.d.(2)(b), IV.A.4.d.(2)(c), and IV.A.4.d.(2)(d) of this final rule. As further described in these sections, we are finalizing these data submission criteria for each performance category as proposed.

As discussed in the CY 2025 PFS proposed rule (89 FR 62033), we note that we did not propose any changes to the existing scoring or reweighting policies described under § 414.1380 for the MIPS performance categories. If the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not have an approved reweighting for one or more of the MIPS performance categories and we do not receive a data submission for a performance category that has not been reweighted, we will assign a score of zero for the applicable performance category.

(b) Quality Performance Category

We refer readers to §§ 414.1325 and 414.1330 through 414.1340 and the CY 2017 Quality Payment program final rule (81 FR 77097 through 77162) and CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641), the CY 2019 PFS final rule (83 FR 59754 through 59765), CY 2020 PFS final rule (84 FR 63949 through 62959), CY 2021 PFS final rule (85 FR 84866 through 84877), CY 2022 PFS final rule (86 FR 65431 through 65445), CY 2023 PFS final rule (87 FR 70047 through 70057), and CY 2024 PFS final rule (88 FR 79329 through 79338) for a description of previously established policies related to the quality performance category. The data submitted from the final list of MIPS quality measures are used to assess the performance of an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity for the quality performance category, to contribute to their overall score, and to help determine the payment adjustment for MIPS eligible clinicians.

In the CY 2025 PFS proposed rule (89 FR 62033), we proposed that a data submission in the quality performance category must include numerator and denominator data for at least one quality measure from the list of MIPS quality measures to be assigned a score in the quality performance category. We previously finalized data submission types for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities as described at § 414.1325. In the CY 2018 Quality Payment Program final rule (82 FR 53780), we stated that we will determine a quality performance category percent score whenever a MIPS eligible clinician has submitted at least one quality measure. As described in the CY 2025 PFS proposed rule (89 FR 62033), we currently assign a score for any data submitted for the MIPS performance categories and have implemented operational measures to limit unintentional overriding of an approved reweighting or existing scorable data submitted for a MIPS performance category. However, we continue to receive unintentional submissions without data that can be scored resulting in the overriding of an approved reweighting application or a prior data submission that can be scored for the quality performance category. We noted that we did not propose any

[838] Attestation is one possible way to for MIPS eligible clinicians participating in APMs to earn credit in the improvement activities performance category but is not required to earn credit. Consistent with our regulation at § 414.1380(b)(3)(i), we automatically award 50 percent credit for the improvement activities performance category to MIPS eligible clinicians participating in APMs when they attest to having completed an improvement activity or submit data for the quality or Promoting Interoperability performance categories. We did not propose to change this.

changes to the current scoring policies described under § 414.1380(b)(1) for the quality performance category. Therefore, we will still assign a score of zero for the quality performance category if an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not submit at least one available quality measure unless the performance category has been reweighted as defined at § 414.1380(c)(2).

We proposed to specify what we consider to be a data submission at § 414.1325(a)(1)(i) to state that, for the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures (89 FR 62033). We anticipate the change will potentially avoid unintentional overriding of an approved reweighting or a prior data submission for the quality performance category due to submissions without any quality measure data. We did not propose any changes to the data submission requirements, data submission criteria, data completeness criteria, and scoring for the quality performance category described under §§ 414.1325, 414.1335, 414.1440, and 414.1380(b)(1) respectively. We requested public comments on this proposal.

We received public comments on this proposal.

Comment: Many commenters supported the proposal to adopt minimum criteria for data submissions in the quality performance category that would require numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures. A few commenters expressed appreciation that this proposal will mitigate negative scoring impacts on clinicians when data submission is unintended. A few other commenters appreciated CMS' efforts to align data submission requirements across all performance categories because it can help standardize reporting. Other commenters also expressed belief that the proposal will help solve problems with the current data submission process by ensuring accuracy and completeness in performance reporting, reducing ambiguity, and preventing incomplete submissions from being scored.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern or did not support the proposal to adopt minimum criteria for data submissions in the quality performance category. One commenter shared their belief that constant tweaks and changes to the program can be detrimental to and complicated for practices, especially for those with limited resources. Another commenter expressed concern that the requirement to provide detailed performance data and attestation statements for the MIPS performance categories could increase administrative burden, particularly for smaller practices with limited resources.

Response: While we acknowledge the commenters' concerns, the proposed minimum criteria for a qualifying data submission will prevent submissions without any scorable data from unintentionally overriding an existing scorable data submission or an approved reweighting for the MIPS performance categories without increasing reporting burden for providers. We note the proposed minimum criteria for a qualifying data submission do not require practices to change how they submit data and will benefit practices by preventing unintended consequences due to submissions without any scorable data.

Comment: One commenter requested clarification regarding whether submission of a single quality data code (QDC) for a single Medicare Part B Claims measure would satisfy the proposed minimum criteria of numerator and denominator data for a data submission in the quality performance category and noted that in the past, practices have reported unintentional overriding of an approved extreme and uncontrollable circumstance (EUC) due to accidental submission of QDCs.

Response: Under the proposed minimum criteria for a quality data submission, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures. Therefore, a submission of a single QDC for a single Medicare Part B Claims measure would be considered a qualifying data submission and under the current reweighting policies at § 414.1380(c)(2)(i)(A)(6) through (8) for an EUC or other type of exception based on certain circumstances, this submission will override an approved reweighting of the quality performance category.

Comment: One commenter recommended that in addition to the proposed minimum criteria for a data submission in the quality performance category, CMS should allow a practice to submit a targeted review request to indicate accidental data submitted on behalf of the practice and to allow for the scoring to be corrected.

Response: At the time of submission, the system on the Quality Payment Program website generates warnings for the submitter (for all the available submission types) if there is an existing approved reweighting for the performance category in which the data is being submitted or an existing data submission for an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. The existing system warnings, combined with the proposed minimum criteria for a data submission, should be sufficient to warn practices against and prevent the accidental submission of data that overrides a previous data submission or an approved reweighting. We encourage group practices and clinicians to continue collaborating with their data submission representatives (third party intermediaries or practice administrators) to avoid unintended submissions.

The targeted review policy established under section 1848(q)(13)(A) of the Act is limited to informal review of our calculation of the MIPS adjustment factor applicable to the MIPS eligible clinician. This includes requests for targeted review of errors in our application of policies governing calculation of scores for measures and activities, performance category scores, and MIPS final scores (81 FR 77353). We proposed minimum criteria for qualifying data submission for the quality, improvement activities, and Promoting Interoperability performance categories to identify where non-scoreable data submissions may have been inadvertent or in error. Adopting these standards will establish clear, objective criteria to assess whether we received a qualifying data submission that we will score for the performance category. If a MIPS eligible clinician submits a targeted review request alleging an accidental data submission, we will apply this qualifying data submission policy, as finalized, to determine whether we calculated the performance category score appropriately, or in error.

After consideration of public comments, we are finalizing the policy as proposed to codify at § 414.1325(a)(1)(i) that for the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures.

(c) Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1360 and the CY 2017 Quality Payment Program final rule (81 FR

77177 and 77178), CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), CY 2019 PFS final rule (83 FR 59776 and 59777), CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2022 PFS final rule (86 FR 65462) and the CY 2024 PFS final rule (88 FR 79328) for a description of previously established policies related to the improvement activities performance category.

We previously finalized at § 414.1360(a)(2) that MIPS eligible clinicians, groups, virtual groups, or subgroups must submit a ''yes'' response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period to receive points in the improvement activities performance category described under § 414.1360(b)(3). We currently assign a score for any submission or attestation received in the improvement activities performance category via the submission types described under § 414.1325(a)(1) regardless of whether the submission or attestation included a ''yes'' response or not. In the event of a submission without ''yes'' responses, we currently assign a score of zero.

Data submitted in the improvement activities performance category is used to assess the performance of an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity on the attestation or data submission for the improvement activities and to determine the payment adjustment for MIPS eligible clinicians. In the CY 2025 PFS proposed rule (89 FR 62033 through 62034), we proposed to specify for clinicians what we consider to be a data submission and that we will score a data submission only if the submission includes a response of ''yes'' for at least one improvement activity included in the improvement activities inventory for the MIPS performance period. We anticipate the change will potentially avoid unintentional overriding of an approved reweighting or a prior data submission for the improvement activities performance category due to submissions or attestations without a response of ''yes'' for any of the improvement activities.

Specifically, we proposed that for the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory (89 FR 62033 and 62034). We note that we did not propose any changes to the data submission criteria and scoring for the improvement activities performance category described under §§ 414.1360 and 414.1380(b)(3) respectively.

We received public comments on this proposal.

Comment: Many commenters supported the proposal to adopt minimum criteria for data submissions in the improvement activities performance category which would require a response of ''yes'' for at least one activity in the MIPS improvement activities Inventory. A few commenters expressed appreciation that this proposal will mitigate negative scoring impacts on clinicians when data submission was unintended. A few other commenters appreciated CMS' efforts to align data submission requirements across all performance categories because it can help standardize reporting. Other commenters also expressed the belief that this proposal will help solve problems with the current data submission process by ensuring accuracy and completeness in performance reporting, reducing ambiguity, and preventing incomplete submissions from being scored.

Response: We thank the commenters for their support.

Comment: A few commenters provided recommendations about the proposal to adopt minimum criteria for data submissions in the improvement activities performance category. One commenter recommended that CMS adopt an alternative policy to score and reweight the improvement activities category and uses the higher of those two scores because the commenter believes this to be the simplest solution that would also avoid unintended consequences for clinicians that qualify for automatic credit within the improvement activities category, such as not receiving credit for participating in an eligible MIPS APM or patient-centered medical home. Another commenter recommended that CMS should ensure that any policy finalized does not override an approved reweighting request for the improvement activities performance category. Another commenter recommended that in addition to the proposed minimum criteria for a data submission in the improvement activities performance category, CMS should allow the practice to submit a targeted review request to indicate accidental data submitted on behalf of the practice and to allow for the scoring to be corrected.

Response: We did not propose this policy to maximize a MIPS eligible clinician's score. The reweighting policy is for clinicians that have been affected by ''extreme and uncontrollable circumstances'' that prevented the clinician from performing functions essential to reporting completion of the activity or in other circumstances such that there are not sufficient measures and activities applicable and available as described in § 414.1380(c)(2)(i)(A)(3) and (6) through (9). If a clinician receives reweighting or otherwise qualifies for the reweighting policy, subsequent affirmative reporting that the clinician completed the improvement activity is clear evidence that the clinician was in fact able to complete the functions necessary to complete reporting of the activity. The proposed policy is therefore most appropriate as it accounts for blank, inadvertent non-scorable submissions, while still permitting clinicians who were approved for reweighting and were able to complete at least one activity to override the reweighting and be scored.

This proposed policy will not interfere with awarding due credit for clinicians that qualify for automatic credit within the improvement activities category, such as those that participate in an eligible MIPS APM or patient-centered medical home as these clinicians automatically receive credit for the category as described under § 414.1380(b)(3)(i) and (ii). We refer readers to section *IV.A.4.e.(3)(b)(iv)* of this final rule for additional details on the changes to the scoring and reporting requirements for the improvement activities performance category.

While we understand the commenter's recommendation to use the targeted review policy for indicating accidental submissions and allow scoring corrections, we note that at the time of submission, the system on the Quality Payment Program website generates warnings to the submitter (for all the available submission types) if there is an existing approved reweighting for the performance category in which the data is being submitted or an existing data submission for an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. The existing system warnings, combined with the proposed minimum criteria for a data submission, will prevent occurrences of accidental data submission resulting in overriding a previous intended data submission or an approved reweighting. We encourage group practices and clinicians to continue collaborating with their data submission representatives (third party intermediaries or practice administrators) to avoid unintended consequences.

Comment: One commenter expressed concern that the requirement to provide detailed performance data and

attestation statements for the MIPS performance categories could increase administrative burden, particularly for smaller practices with limited resources.

Response: We acknowledge the commenter's concerns; however, the proposed minimum criteria for a qualifying data submission will prevent submissions without any scorable data from unintentionally overriding an existing scorable data submission or an approved reweighting for the MIPS performance categories without increasing reporting burden. We note the proposed minimum criteria for a qualifying data submission do not require practices to change the way they already submit data and will benefit practices by preventing unintended consequences due to submissions without any scorable data.

After consideration of public comments, we are finalizing the policy as proposed and codify at § 414.1325(a)(1)(ii) that for the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory.

(d) Promoting Interoperability Performance Category

We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and § 414.1380(b)(4) for Promoting Interoperability performance category scoring. We refer readers to § 414.1380(c)(2)(i)(C) for our previously finalized policies regarding scoring of data submission in the Promoting Interoperability performance category after an approved reweighting for the performance category. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59785 through 59820, 84 FR 62991 through 63006, 85 FR 84886 through 84895, 86 FR 65466 through 65490, 87 FR 70060 through 70087, and 88 FR 79351 through 79365, respectively) for a description of previously established policies related to the Promoting Interoperability performance category.

Under our current policy, we consider any information received for the Promoting Interoperability performance category in the Quality Payment Program Submission environment a data submission and assign a performance category score based on the submission. We assign a score of zero for incomplete submissions in the Promoting Interoperability performance category, for example, submissions that include only a date and CMS EHR Certification ID (CEHRT ID) without any data that can be scored with respect to the required objectives, measures, or attestations, as specified by CMS. Under § 414.1375, if we receive a complete data submission for the Promoting Interoperability performance category with responses included for all the required Promoting Interoperability objectives, associated measures, and attestation statements as specified by CMS and utilizing the CEHRT (meeting the definition at § 414.1305) as required, we score the data submission under our established scoring policies for the performance category.

We previously finalized at § 414.1380(c)(2)(i)(C) that, if a MIPS eligible clinician with an approved reweighting for the Promoting Interoperability performance category submits data, they will be scored in this performance category and the reweighting will not be applied, except as provided in § 414.1380(c)(2)(i)(C)(*10*) and (*11*). We also included in the educational materials available on the Quality Payment Program resource library (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2602/2023MIPSSubmissionGuide.pdf*) that a MIPS eligible clinician will be scored in this performance category if they attest to any data, such as selecting performance period dates or responding to attestation statements during the submission period. As set forth under § 414.1380(c)(2)(i)(C), submission of any data for the Promoting Interoperability performance category overrides reweighting, including reweighting due an approved significant hardship exception and automatic reweighting for clinicians that are Ambulatory Surgical Center (ASC)-based, hospital-based, non-patient facing, and small practices. Similarly, under § 414.1380(c)(2)(i)(A)(*4*)(*iii*), submission of any data also overrides our automatic reweighting of the Promoting Interoperability performance category for clinical social workers.[839]

Furthermore, to earn a performance category score for the Promoting Interoperability performance category, we established at § 414.1375 that, for the performance period established at § 414.1320, individual MIPS eligible clinicians, groups, virtual groups, subgroups, or APM Entities must use CEHRT as defined at § 414.1305, report on objectives and associated measures as specified by CMS, and submit attestations as specified by CMS. Under § 414.1325(b) and (c), individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities (or authorized representatives submitting on their behalf) can submit data for the Promoting Interoperability performance category using the direct, login and attest, or login and upload submission types. Specifically, to submit data for the Promoting Interoperability performance category, individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities (or authorized representatives submitting on their behalf) must use CEHRT as required (meeting the definition at § 414.1305) for the continuous 180-day performance period (§ 414.1320(i)) to report the applicable objectives, measures, and attestations. We refer readers to section IV.A.4.e.(4) of this final rule for additional details on CEHRT requirements (including applicable ONC health IT certification criteria set forth under 45 CFR 170.315) and objectives, measures, and attestations required for the Promoting Interoperability performance category.

Under our current policy, we receive submissions in the Promoting Interoperability performance category without completed responses for all the required objectives, measures, and attestations. For example, if a submission for the Promoting Interoperability performance category includes only a date, practice ID, and/or a CEHRT ID, or the submission does not include all of the required objectives, measures, and attestations, then we consider these to be incomplete data submissions. Currently, an incomplete data submission would void an approved reweighting of the Promoting Interoperability performance category in accordance with § 414.1380(c)(2)(i)(C), except as provided in § 414.1380(c)(2)(i)(C)(*10*) and (*11*). As described in the proposed rule and this section of this final rule, we believe that we should not consider data submissions for the Promoting Interoperability performance category if the submission is incomplete, and does not include all necessary required data. We proposed that the minimum criteria for a qualifying data submission for the Promoting Interoperability performance category must include all required reporting elements for the performance category, as specified in this section.

We considered whether CMS should accept incomplete submissions for the

[839] We note that this automatic reweighting policy for clinical social workers only applies through the CY 2024 performance period/2026 MIPS payment year.

Promoting Interoperability performance category. If CEHRT is utilized as required to collect and report measure data and submit attestation statements and other requirements, it would generally result in only complete submissions for the Promoting Interoperability performance category. We recognize that some of the measures in the Promoting Interoperability performance category (such as the SAFER Guides measure and security risk analysis) do not directly require the use of CEHRT, whereas some measures (such as e-prescribing) directly require the use of CEHRT. However, all the requirements for the Promoting Interoperability performance category are directly related to a MIPS eligible clinician demonstrating whether they are a meaningful user of CEHRT in accordance with sections 1848(q)(2)(A)(iv), (B)(iv) and 1848(o)(2)(A) of the Act. Further, section 1848(o)(2)(A) requires that all requirements set forth therein (meaningful use of CEHRT, electronic exchange of health information, and reporting on clinical quality and other measures using CEHRT) be met for a MIPS eligible clinician to be treated as a meaningful EHR user for the applicable performance period. Therefore, accepting an incomplete data submission for the Promoting Interoperability performance category would be counterintuitive to a MIPS eligible clinician demonstrating whether they are a meaningful user of CEHRT in accordance with sections 1848(q)(2)(A)(iv), (B)(iv) and 1848(o)(2)(A) of the Act.

In the CY 2025 PFS proposed rule (89 FR 62034 through 62035), we proposed to adopt minimum criteria for a qualifying data submission for the Promoting Interoperability performance category submission to include all of the required reporting elements for the category, including data on all required measures (including any claim of an applicable exclusion), required attestation statements, the CEHRT ID, and the start and end date for the applicable performance period. This proposal will clarify what counts as a data submission for MIPS eligible clinicians and it will potentially avoid partial data submissions from overriding an approved reweighting or a previously scored submission for the Promoting Interoperability performance category.

Specifically, we proposed to specify minimum criteria as a qualifying data submission for the Promoting Interoperability performance category at § 414.1325(a)(1)(iii) to provide that a data submission must include all of the following elements:

- Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;
- Required attestation statements, as specified by CMS;
- CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and
- The start date and end date for the applicable performance period as set forth in § 414.1320.

As discussed previously, we did not propose any changes to the existing scoring or reweighting policies described under § 414.1380 for the MIPS performance categories in this section of this final rule. If the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity does not have an approved reweighting for one or more of the MIPS performance categories and we do not receive a data submission meeting the proposed minimum criteria for a performance category that has not been reweighted, we will assign a score of zero for the applicable performance category. If we receive a qualifying data submission meeting the minimum criteria for reporting, then we will review the data submission and score the Promoting Interoperability performance category in accordance with our applicable scoring policies.

We refer readers to section IV.A.4.e.(4) of this final rule for additional details on the reporting requirements and scoring of the objectives, measures, and attestations the Promoting Interoperability performance category.

We received public comments on this proposal.

Comment: Many commenters supported the proposal to adopt minimum criteria for data submissions in the Promoting Interoperability performance category. A few commenters expressed appreciation that this proposal will mitigate negative scoring impacts on clinicians when data submission was unintended. A few other commenters appreciated CMS' efforts to align data submission requirements across all performance categories because it can help standardize reporting. Other commenters also expressed their belief that this proposal will help solve problems with the current data submission process by ensuring accuracy and completeness in performance reporting, reducing ambiguity, and preventing incomplete submissions from being scored.

Response: We thank the commenters for their support. We intend to standardize data submission requirements for MIPS to the extent feasible. To this end, while we proposed to establish minimum criteria for a qualifying data submission for all three performance categories for which we require data submission under § 414.1325(a), we note that the specific minimum criteria we proposed for each performance category varies. This variation is by necessity as these criteria reflect the differences in the requirements of, and the individual measures and activities specified for, each performance category.

Comment: A few commenters expressed concern or did not support the proposal to adopt minimum criteria for data submissions in the Promoting Interoperability performance category. One commenter expressed concern about increasing complexity in the Promoting Interoperability performance category. Another commenter expressed concern that the requirement to provide detailed performance data and attestation statements for the MIPS performance categories could increase administrative burden, particularly for smaller practices with limited resources. A few commenters expressed concern about using an ''all-or-nothing'' approach for minimum criteria for data submission for the Promoting Interoperability performance category because they believe the policy is overly punitive and penalizes clinicians for administrative errors. One commenter recommended that CMS instead require performance data on one reporting option within the Health Information Exchange (HIE) objective and not each measure within the objective. Another commenter recommended that CMS instead score all Promoting Interoperability measures that include a numerator and denominator.

Response: We believe that the proposed minimum criteria for what would qualify as a data submission will prevent submissions without any scorable data from unintentionally overriding an existing scorable data submission or an approved reweighting for the Promoting Interoperability performance category. The proposed minimum criteria for a qualifying data submission do not require practices to change the way they already submit data and will benefit practices by preventing unintended consequences due to submissions without any scorable data. We did not propose any changes to existing scoring or reweighting policies described under § 414.1380 with respect to these proposed data submission policies (89 FR 62033). The data submission policies discussed in this section IV.A.4.d.(2) of the final rule will establish clear

minimum criteria so we may identify when we have received a qualifying data submission for a performance category, and thus apply our existing scoring policies or override an approved reweighting in accordance with § 414.1380(c)(2)(i).

For example, as described in § 414.1380(c)(2)(i)(C)(*9*), we automatically reweight the Promoting Interoperability performance category to zero percent for MIPS eligible clinician(s) in a small practice as defined at § 414.1305. Therefore, MIPS eligible clinician(s) in a small practice are not required to submit data for the Promoting Interoperability performance category. However, if MIPS eligible clinician(s) in the small practice submit data meeting the minimum criteria of a qualifying data submission for the Promoting Interoperability performance category as finalized in this rule, then we will override the automatic reweighting and score the Promoting Interoperability performance category, as specified in § 414.1380(c)(2)(i)(C).

In response to the commenter's concerns about using an ''all-or-nothing'' approach for the minimum criteria for a qualifying data submission for the Promoting Interoperability performance category, if CEHRT is utilized as required to collect and report measure data and submit attestation statements and other requirements, it will generally result in only complete submissions for the Promoting Interoperability performance category. Additionally, we believe that accepting an incomplete data submission for the Promoting Interoperability performance category would be counterintuitive to a MIPS eligible clinician demonstrating whether they are a meaningful user of CEHRT in accordance with sections 1848(q)(2)(A)(iv), (B)(iv) and 1848(o)(2)(A) of the Act. The proposed minimum criteria for a qualifying data submission for the Promoting Interoperability performance category are intended to prevent penalties and errors that may occur due to unintentional submissions without data on measures overriding prior data submissions or reweighting. Only scoring data submissions with all elements required for reporting in the Promoting Interoperability performance category should minimize the chance of MIPS eligible clinicians receiving a score of zero due to unintentional submissions.

Regarding the commenters' recommendations to use one reporting option under the HIE objective or score all measures within the category that require a numerator and denominator, we note that we did not propose any changes to the existing reporting and scoring requirements in the Promoting Interoperability performance category in relation to this qualifying data submission policy. This qualifying data submission policy does not alter our reporting requirements for the Promoting Interoperability performance category, including what measure(s) fulfill the HIE objective. We refer readers to § 414.1375(b) and section *IV.A.4.e.(4)(f)* of this final rule for details on the requirements for the Promoting Interoperability performance category. As previously noted, once we receive a qualifying data submission for the Promoting Interoperability performance category, we will score it in accordance with our existing policies.

After consideration of public comments, we are finalizing the policy as proposed and codify at § 414.1325(a)(1)(iii) that a data submission in the Promoting Interoperability performance category must include all of the following elements:

- Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;
- Required attestation statements, as specified by CMS;
- CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and
- The start date and end date for the applicable performance period as set forth in § 414.1320.

(3) Treatment of Multiple Data Submissions

(a) Background

Under the current policies described at § 414.1325(d), individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities may submit their MIPS data using multiple data submission types for any performance category in accordance with § 414.1325(a)(1), as applicable; provided, however, that the individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity uses the same identifier for all performance categories and all data submissions. We established the policy to offer flexibility for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities with reporting, as it provides more options for submission of data for the applicable performance categories. We refer readers to the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77094 and 77095 and 82 FR 53619 through 53626, respectively) for additional details on the use of multiple data submission mechanisms for any MIPS performance category.

As described in this section of this final rule, at § 414.1305, we define a submitter type as a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, or third-party intermediary acting on behalf of a MIPS eligible clinician, group, virtual group, subgroup, APM Entity, as applicable, that submits data on measures and activities under MIPS. During a submission period, a submitter associated with an organization (for example, registry, practice administrator, or EHR vendor) could submit data for a MIPS eligible clinician, group, subgroup, virtual group, or APM Entity. If needed, the submitter could also review and correct the data submission resulting in multiple data submissions for the MIPS performance categories. Additionally, there could be instances when a submitter unintentionally submits data multiple times. There could also be instances when we receive data for a MIPS eligible clinician, group, subgroup, virtual group, or an APM Entity from multiple organizations. For example, both a qualified registry and a qualified clinical data registry (QCDR) could submit MIPS data on behalf of a group practice for a performance period. Individual MIPS eligible clinicians, groups, practice representatives, and third-party intermediaries benefit from the flexibility to submit data multiple times as it provides opportunities to correct errors in a prior submission and allows clinicians to submit data from multiple sources (for example, qualified registry and group submission) to increase their chances to provide the most clinically relevant data.

For the quality, improvement activities, and Promoting Interoperability performance categories, there is an established policy governing our treatment of multiple data submissions received for a performance period. However, we have not codified this policy in prior rules. We provided additional guidance on how we process and score multiple submissions received in the MIPS performance categories via educational and outreach materials is available on the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*.)

We proposed to codify at § 414.1325(f)(1) our existing policies governing our treatment of multiple data submissions received for the quality and improvement activities performance categories. We also proposed to modify our policy governing our treatment of multiple data submissions received for

the Promoting Interoperability performance category, which we also proposed to codify at § 414.1325(f)(2). As further described in these sections, we are finalizing these multiple data submission policies for each performance category as proposed.

(b) Quality and Improvement Activities Performance Categories

In the CY 2018 Quality Payment Program final rule (82 FR 53619 through 53626), we discussed scoring policies for multiple submissions received in the MIPS performance categories. Specifically, we stated that if an individual MIPS eligible clinician or group submits the same measure through two different mechanisms, each submission would be calculated and scored separately and that we do not have the ability to aggregate data on the same measure across submission mechanisms. We would only count the submission that gives the clinician the higher score, thereby avoiding double counting (82 FR 53620). We refer readers to CY 2019 PFS final rule (83 FR59747 through 59749) for our discussion of previously finalized policies related to the use of the term ''submission mechanism.''

Under the existing policy for the quality and improvement performance categories, if we receive multiple submissions for an individual clinician, group, subgroup, or virtual group from submitters from separate organizations (for example, registry, practice administrator, or EHR vendor), we score each submission and assign the highest of the scores for the performance category. If we receive multiple submissions for an individual clinician, group, subgroup, or virtual group from a submitter or submitters from the same organization, we will use the most recent submission. For example, if a qualified registry submits improvement activities for a group on Tuesday and a practice administrator submits improvement activities data for the same group on Wednesday, we will score all the data submissions and assign the highest of the scores. If the practice administrator from a group practice submits improvement activities data for the group on Tuesday and either the practice administrator or another submitter employed by the group practice submits improvement activities data for the group again on Wednesday, we will score only the data submission received on Wednesday because a new data submission received from the same organization on Wednesday will override the prior data submission on Tuesday.

In the CY 2025 PFS proposed rule (89 FR 62035 through 62036), we proposed to codify the existing process for multiple data submissions for the quality and improvement activities performance categories, we proposed to add at § 414.1325(f)(1) that for multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. We also proposed to codify our policy governing our treatment of multiple data submissions for the quality and improvement activities performance category received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization to score the most recent submission (89 FR 62036).[840] We requested public comments on this proposal.

We received public comments on these proposals.

Comment: Several commenters supported the proposal to codify the current process for the treatment of multiple data submissions for a clinician from separate organizations in the quality and improvement activities performance categories, which uses the highest score when multiple data submissions are received from separate organizations. The commenters shared their belief that this approach allows clinicians to submit data from multiple sources and be assessed based on their best performance without being penalized.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposal to codify the current policy for the treatment of multiple data submissions from the same organization in the quality and improvement activities performance categories, which uses the most recent submission when multiple data submissions are received from submitters in the same organization. The commenters shared their belief that this approach is inconsistent with the current policy for CMS assigning the highest score for multiple submissions received from separate organizations. The commenters recommended that CMS maintain the same policy for all multiple submissions, regardless of whether the submissions are from the same or multiple organizations, as they believe this would avoid confusion and would be consistent with other multiple submissions policies in the quality, improvement activities, and Promoting Interoperability performance categories. The commenters also shared their concerns that using only the most recent submission would result in unintended consequences for clinicians as the Quality Payment Program submission system does not allow making corrections to a completed data submission. A few commenters expressed concern that the proposed approach would prevent a practice's ability to submit data multiple times if the clinicians in the practice submitted MIPS and MVP data via different participation options (for example, as a group, individual and APM Entity). Another commenter recommended that CMS provide an option for submitters to indicate whether a previous submission should be overridden.

Response: Separate approaches for multiple submissions based on whether the submitter is from the same organization or multiple organizations are appropriate as these are not equivalent circumstances. Individual MIPS eligible clinicians, groups, practice representatives, and third-party intermediaries use multiple sources (for example, a QCDR and qualified registry) to submit data, resulting in multiple submissions. This offers flexibility for clinicians to submit data from multiple sources (for example, qualified registry and group submission) and increases their ability to provide the most clinically relevant data. For example, a small practice may report three measures via claims and upload a QRDA III file with three eCQMs to meet the requirement of submitting 6 measures.

On the other hand, we expect a submitter from a single organization would generally submit data multiple times to update a previous submission with additional information or to fix data errors in a previous submission. When a single submitter or multiple submitters from the same organization submit data multiple times, the new submission overrides a previous submission only if the new quality or improvement activity data submission is for the same participation type (individual eligible clinician, group, subgroup, or virtual group) under the same reporting option (traditional MIPS

[840] In the CY 2025 proposed rule (89 FR 62036), we inadvertently stated that we were proposing to modify the policy governing our treatment of multiple submissions received for the quality and improvement activities performance categories from the same organization. We intended to state that we are proposing to codify the existing policy.

or MVP) for the MIPS performance period. For example, if a group practice submitted traditional MIPS data for an individual eligible clinician in January 2024 and the practice administrator from the same group submitted MVP data at the group level in March 2024, we will accept and score both the individual MIPS submission and the group's MVP submission and assign the highest score for the MIPS eligible clinicians in the group. However, if the practice administrator from a group practice submits quality data for the group on Tuesday and either the practice administrator or another submitter employed by the group practice submits quality data for the group again on Wednesday, we will score only the data submission received on Wednesday because a new data submission received from the same organization on Wednesday will override the prior data submission on Tuesday. We acknowledge the Quality Payment Program submission system does not allow making changes to an existing submission, however, the flexibility to submit data multiple times provides the opportunity for submitters to override a previous submission to fix data errors. We note that we are not changing the current policy for multiple data submissions received for the quality and improvement activities performance categories. We are only codifying the existing policies as described previously.

While we understand the commenter's recommendation to add an option for submitters to indicate whether they would want to keep or delete a prior submission, we note that at the time of submission, the system generates warnings to the submitter (for all the available submission types) if there is an existing data submission for an individual MIPS eligible clinician, group, virtual group, subgroup, or APM Entity. We refer readers to the Quality Payment Program Resource Library (*https://qpp.cms.gov/resources/resource-library*) for additional details on the process to submit MIPS data for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities.

Comment: Several commenters supported the proposal to codify the current process to use only the most recent submission when multiple data submissions are received in the quality and improvement activities performance categories from the same organization. One commenter shared their belief that this approach allows overriding of a previous submission from the same organization and would eliminate confusion for submitters.

Response: We thank the commenters for their support.

Comment: One commenter acknowledged the technical complexity for CMS to accept all submissions from a single organization and recommended that CMS explore the feasibility of accepting and scoring multiple submissions from the same organization.

Response: We appreciate the commenter's recommendation to explore operational feasibility for us to accept and score all submissions from the same organization. Technical feasibility is not the only reason for using the most recent submission when we receive multiple submissions from the same organization. We expect that a submitter associated with an organization (for example, registry, practice administrator, or EHR vendor) would coordinate with the individual clinician, group, subgroup, virtual group, or APM Entity to submit relevant data appropriately and avoid multiple submissions for the same reporting option. There could be instances when a submitter would need to resubmit data. For example, a submitter may resubmit quality data to review and correct the data submission or to update the quality data submission with additional information, resulting in multiple data submissions for the quality performance category. Overriding a previous submission in such instances would eliminate confusion and allow the clinicians to be scored appropriately on the updated most recent submission. We will continue to monitor for any potential issues or concerns with using the most recent submission for multiple submissions from the same organization and will revisit the policy in the future, as needed.

After consideration of public comments, we are finalizing the proposal as proposed to codify at § 414.1325(f)(1) that for multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. Additionally, we are finalizing the proposal to codify that for multiple data submissions for the quality and improvement activities performance categories received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization, CMS will calculate a score for the most recent submission.

(c) Promoting Interoperability Performance Category

For the Promoting Interoperability performance category, we explained in the educational materials published on the Quality Payment Program Resource Library (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2602/2023MIPSSubmissionGuide.pdf*.) that any data submitted through multiple submission types or multiple submissions submitted through the same submission type will result in a score of zero for the Promoting Interoperability performance category. Additionally, we recommended using a single submission type (file upload, API, or attestation by an individual MIPS eligible clinician, group, virtual group, subgroup or a third-party intermediary) to submit data for the Promoting Interoperability performance category. As described in section IV.A.4.d.(2)(d) of this final rule, the utilization of the CEHRT should not generate conflicting data for measures and objectives in the Promoting Interoperability performance category. However, we have received inquiries from MIPS eligible clinicians that were impacted by the existing policy to assign a score of zero for multiple submissions in the Promoting Interoperability performance category. Specifically, we identified scenarios when a complete submission from an individual MIPS eligible clinician or group followed by an incomplete submission resulted in a score of zero, either overriding a previous score greater than zero or voiding an approved reweighting for the performance category.

In the CY 2025 PFS proposed rule (89 FR 62036), we proposed to amend our policy for treatment of multiple data submissions for the Promoting Interoperability performance category. We proposed that, for multiple data submissions received, CMS will calculate a score for each data submission received and assign the highest of the scores. We also proposed to codify this proposal at § 414.1325(f)(2).

We believe this proposed change is consistent with our existing policy for treatment of multiple data submissions received in the quality and improvement activities performance categories, as discussed previously. Implementing a similar policy for allowing multiple data submissions in the Promoting Interoperability performance category may provide flexibility for individual MIPS eligible

clinicians, groups, virtual groups, subgroups, and APM Entities to fix errors in a prior data submission. Additionally, we recognize there may be instances when a practice switches EHR vendors during a performance period, potentially resulting in separate data submissions for the Promoting Interoperability performance category. This policy also aligns with our intent to maintain consistency in data submission requirements across all MIPS performance categories, to the extent possible, as it significantly reduces the complexity for MIPS eligible clinicians participating in MIPS.

We received public comments on this proposal.

Comment: Many commenters supported CMS' proposal to modify the policy for handling multiple data submissions in the Promoting Interoperability performance category as this change would not penalize clinicians who inadvertently submitted data multiple times and is consistent with the scoring policy for other MIPS performance categories.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS implement the revised policy for the CY 2023 performance period/2025 MIPS payment year to mitigate negative impacts to MIPS eligible clinicians who received a zero score in the Promoting Interoperability performance category due to multiple submissions. Specifically, the commenters suggested that CMS should allow targeted review requests beyond the deadline for the CY 2023 performance period to implement the amended policy.

Response: We acknowledge the commenters' recommendation to implement the proposed modified policy for scoring multiple data submissions in the Promoting Interoperability performance category beginning in the CY 2023 performance period/2025 MIPS payment year to mitigate zero scores for multiple submissions in this performance category. Section 1848(q)(7) of the Act requires that we finalize and notify all MIPS eligible clinicians of their final MIPS payment adjustment factors for the 2025 MIPS payment year no later than 30 days prior to January 1, 2025, which occurs prior to the effective date of this final rule. Applying new, modified scoring policies after we have finalized our calculations for the performance period/MIPS payment years, even as we identify and seek to apply improvements for future MIPS payment years, is not feasible. Further, MIPS eligible clinicians generally rely on the finality of our calculation and application of MIPS payment adjustment factors to their Medicare Part B claims during the MIPS payment year. We proposed that these modified data submission policies be effective as soon as feasible: beginning with the CY 2024 performance period/2026 MIPS payment year for the data submission period in CY 2025 (January 1, 2025 through March 31, 2025) (89 FR 62031).

Comment: One commenter recommended that CMS implement a process to ensure that the submission used for the highest score is accurately reflective of the performance and to resolve any potential issues with discrepancies in data from multiple sources.

Response: We understand the commenter's concern regarding potential issues with the accuracy of discrepancies in data from multiple data submissions in the Promoting Interoperability performance category. We have an established policy for validating and auditing MIPS data submissions as described under § 414.1390. We will continue monitoring multiple submissions in the Promoting Interoperability performance category for this issue and consider revisiting the policy in the future, as needed.

We also note that individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities (or authorized representatives submitting on their behalf) have the flexibility to submit data using multiple submission types (the direct, login and attest, or login and upload) as established under § 414.1325(b) and (c). However, the submitters do not have the ability to use multiple data sources. Regardless of the submission type, data submission for the Promoting Interoperability performance category requires the use of CEHRT (meeting the definition at § 414.1305) as the single data source to report the applicable objectives, measures, and attestations. We expect that the use of CEHRT combined with the proposed minimum criteria for a qualifying data submission in the Promoting Interoperability performance category will minimize potential issues with accuracy of the data being submitted.

After consideration of public comments, we are finalizing our policy as proposed and codify the proposal at § 414.1325(f)(2) providing that, for multiple data submissions received for the Promoting Interoperability performance category, CMS will calculate a score for each data submission received and assign the highest of the scores.

f. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, and 88 FR 79329 through 79338, respectively) for a description of previously established policies and statutory basis for policies regarding the quality performance category.

In the CY 2025 PFS proposed rule (89 FR 62037 through 62042), we proposed to:

- Establish the data submission criteria for the Alternative Payment Model (APM) Performance Pathway (APP) quality measure set.
- Maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years.
- Codify previously established criteria pertaining to the removal of MIPS quality measures.
- Modify the MIPS quality measure set as described in Appendix 1 of the CY 2025 PFS proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Data Submission Criteria

(i) Data Submission Criteria for the Quality Performance Category

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we established the APP in § 414.1367 as an available reporting option starting with the CY

2021 performance period/2023 MIPS payment year, which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. Additionally, we finalized a quality measure set (85 FR 84860 through 84861) for purposes of the quality performance category scoring for the APP.

The APP and the APP quality measure set were designed to reduce the reporting burden and create new scoring opportunities for MIPS APMs by having a stable, streamlined pathway for reporting and scoring in MIPS while recognizing the reporting burden and performance scoring that MIPS eligible clinicians, groups, and APM Entities already experience in their respective MIPS APMs. We believed that using a broadly applicable population health-based measure set would enable MIPS APM participants to focus on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from year to year. (85 FR 84862).

In section IV.A.4.c.(2) of the CY 2025 PFS proposed rule (89 FR 62023 through 62024), we proposed to create a second quality measure set as an available option under the APP, specifically the APP Plus quality measure set, which is a set of measures that leverages the Adult Universal Foundation measure set. Of the ten Adult Universal Foundation measures, five of the measures are already included in the APP quality measure set for the CY 2025 performance period/2027 MIPS payment year (88 FR 79113 through 79114). As originally proposed, the APP Plus quality measure set would initially consist of all the measures currently within the APP quality measure set (five Adult Universal Foundation measures and a separate quality measure) plus two additional measures from the Adult Universal Foundation measure set. The set would incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. (We refer readers to section IV.A.4.c.(3) of the CY 2025 PFS proposed rule (89 FR 62024 through 62031) for further discussion regarding the APP Plus quality measure set proposal.) Leveraging the APP Plus quality measure set with the Adult Universal Foundation measure set serves to advance Medicare's overall value-based care strategy and maintain alignment within and across CMS's quality programs. The alignment of quality measures across CMS programs allows clinicians to better focus their quality efforts, reduce administrative burden, and drive digital transformation and stratification of a focused quality measure set to assess the impact on disparities.[841] For further discussion on the quality measures included in the APP Plus quality measure set and the timeline for incorporating such quality measures, please see section IV.A.4.c.(3) of this final rule.

For the APP Plus quality measure set, we proposed in § 414.1335(b) to require MIPS eligible clinicians, groups, and APM Entities, including Medicare Shared Saving Program (Shared Savings Program) Accountable Care Organizations (ACOs), reporting the APP Plus measure set to report on all measures in the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS) for the applicable performance period. As discussed further in section IV.A.4.c.(3) of this final rule, the APP Plus quality measure set would be optional for MIPS eligible clinicians, groups, and APM Entities (not including Shared Savings Program ACOs) meeting the reporting requirements under the APP starting with the CY 2025 performance period/2027 MIPS payment year. However, Shared Savings Program ACOs would be required to report the APP Plus quality measure set to meet the reporting requirements of the Medicare Shared Savings Program's quality performance standard as outlined in section IV.A.4.c.(2) of this final rule. Under the proposal in § 414.1335(b), the requirement to report all measures within the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS) would be the same regardless of whether a MIPS eligible clinician, group or APM Entity is reporting the APP Plus quality measure set on a mandatory or optional basis. We proposed conforming amendments in § 414.1335(a).

Lastly, we note that the existing reporting requirements and scoring policies established in § 414.1367(c)(1) would continue to be applicable to the APP quality measure set. Similarly, the existing scoring policies established in § 414.1367(c)(1) would be applicable to the APP Plus quality measure set. As described in more detail in section IV.A.4.c.(3) of this final rule, all measures in the APP Plus quality measure set would be scored, unless a quality measure does not have a benchmark or meet the case minimum requirements. If a measure within the APP Plus quality measure set does not have a benchmark or meet the case minimum requirements, the measure would still be required to be reported in order to meet the reporting requirements of the APP and for the measure to be excluded from scoring (such measure would not contribute to the quality performance category score as long as the measure is reported). If such a measure is not reported, then the measure would fail to meet the reporting requirements of the APP and as a result, it would receive 0 achievement points.

We solicited public comment on the proposal to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS). The following is a summary of the public comments received.

Comment: Some commenters supported the fundamental establishment of the APP Plus quality measure set. However, many commenters did not support the mandatory reporting requirements for the Shared Savings Program ACOs associated with the APP Plus quality measure set or the number of quality measures required to be reported. Also, many commenters did not support the limitation of collection types to only include Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) and electronic clinical quality measures (eCQMs).

Response: We appreciate the support from commenters regarding the fundamental establishment of the APP Plus quality measure set. For all comments and responses pertaining to the measure composition of the APP Plus quality measure set, specific measures within the APP Plus quality measure set, the reporting requirements of the APP Plus quality measure set, and the timeline for increasing the number of measures associated with the APP Plus quality measure set, we refer readers to section IV.A.4.c. of this final rule.

After consideration of public comments, we are finalizing, as proposed, the proposal in § 414.1335(b) to establish the data submission criteria for the APP Plus quality measure set, specifically the proposal to require the reporting of all measures within the

[841] Update On The Medicare Value-Based Care Strategy: Alignment, Growth, Equity'', Health Affairs Forefront, March 14, 2024. *DOI: 10.1377/forefront.20240311.141546.*

APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS). MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set will be scored based on data submitted for eCQMs, MIPS CQMs and/or Medicare CQMs (available only to Shared Savings Program ACOs), and data automatically calculated for administrative claims-based quality measures, which includes the following number of quality measures: 6 quality measures for the CY 2025 performance period/2027 MIPS payment year; 8 quality measures for the CY 2026 performance period/2028 MIPS payment year; 9 quality measures for the CY 2027 performance period/2029 MIPS payment year; and 11 quality measures for the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specifications become available for each respective measure, whichever is later. For the reporting requirements pertaining to the APP Plus quality measure set, we refer readers to section IV.A.4.c.(2) of this final rule.

(c) Data Completeness Criteria

(i) Data Completeness Criteria for the Quality Performance Category

As described in the CY 2017 Quality Payment Program final rule (81 FR 77125 through 77126), to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance, we established a data completeness requirement. Section 1848(q)(5)(H) of the Act provides that analysis of the quality performance category may include quality measure data from other payers, specifically, data submitted by MIPS eligible clinicians with respect to items and services furnished to individuals who are not entitled to benefits under Part A or enrolled under Part B of Medicare. For the CY 2017 performance period/2019 MIPS payment year (first year of the implementation of MIPS), we established the data completeness criteria threshold to reflect a threshold of at least 50 percent (81 FR 77125). The data completeness criteria threshold means the following: an individual MIPS eligible clinician, group, virtual group, or APM Entity submitting measure data on qualified clinical data registry (QCDR) measures, MIPS clinical quality measures (CQMs), or eCQMs must submit data on at least a specific percent (that is, 50 percent as specified above and 60 percent, 70 percent, and 75 percent as specified in the following paragraphs) of their patients that meet the measure's denominator criteria, regardless of payer; an individual MIPS eligible clinician, group, virtual group, or APM Entity submitting quality measure data on Medicare Part B claims measures must submit data on at least a specified percent (that is, 50 percent as specified above and 60 percent, 70 percent, and 75 percent as specified in the following paragraphs) of their Medicare Part B patients seen during the corresponding performance period; and an APM Entity, specifically a Shared Savings ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least a specified percent (that is, 70 percent and 75 percent as specified in the following paragraphs) of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

In the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2020 PFS final rule, we noted that we would increase the data completeness criteria threshold over time (81 FR 77121, 82 FR 53632, and 84 FR 62951). We increased the data completeness criteria threshold from at least 50 percent to at least 60 percent for the CY 2018 performance period/2020 MIPS payment year (81 FR 77125 and 82 FR 53633) and maintained a threshold of at least 60 percent for the CY 2019 performance period/2021 MIPS payment year (82 FR 53633 and 53634). For the CY 2020 performance period/2022 MIPS payment year, we increased the data completeness criteria threshold from at least 60 percent to at least 70 percent (84 FR 62952). We maintained data completeness criteria threshold of at least 70 percent for the CY 2021, CY 2022, and CY 2023 performance periods/2023, 2024, and 2025 MIPS payment years (86 FR 65435 through 65438). For the CY 2024 and CY 2025 performance periods/2026 and 2027 MIPS payment years, we increased the data completeness criteria threshold from at least 70 percent to at least 75 percent (87 FR 70049 through 70052). Lastly, we maintained the data completeness criteria threshold of at least 75 percent for the CY 2026 performance period/2028 MIPS payment year (88 FR 79334 through 79337).

We continue to believe that it is important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and Alternative Payment Model (APM) Entities gain experience with MIPS. The incorporation of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, 87 FR 70049, and 88 FR 79334). To improve compliance with the data completeness threshold, we have encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients (82 FR 53632, 86 FR 65436, 87 FR 70049, and 88 FR 79334) such that all applicable cases may be used when calculating a measure. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure.

Increasing the data completeness criteria threshold provides for a more accurate assessment of performance. We want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[842] it is generally feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform well in MIPS. Our approach for increasing the data completeness criteria threshold slowly and incrementally over time enhances the ability for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to meet the data completeness criteria threshold as it increases and consequently, enables successful participation under MIPS. Thus, a data completeness criteria threshold of less than 100 percent may reduce clinician burden and accommodate operational issues that may arise during data collection during the initial years of the program (82 FR 53632, 86 FR 65436, 87 FR 70049, and 88 FR 79334).

As MIPS eligible clinicians, groups, virtual groups, and APM Entities have gained experience participating in MIPS, particularly meeting the data completeness criteria threshold over the last 8 years (from the CY 2017 performance period to the CY 2024 performance period), such experience has prepared MIPS eligible clinicians, groups, virtual groups, subgroups

[842] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

(participation option available starting with the CY 2024 performance period), and APM Entities to meet incremental increases in the data completeness criteria threshold. We have maintained a data completeness criteria threshold of at least 70 percent for 4 years from the CY 2020 performance period through the CY 2023 performance period and as a result, individual MIPS eligible clinicians, groups, virtual groups, and APM Entities had 4 years of a maintained data completeness criteria threshold of at least 70 percent before transitioning to an increased data completeness criteria threshold of at least 75 percent starting with the CY 2024 performance period. We believed that maintaining the data completeness criteria threshold of at least 70 percent for 4 years provided adequate time for individual MIPS eligible clinicians, groups, virtual groups, and APM Entities to adjust to the increase that went into effect at the onset of the COVID–19 public health emergency and account for the implications the COVID–19 pandemic had on the healthcare system.

As we assessed the timeframe for a potential future increase to the data completeness criteria threshold, we determined that maintaining the data completeness criteria threshold of at least 75 percent for a total of 5 years would provide sufficient time for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to adjust to the data completeness criteria threshold of at least 75 percent. In response to the proposal in the CY 2023 PFS proposed rule to increase the data completeness criteria threshold to at least 80 percent starting with the CY 2026 performance period/2028 MIPS payment year, interested parties indicated in the public comments that increasing the data completeness threshold from 75 to 80 percent within two years of increasing the threshold from 70 to 75 percent would present various challenges such as the following, which would make it more difficult to meet the data completeness criteria threshold: increased burden (in particular, disproportionately increase burden for smaller and rural practices due to limited resources and staff, and some practices that are continuing to recover from the COVID–19 Public Health Emergency); and exacerbated technical and interoperability challenges pertaining to data aggregation across multiple EHRs, systems (utilizing different registries, and EHR developers and vendors), and sites (including multiple TINs participating in the Shared Savings Program as an ACO) (88 FR 79337). We accept these concerns, and we thus believe that MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities require more time to adjust and prepare for an increase. We previously established that for the CY 2024 performance period through the CY 2026 performance period/2026 MIPS payment year through the 2028 MIPS payment year, we will establish and maintain the data completeness threshold of at least 75 percent (87 FR 70049 through 70052, 88 FR 79334 through 79337). To maintain such threshold for a total of 5 years, we proposed in the CY 2025 PFS proposed rule, to maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years. It is advantageous to delineate the expectations for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities in advance of an applicable performance period as it provides sufficient notice of the expectation and subsequently allows such MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to prepare for a potential increase in future years.

In the CY 2025 PFS proposed rule, we proposed to maintain the data completeness criteria threshold of at least 75 percent for 2 additional years. Specifically, in § 414.1340(a), we proposed the following data completeness criteria thresholds pertaining to QCDR measures, MIPS CQMs, and eCQMs:

- At paragraph (a)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.

Similarly, in § 414.1340(b), respectively, we proposed the following data completeness criteria thresholds pertaining to Medicare Part B claims measures:

- At paragraph (b)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.

Additionally, in § 414.1340(d), respectively, we proposed the following data completeness criteria thresholds pertaining to Medicare CQMs:

- At paragraph (d)(1), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

Lastly, for the data completeness criteria pertaining to the quality performance category, we proposed a conforming amendment to recognize that an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, must meet the data completeness criteria requirements established at § 414.1340(d)(1).

We solicited public comment on these proposals. The following is a summary of the public comments received.

Comment: Many commenters supported the data completeness criteria threshold to be maintained at 75 percent and appreciated that CMS took into consideration the challenges and burden associated with raising the threshold. Many commenters expressed that the threshold is achievable and provides an accurate picture of quality without placing undue burden on clinicians. A few commenters noted that maintaining the threshold will provide stability to clinicians, especially small practices and solo practitioners who have fewer resources and staff to handle increased reporting requirements. One commenter noted that such consistency would allow clinicians to focus on delivering high-quality care without the added pressure of changing reporting requirements on top of other capacity issues such as staffing shortages.

Response: We appreciate the support from commenters.

Comment: Many commenters requested for CMS to maintain the data completeness criteria threshold of at least 75 percent permanently or indefinitely. Many commenters expressed concerns regarding any future increases to the data completeness criteria threshold and requested for CMS to consider barriers or burden associated with meeting the data completeness criteria threshold. Commenters indicated that future increases to the data completeness criteria threshold would exacerbate the

technical challenges associated with data aggregation, data integration, and interoperability across multiple EHR systems, particularly for clinicians providing care across multiple sites under the same Taxpayer Identification Number (TIN) and Shared Savings Program ACOs with multiple TINs that utilize several different EHR systems and vendors. A few commenters indicated that technical limitations, data privacy concerns, patient misidentification and varying interpretations of data completeness requirements may lead to inaccurate reporting and difficulty in meeting the threshold. A few commenters noted that higher data completeness criteria thresholds have a disparate impact on practices that manually extract and report quality data. Some commenters requested for CMS to consider the impact of increasing the data completeness criteria threshold would have on small and rural practices. A few of such commenters indicated that an increased data completeness criteria threshold would result in a disproportionate burden for many small or rural practices without improving data accuracy. One commenter asserted that current health IT standards are insufficient for seamless data aggregation from EHRs or registries, particularly for clinicians and Shared Savings Program ACOs operating across multiple sites and EHR systems. The commenter requested for CMS to collaborate with clinicians, Shared Savings Program ACOs, and EHR vendors to address such issues before increasing the data completeness criteria threshold.

Response: We recognize that there are technical challenges associated with data aggregation across multiple sites and EHR systems. We previously noted concerns raised by interested parties regarding the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinician's ability to participate and perform well under MIPS (81 FR 77121, 82 FR 53632, 84 FR 62951, and 87 FR 70049). However, the adoption of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049). It is therefore important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS. Thus, we want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS. Prior to determining whether or not to increase the data completeness criteria threshold in the future, we will analyze data completeness rates from data submission and assess if it is feasible for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities to achieve a higher data completeness criteria threshold without jeopardizing their ability to successfully participate and perform in MIPS.

Comment: A few commenters requested for CMS to provide the following if the data completeness criteria threshold is increased in future years: offer CMS-facilitated quality data aggregation, allow the direct reporting of quality data from multiple EHR systems, and shorten the performance period for the quality performance category for cases involving the switching of EHR systems during a performance period.

Response: We recognize there are some concerns with the potential increase in the data completeness threshold in future years and appreciate the commenters' suggestions on how we could mitigate these concerns. We will take this feedback into account when considering future increases in the data completeness threshold.

Comment: Some commenters did not support the proposal to maintain the data completeness criteria threshold of at least 75 percent. A few commenters requested for CMS to lower the data completeness criteria threshold to at least 70 percent while one commenter requested for CMS to lower the data completeness criteria threshold to at least 60 percent. A few commenters expressed their belief that the threshold should be lowered to 60 percent while one commenter recommended 70 percent due to administrative burden and technical challenges associated with data aggregation, data integration, and interoperability across multiple EHR systems as experienced by Shared Savings Program ACOs.

Response: We disagree with commenters regarding their request to lower the data completeness criteria threshold from its current threshold of at least 75 percent. Based on our analysis of data completeness rates from data submission for the CY 2017 performance period,[843] it is feasible for eligible clinicians and groups to achieve a higher data completeness criteria threshold above 60 percent and 70 percent without jeopardizing their ability to successfully participate and perform in MIPS. The adoption of higher data completeness criteria thresholds in future years ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures and prevents selection bias to the extent possible (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049). It is therefore important to incrementally increase the data completeness criteria threshold as MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities gain experience with MIPS. Thus, we want to ensure that an appropriate, yet achievable, data completeness criteria threshold is applied to all eligible clinicians participating in MIPS.

Also, due to the complex technical challenges that Shared Savings Program ACOs encounter as they prepare for the reporting of eCQMs and/or MIPS CQMs, we established the Medicare CQMs collection type to serve as a transition collection type under the APP quality measure set starting with the CY 2024 performance period (88 FR 79329 through 79330 and 79332) and under the APP Plus quality measure set starting with the CY 2025 performance period (as discussed in section IV.A.4.c.(3) of this final rule). The reporting of eCQMs and/or MIPS CQMs is new for some Shared Savings Program ACOs under the APP quality measure set and the APP Plus quality measure set due to the CMS Web Interface sunsetting and no longer being available starting with the CY 2025 performance period. In order to facilitate the transition to the reporting of eCQMs and/or MIPS CQMs, the availability of the Medicare CQMs as a collection type assists with the transition of reporting eCQMs and/or MIPS CQMs as the complex technical challenges specific to Shared Savings Program ACOs are mitigated and addressed. For the Medicare CQMs collection type, Shared Savings Program ACOs report quality data on a subset of Medicare beneficiaries (beneficiaries eligible for Medicare CQMs as defined at § 425.20) instead of the reporting of quality data on all-payers as required for eCQMs and MIPS CQMs. We note that the Medicare CQMs collection type, serving as a transition collection type for Shared Savings Program ACOs, is not an available collection type for MIPS eligible clinicians, groups, virtual groups, subgroups, and other APM Entities participating in MIPS.

Comment: A few commenters requested for CMS to include exceptions

[843] As described in the CY 2020 PFS final rule (84 FR 62951), the average data completeness rates were as follows: for individual eligible clinicians, it was 76.14; for groups, it was 85.27; and for small practices, it was 74.76.

for meeting the data completeness criteria threshold due to unforeseen circumstances such as patient self-discharges, interruptions to an episode of care, and practices switching EHR technology or systems.

Response: We disagree with commenters regarding the establishment of exclusions for MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities not able to meet the data completeness criteria threshold for circumstances pertaining to patient self-discharges, interruptions to an episode of care, and practices switching EHR technology or systems. Cases pertaining to patient self-discharges and interruptions to an episode of care are items that would be more appropriately addressed in a measure specification. We encourage interested parties to contact measure stewards to discuss revisions for possible implementation in future years. Also, switching of EHR technology or systems does not warrant an exception to meeting the reporting requirements for the quality performance category as it relates to meeting the data completeness criteria threshold. We recognize that there are certain circumstances outside the control of clinicians, but we believe that the reporting requirements can be met even when EHR technology or systems are switched during a performance period. However, we recognize the importance of not penalizing clinicians for certain circumstances outside their control. For example, many of our policies, including the extreme and uncontrollable circumstances exception and the reweighting policy discussed in section IV.A.4.i.(2) of this final rule relating to the reweighting of the quality, improvement activities, and Promoting Interoperability performance categories when contractually-obligated third party intermediaries do not submit MIPS data, are aimed at ensuring that a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity is not unfairly penalized due to unforeseen circumstances outside their control.

Comment: A few commenters requested for CMS to consider establishing different data completeness thresholds for each measure type and collection type. The commenters indicated that while a 75 percent data completeness criteria threshold may be reasonable for process measures, it is significantly more challenging to meet such threshold for patient-reported outcome measures; therefore, the commenters requested for CMS to apply a lower threshold for patient-reported outcome measures to encourage broader adoption of these measures. One commenter recommended that CMS offer an alternative data completeness criteria threshold for Shared Savings Program ACOs reporting eCQMs due to the technical challenges with such measures such as data aggregation across multiple EHR systems and de-duplicating patient data.

Response: To provide consistency regarding the data completeness criteria threshold across measure types (that is, process and outcome quality measures) and collection types, and prevent confusion regarding the expectations concerning the data completeness criteria threshold, it is imperative to establish the same data completeness criteria threshold requirements for QCDR measures, eCQMs, MIPS CQMs, Medicare Part B claims measures, and Medicare CQMs. In regard to patient-reported outcome measures, we note that the CAHPS for MIPS Survey measure, which is a patient-reported outcome measure, has different data completeness criteria requirements from QCDR measures, eCQMs, MIPS CQMs, Medicare Part B claims measures, and Medicare CQMs. For the CAHPS for MIPS survey measure, groups, virtual groups, subgroups, and APM Entities report data on a sample of Medicare Part B patients provided by CMS.

We recognize that there are technical challenges for Shared Savings Program ACOs as they prepare to report eCQMs under the APP Plus quality measure set. As a result of the aforementioned technical challenges, we are finalizing, with modification, the proposed policy pertaining to collection types available for the newly established APP Plus quality measure set, which excluded MIPS CQMs as an available collection type from the newly established APP Plus quality measure set. Particularly, we are finalizing, with modification, the proposed policy by including the availability of MIPS CQMs as a collection type within the APP Plus quality measure set for a two-year period from CY 2025 performance period/2027 MIPS payment year through CY 2026 performance period/2028 MIPS payment year in order to provide another option for meeting the reporting requirements under the APP Plus quality measure set. We refer readers to section IV.A.4.c.(3) of this final rule for further discussion regarding the extension of the availability of MIPS CQMs as a collection type under the newly established APP Plus quality measure set. Lastly, we note that we will continue to engage in conversations with interested parties as we mitigate the complex technical challenges.

Comment: Some commenters requested for CMS to consider other methodologies and approaches for data completeness. One commenter expressed concerns that the data completeness percentage received by CMS does not accurately capture the eligible population for each TIN due to vendors or practices only capturing the cases within a single EHR site and do not include the eligible encounters from other sites of service. A few commenters requested for CMS to consider the data completeness criteria threshold based on sample size. One commenter noted that smaller sample sizes are considered sufficient for Medicare Part C and D Star Ratings, as well as clinical data for hospitals to report on care measures. Another commenter indicated that a higher data completeness criteria threshold amounts to a census of available patient data, as opposed to a sample, which can be prone to error and as a result, higher data completeness thresholds do not always yield more accurate depictions of quality performance. As another option for CMS to explore, one commenter suggested that CMS consider a data completeness criteria threshold that meets a minimum reliability score of 0.80, which would increase the reliability and confidence of quality measure performance scores.

Response: We established the data completeness criteria with the intention of ensuring that more quality data is reported (compared to the previous reporting program, Physician Quality Reporting System (PQRS)) and the data submitted for quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance. With regard to some commenters' suggestion to consider the data completeness criteria threshold based on sample size, we are concerned that having MIPS eligible clinicians report on a fixed number of patients may not necessarily be a representative sample of the MIPS eligible clinician's patient population and, therefore, may not allow for accurate assessment of each MIPS eligible clinician's quality performance. The establishment of the data completeness criteria threshold and the adoption of higher data completeness criteria thresholds ensures a more accurate assessment of a MIPS eligible clinician's performance on quality measures (81 FR 77120, 82 FR 53632, 83 FR 59758, 86 FR 65436, and 87 FR 70049).

After consideration of public comments, we are finalizing, as proposed, to maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and

2030 MIPS payment years. Specifically, we are finalizing, as proposed, the proposals in § 414.1340(a), (b), and (d):

- At paragraph (a)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients that meet the measure's denominator criteria, regardless of payer.
- At paragraph (b)(4), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, a MIPS eligible clinician, group, virtual group, subgroup, and APM Entity submitting quality measures data on Medicare Part B claims measures must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's patients seen during the corresponding performance period to which the measure applies.
- At paragraph (d)(1), for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years, an APM Entity, specifically a Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

(d) Selection of Quality Measures

(i) Addition of New Quality Measures

(A) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, CMS receives public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Pursuant to the established PRMR process (additional information regarding the PRMR process is available at *https://p4qm.org/PRMR*), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-stakeholder panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The pre-rulemaking process begins with CMS's publication of measures under consideration for use in Medicare (the MUC List). Each measure on the MUC List is reviewed by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.

The final vote of a multistakeholder committee convened by the CBE may result in the following disposition of a measure: recommended, recommended with conditions, do not recommend, or no consensus. A ''no consensus'' recommendation signals continued disagreement among the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. Quality measures that are considered for potential implementation in MIPS starting with the CY 2025 performance period were included on the 2023 Measures Under Consideration (MUC) List (available at *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx*). The new MIPS quality measures finalized, as proposed, are described in Table Group A of Appendix 1 of this final rule. There may be cases in which the CBE does not recommend for a measure to move forward to the rulemaking process and eventual implementation due to a measure not being endorsed by the CBE or other CBE, but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

(ii) Removal of Quality Measures

In the CY 2025 PFS proposed rule, we proposed to codify previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range); the MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to the following:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measuredevelopment.html*.
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and

improvement in performance can no longer be made.

Lastly, in the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure.

We are finalizing, as proposed, the codification of the aforementioned criteria established for the removal of MIPS quality measures from the MIPS quality measure inventory in § 414.1330(c), respectively.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2024 PFS final rule (88 FR 79556 through 79964), CY 2023 PFS final rule (87 FR 70250 through 70633), CY 2022 PFS final rule (86 FR 65687 through 65968), CY 2021 PFS final rule (85 FR 85045 through 85377), CY 2020 PFS final rule (84 FR 63205 through 63513), CY 2019 PFS final rule (83 FR 60097 through 60285), CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174), and CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). We proposed changes to the MIPS quality measure inventory, as set forth in Appendix 1 of the CY 2025 PFS proposed rule, including the following: the addition of new measures; updates to specialty sets (that is, creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets); removal of existing measures; and substantive changes to existing measures. For the CY 2025 performance period, we proposed an inventory of 196 MIPS quality measures.

The new MIPS quality measures that we proposed to include in MIPS for the CY 2025 performance period and future years can be found in Table Group A of Appendix 1 of the CY 2025 PFS proposed rule. For the CY 2025 performance period, we proposed 9 new MIPS quality measures, which includes 5 high priority measures, of which 2 are also patient-reported outcome measures.

On January 3, 2024, we announced that we will be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 9 (CY 2017 performance period/2019 MIPS payment year through CY 2025 performance period/2027 MIPS payment year) of MIPS under the Quality Payment Program.[844] The recommendations we received were based on the MIPS quality measures finalized in the CY 2024 PFS final rule and the 2023 MUC List; the recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are proposed in this proposed rule. We proposed the addition of a new specialty set and additionally proposed modifications to existing specialty sets as described in Table Group B of Appendix 1 of the CY 2025 PFS proposed rule. Modifications to specialty sets include the addition of new measures and/or existing measures within the MIPS quality measure inventory, removal of measures, and/or substantive changes to previously finalized measures (we referred readers to Table Group D of Appendix 1 in the CY 2025 PFS proposed rule). Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In addition to establishing new individual MIPS quality measures, modifying existing specialty sets, and creating new specialty sets as described in Tables Group A and Group B of Appendix 1 of the CY 2025 PFS proposed rule, we referred readers to Table Group C of Appendix 1 of the CY 2025 PFS proposed rule for a list of MIPS quality measures proposed for removal and applicable rationale for each measure. We have previously specified certain criteria that will be used when we are considering the removal of a measure (81 FR 77136 and 77137; 83 FR 59763 through 59765; 84 FR 62957 through 62959); and such criteria is outlined in the proposed § 414.1330(c) (as further discussed in section IV.A.4.e.(1)(d)(ii) of the CY 2025 PFS proposed rule (89 FR 62040)). For the CY 2025 performance period, we proposed to remove 11 MIPS quality measures based on the previously established criteria. Of the 11 MIPS quality measures proposed for removal, 2 MIPS quality measures are duplicative to a proposed new MIPS quality measure; 3 MIPS quality measures are duplicative of current measures; 1 MIPS quality measure has reached the topped out lifecycle; 2 MIPS quality measures are extremely topped out; 1 MIPS quality measure is no longer owned/maintained; and 2 MIPS quality measures have limited adoption and consequently, have not been able to establish benchmarks to provide a meaningful impact to quality improvement. We have continuously communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set (*see,* for example, 83 FR 59763 through 59765). Seven of the MIPS quality measures proposed for removal are process measures that would not provide granular information related to disparities. The proposal to remove the MIPS quality measures described in Table Group C of Appendix 1 of the CY 2025 PFS proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to removing measures should occur through an iterative process that includes an annual review of the MIPS quality measures to determine whether they meet our removal criteria.

Also, we proposed substantive changes to several MIPS quality measures, which can be found in Table Group D of Appendix 1 of the CY 2025 PFS proposed rule. We have previously established criteria that would apply when we are considering making

[844] Message to the Quality Payment Program listserv on January 3, 2024, entitled ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2025 Performance Year of the Merit-based Incentive Payment System (MIPS).''

substantive changes to a quality measure (81 FR 77137, and 86 FR 65441 through 65442). We proposed substantive changes to 66 MIPS quality measures, which includes 2 MIPS quality measures previously retained for utilization only in MVPs (we referred readers to Table Group DD of Appendix 1 of the CY 2025 PFS proposed rule for such measures). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The aforementioned proposed inventory of 196 MIPS quality measures includes 193 MIPS quality measure available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)). In the CY 2024 PFS final rule, we removed the following 3 MIPS quality measures from traditional MIPS, but retained for utilization in MVPs: Quality #112: Breast Cancer Screening; Quality #113: Colorectal Cancer Screening; and Quality #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79338 and 79897 through 79902). As noted in the CY 2025 PFS proposed rule, some MIPS quality measures available in traditional MIPS and/or MVPs are measures adopted by the Shared Savings Program for utilization under the APP, specifically the APP quality measure set and the newly established APP Plus quality measure set, as discussed in section IV.A.4.c.(3) of the CY 2025 PFS proposed rule. For the MIPS quality measures available in the APP quality measure set and APP Plus quality measure set for the CY 2025 performance period, we refer readers to section IV.A.4.c.(1) and section IV.A.4.c.(3) of this final rule.

Lastly, as described in the CY 2025 PFS proposed rule, we proposed a substantive change to the following administrative claims measure, Quality #492: Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (we refer readers to Table Group D of Appendix 1 of this final rule), that would be applied retroactively starting with the CY 2023 performance period/2025 MIPS payment year (89 FR 62042). In the CY 2023 PFS final rule, we inadvertently specified the measure was available at the individual clinician level. The inclusion of the availability of the measure at the individual clinician level is a misrepresentation and erroneously conveys to MIPS eligible clinicians reporting at the individual clinician level that the measure is available to meet the minimum required number of measures to report under traditional MIPS or an MVP. The measure was tested and developed for implementation at the group, virtual group, subgroup via an MVP, and APM Entity levels. Thus, the measure is limited to groups, virtual groups, subgroups via an MVP, and APM Entities participating in MIPS. We believe that a failure to apply this substantive change retroactively would be contrary to the public interest.

Prior to the finalization of this measure as a new measure available within the MIPS quality measure inventory in the CY 2023 PFS final rule, the measure was initially proposed as a new measure in the CY 2022 PFS proposed rule. Based on the public comments received in response to the initial proposal of this measure in the CY 2022 PFS proposed rule, there were concerns regarding the attribution of certain patients to clinicians, particularly the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. As a result, the measure was not finalized as part of the CY 2022 PFS final rule; however, we noted that we would continue to consider how to implement condition-specific measures such as this measure under MIPS (86 FR 65692 through 65694).

In the CY 2023 PFS proposed rule, we re-proposed this measure, which mitigated the concerns regarding the attribution of such patients to clinicians by excluding patients at advanced stages of heart failure and requiring that a group, virtual group, subgroup via an MVP, and APM Entity to include at least 1 cardiologist (and a 21-patient case minimum); and subsequently, the measure was finalized in the CY 2023 PFS final rule (87 FR 70266 through 70271). The intent of the measure is for assessment of performance to be conducted at the group, virtual group, subgroup via an MVP, and APM Entity levels. The measure was not tested, developed, or implemented at the individual clinician level. For this measure to be available at the individual clinician level, the measure would need to be tested at the individual clinician level to establish validity, reliability, and risk adjustments at the individual clinician level (89 FR 62042). It is not appropriate for the measure to be available at the individual clinician level without further testing. Consequently, any assessment of data for this measure at the individual clinician level would produce invalid and unreliable results. By retroactively applying the substantive change to this measure (modifying the measure to remove the individual clinician level as an option) effective starting with the CY 2023 performance period/2025 MIPS payment year, the level of reporting available for the measure will align with the intent, implementation, and operationalization of the measure, and clarify that the measure is not available at the individual clinician level.

We solicited public comment on the proposals to modify the quality performance category measure inventory, a set of 196 MIPS quality measures for the CY 2025 performance period, which includes the following:

- Implementation of 9 new MIPS quality measures: 5 high priority measures, of which 2 are also patient-reported outcome measures;
- Removal of 11 MIPS quality measures: 2 MIPS quality measure are duplicative to a proposed new quality measure; 3 MIPS quality measures are duplicative to current quality measures; 1 MIPS quality measure has reached the topped-out lifecycle; 2 MIPS quality measures are extremely topped out; 1 MIPS quality measure is no longer owned/maintained; and 2 MIPS quality measures have limited adoption and consequently, have not been able to establish benchmarks to provide a meaningful impact to quality improvement; and
- Substantive changes to 66 MIPS quality measures.

We refer readers to Table Groups A through DD of Appendix 1 of this final rule for a summary of the public comments received regarding the proposed modifications to the MIPS quality measure inventory for the CY 2025 performance period and the discussion regarding final decisions.

After consideration of public comments, and for the reasons stated in the aforementioned Table Groups A through DD of Appendix 1 of this final rule and the CY 2025 PFS proposed rule (89 FR 62251 through 62570), we are finalizing, with modification, a measure set of 195 MIPS quality measures (192 MIPS quality measures are available in traditional MIPS and 3 MIPS quality measures are available only in MVPs) in the inventory for the CY 2025 performance period, which includes the following:

- Implementation of seven new MIPS quality measures of which three are high priority measures;
- Removal of 10 MIPS quality measures: 2 MIPS quality measure are duplicative to a proposed new quality measure; 2 MIPS quality measures are

duplicative to current quality measures; 1 MIPS quality measure has reached the topped-out lifecycle; 2 MIPS quality measures are extremely topped out; 1 MIPS quality measure is no longer owned/maintained; and 2 MIPS quality measures have limited adoption and consequently, have not been able to establish benchmarks to provide a meaningful impact to quality improvement; and

- Substantive changes to 66 MIPS quality measures.

(e) Quality Performance Category Requests for Information

In the CY 2025 PFS proposed rule, we included the following Requests for Information (RFIs) (89 FR 62042 through 62044).

(i) Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey Request for Information

We solicited public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. During the 2023 CAHPS for MIPS Web Mode Field Test, we found that adding the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration resulted in an increased response rate. We specifically requested comment on (1) whether the increase in response rate would outweigh a possible increase in the cost of survey administration associated with the addition of a web-based survey mode to the current mail-phone survey protocol, and (2) if providing email addresses to vendors would be feasible for groups, virtual groups, subgroups, and APM Entities (including Shared Savings Program ACOs).

We thank commenters for their feedback on this RFI, which may be considered in future rulemaking.

(ii) Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs Request for Information

We are committed to elevating the patient voice in healthcare. One critical approach to elevating the patient voice that is aligned with the CMS National Quality Strategy and strategy of the CMS Innovation Center is to include more Patient-Reported Outcome Measures (PROMs) and Patient-Reported Outcome Performance Measures (PRO–PMs) in CMS quality reporting and payment programs and CMS Innovation Center Models. As we move forward with including more PROMs and PRO–PMs in CMS quality reporting and payment programs and CMS Innovation Center Models, it is important to develop a set of guiding principles and considerations for the selection and implementation of PROMs or PRO–PMs. Through this RFI, we sought comment regarding the overarching principles and considerations related to data infrastructure, selection, feasible implementation, and patient engagement of PROMs and PRO–PMs.

We thank commenters for their feedback on this RFI, which may be considered in future rulemaking.

(2) Cost Performance Category

Section 1848(q)(2)(A) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

We proposed to add six new episode-based measures to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. These six measures include:

- Chronic Kidney Disease (CKD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive care to manage and treat CKD stages 4 and 5;
- End-Stage Renal Disease (ESRD), which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for patients who receive medical care to manage ESRD;
- Kidney Transplant Management, which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for ongoing kidney transplant-related care and management starting at least 90 days after transplant surgery;
- Prostate Cancer, which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for the management and treatment of prostate cancer;
- Rheumatoid Arthritis, which assesses MIPS eligible clinicians on the risk-adjusted and specialty-adjusted cost to Medicare for the management and treatment of rheumatoid arthritis; and
- Respiratory Infection Hospitalization, which assesses MIPS eligible clinicians on the risk-adjusted cost to Medicare for the inpatient treatment of respiratory infection.

We proposed modifications to two existing episode-based measures so that their specifications reflect modified versions beginning with the CY 2025 performance period/2027 MIPS payment year. These two measures are:

- Cataract Removal with Intraocular Lens (IOL) Implantation,[845] which assesses MIPS eligible clinicians on the risk-adjusted cost to Medicare for cataract removal procedures; and
- Inpatient (IP) Percutaneous Coronary Intervention (PCI),[846] which assesses MIPS eligible clinicians on the risk-adjusted cost to Medicare for the inpatient PCI treatment of patients who present with a cardiac event.

We proposed that MIPS eligible clinicians must be attributed a minimum of 20 cases for each of the proposed six new measures. In addition, we proposed to maintain the existing case minimums for the two measures we proposed to modify in this rulemaking, which are a 20-episode case minimum for the IP PCI measure and a 10-episode case minimum for the Cataract Removal with IOL Implantation measure. We also proposed to update the operational list of care episode and patient condition groups and codes to reflect these new and modified measures.

Finally, we proposed to adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category, which we also proposed to codify at § 414.1350(e).

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to § 414.1350 and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), and CY 2024 PFS final rule (88 FR 79339 through 79349).

For more details on the proposals in this section on which we invited comments, we refer readers to the CY

[845] The current title of this measure is the Routine Cataract Removal with Intraocular Lens (IOL) Implantation measure, which we proposed this retitled, modified measure would replace.

[846] The current title of this measure is the ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) measure, which we proposed this retitled, modified measure would replace.

2025 PFS proposed rule (89 FR 62044 through 62055).

(a) Updates to MIPS Cost Measure Inventory

(i) Background on Episode-Based Cost Measure Development, Reevaluation, and Pre-Rulemaking Review

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 29 cost measures in the cost performance category for the CY 2024 performance period/2026 MIPS payment year, comprising of 27 episode-based measures covering a range of conditions and procedures and 2 population-based measures.

We worked with the measure development contractor to identify the proposed six new episode-based measures through empirical analyses and public comment. These measures cover clinical topics and MIPS eligible clinicians practicing in certain specialties for whom there are currently limited or no applicable cost measures. As such, these measures will help fill gaps in the cost performance category's measure set and support the transition from traditional MIPS to MVPs by allowing new MVPs to be created and enhancing existing MVPs. They also address interested parties' feedback about the need for more clinically refined episode-based measures in the cost performance category. Finally, they increase the cost coverage of care episode and patient condition groups, moving closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act.

The measure development contractor also conducts comprehensive reevaluation every 3 years after a measure is implemented in MIPS to ensure that measures continue to meet criteria for importance, scientific acceptability, and usability in line with the CMS Measures Management System Blueprint (*https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*). As a result of this process, we proposed to modify two episode-based measures currently in use (the Routine Cataract Removal with Intraocular Lens (IOL) Implantation and ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) measures), and proposed the modified Respiratory Infection Hospitalization as a new measure, replacing the Simple Pneumonia with Hospitalization measure previously removed from the cost performance category.

We refer readers to the CY 2025 PFS proposed rule (89 FR 62045 through 62046; 89 FR 62048 through 62050) for more detailed information on the development and reevaluation of episode-based measures, particularly the episode-based measures we proposed to adopt and modify in the proposed rule.

Following development and reevaluation processes, the episode-based measures were submitted to the Measures Under Consideration (MUC) List and evaluated for potential use in MIPS by the Pre-Rulemaking Measure Review (PRMR) process. This process involved reviews by the PRMR Clinician Committee Advisory and Recommendation Groups, as well as 2 public comment periods. The PRMR Clinician Committee Advisory and Recommendation Groups review the measure information, a preliminary analysis of the measures and their testing information developed by the consensus-based entity (CBE) (contracted in accordance with section 1890 of the Act), and public comments. The PRMR Clinician Committee Recommendation Group met in January 2024 to discuss in more detail the measures we proposed to adopt and modify and voted on their recommendations for the appropriateness of these measures' use in MIPS. We refer readers to the CY 2025 PFS proposed rule (89 FR 62051 through 62053) for more detailed information regarding the PRMR process and the PRMR groups' discussions, voting results, and recommendations for the measures we proposed to adopt and modify.

Although we may pursue endorsement by the CBE, contracted in accordance with section 1890 of the Act, for the proposed measures at a later time, we are not required to use only CBE endorsed measures in MIPS. We emphasize that cost measures undergo extensive review and testing before they are implemented in MIPS. We continue to believe in the strength of the episode-based measures proposed for adoption and modification in this rulemaking, based on valid and reliable testing results and extensive review from interested parties as part of the measure development and PRMR process. We refer readers to our discussion in the CY 2025 PFS proposed rule (89 FR 62051) for more information regarding this testing and review process.

In section IV.A.4.e.(2)(a)(ii) of this final rule, we describe our proposal to adopt six new measures in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. In section IV.A.4.e.(2)(a)(iii) of this final rule, we describe our proposal to modify two existing measures in the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. In section IV.A.4.e.(2)(b)of this final rule, we describe our proposal that MIPS eligible clinicians must be attributed a minimum number of cases for each of these measures to be assessed and scored on such measure.

(ii) Proposals to Adopt Six New Episode-Based Measures Beginning with the CY 2025 Performance Period/2027 MIPS Payment Year

In this section of this final rule, we describe generally the six new episode-based measures, which we proposed to add to the cost performance category beginning with the CY 2025 performance period/2027 MIPS payment year. While we generally describe these six episode-based measures in this section of this final rule, we refer readers to our description of these measures in the CY 2025 PFS proposed rule (89 FR 62046 through 62048) for more detailed information.

In conjunction with our measure development contractor, we developed these measures with consideration of the common standards that are described in the CY 2022 PFS final rule (86 FR 65455 through 65459) to ensure consistency across episode-based measures being developed. The six new episode-based measures we proposed met all the requirements described in the CY 2022 PFS final rule, including the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment. Generally, for all episode-based measures, we exclude episodes where costs cannot be fairly compared to the costs for the whole cohort in the episode-based measure. These exclusions, like other features of each episode-based measure, are developed with extensive clinician and interested parties' engagement. We have specified exclusions for all six proposed episode-based measures. We also apply a risk adjustment model to each episode-based measure in the cost performance category. All six proposed episode-based measures have been risk-adjusted in accordance with the measure's risk adjustment model. We refer readers to our description of the risk adjustment model applied to each of the proposed measures in the CY 2025 PFS proposed rule (89 FR 62047).

More information on the episode-based measure development requirements, which were outlined so that external interested parties could develop measures in the future, are available in the Blueprint for the CMS Measures Management System (*https://mmshub.cms.gov/blueprint-measure-lifecycle-overview*) and the Meaningful Measures Initiative (*https://www.cms.gov/medicare/quality/meaningful-measures-initiative*).

The episode-based measures that we proposed for adoption beginning with the CY 2025 performance period/2027 MIPS payment year are set forth in Table 72.

TABLE 72: Episode-Based Measures Beginning with CY 2025 Performance Period/2027 MIPS Payment Year

Measure Name	Episode Type
Chronic Kidney Disease (CKD)	Chronic condition
End-Stage Renal Disease (ESRD)	Chronic condition
Kidney Transplant Management	Chronic condition
Prostate Cancer	Chronic condition
Rheumatoid Arthritis	Chronic condition
Respiratory Infection Hospitalization	Acute inpatient medical condition

The five chronic condition episode-based measures assess outpatient treatment and ongoing management of the following chronic conditions: CKD, ESRD, kidney transplant management, prostate cancer, and rheumatoid arthritis. These measures assess the costs of services related to these conditions, such as physician services, imaging or diagnostic services, emergency room care or hospitalizations, medications, or other services related to ongoing management or post-acute care. The measure construction for these proposed measures follows the approach described in the CY 2022 PFS final rule (86 FR 65445 through 65461), which also includes detailed discussion of the attribution methodology and examples of how episodes are attributed.

We refer readers to our description of our overall attribution methodology for cost measures in the CY 2025 proposed rule (89 FR 62047 and 62048). More information about the chronic condition episode-based measures attribution methodology, including a one-page summary and a Frequently Asked Questions (FAQ) document, is available at *https://www.cms.gov/files/zip/mips-chrcondition-episode-based-cost-measures-attribution-methodology-2023-zip.zip*. More general information about the overall chronic condition cost measure framework is available at *https://www.cms.gov/files/document/chronic-condition-cost-measure-framework-poster.pdf*.

The Respiratory Infection Hospitalization measure is an acute inpatient medical condition episode-based measure, which focuses on the inpatient treatment of respiratory infection and is attributed to clinicians and clinician groups treating a patient during the hospitalization. It includes the cost of services related to the inpatient treatment of a respiratory infection, such as initial inpatient services, subsequent outpatient physician visits, and emergency room care or hospitalizations for related complications. As described further in the CY 2025 PFS proposed rule (89 FR 62049), the Respiratory Infection Hospitalization measure is the reevaluated version of the Simple Pneumonia with Hospitalization measure, adopted for MIPS in the CY 2019 PFS final rule (83 FR 59767 through 59773) and removed from MIPS in the CY 2024 PFS final rule (88 FR 79348 and 79349). This new, modified measure addresses the concerns with the previous version of the measure by expanding the patient cohort to include beneficiaries hospitalized for pneumonia and related respiratory infections, reflecting the coding changes as described in the CY 2024 PFS final rule (*88 FR 79348* and *79349*). The modified measure also incorporates feedback we received from interested parties about appropriate risk adjustment and exclusions during the reevaluation process of the prior Simple Pneumonia with Hospitalization measure.

The specifications for all six episode-based measures we proposed for adoption in this rulemaking are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*. The specifications documents for each measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides detailed methodology describing each step to construct the measure, including: identifying patients receiving care; defining an episode-based measure; attributing episodes to MIPS eligible clinicians and clinician groups; assigning costs; defining exclusions; risk adjusting; and calculating measure score. Second, the measure codes list file contains the codes used in the measure specifications, including the episode triggers, attribution, stratification, assigned items and services, exclusions, and risk adjustors.

More information about the episode-based measures is available in the Measure Justification Forms, which were posted to support PRMR discussions. These documents provide a comprehensive characterization of the measures, their justification, and testing results of the measures' specifications at this time. These documents are available through the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures*.

We invited comments on the proposals in this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters shared their support of our proposal to adopt and implement the six new episode-based measures and also shared support generally for our development of additional episode-based measures. One commenter stated that they appreciate that cost measurement can reduce healthcare costs. Another commenter supported CMS's efforts to expand the set of available episode-based measures so that all specialists and sub-specialists have adequate measures available for

scoring in the MIPS cost performance category.

Response: We appreciate the commenters' support of our proposal to adopt the six new episode-based measures in the MIPS cost performance category and our efforts to develop additional episode-based measures in the future.

Comment: One commenter supported the adoption and implementation of the proposed Chronic Kidney Disease and End-Stage Renal Disease episode-based measures. The commenter noted the adoption of these measures would further support the idea that early identification is essential and beneficial for both patients and providers, and emphasized the importance of kidney health evaluation screening in chronic kidney disease and high-risk populations.

Response: We thank the commenter for their support for the adoption and implementation of the Chronic Kidney Disease and End-Stage Renal Disease episode-based measures in MIPS, and we agree with the importance of measuring performance related to the management and treatment of kidney health.

Comment: One commenter did not support the inclusion of the Kidney Transplant Management episode-based measure. The commenter raised concerns that the measure may create unintended consequences for the care outcomes of kidney transplant patients and potentially impact incentives for clinicians to use hard-to-place organs in kidney transplants, which may result in higher costs of care for kidney transplant management. The commenter stated that there is not enough information available on optimal post-renal transplant patient care and that an episode-based measure could lead to the possibility of patient harm and decreased survival of transplant organs. Another commenter urged CMS to monitor for impacts of implementation of this measure on access to appropriate transplantation care and to ensure the measure does not disincentivize referrals of medically appropriate patients for transplant evaluation or the use of breakthrough pharmaceuticals.

Response: We disagree that the Kidney Transplant Management episode-based measure would create unintended consequences for the care outcomes of patients or that it would disincentivize the use of hard-to-place organs, which are organs that are accepted and transplanted later in the donor organ matching process.[847] This is the process where a donor kidney is matched with a transplant recipient, ranked in order of need and likelihood of survival. In our testing, we understood hard-to-place organs as typically organs from a deceased donor kidney with a high Kidney Donor Profile Index (KDPI). A higher value indicates that the donor kidneys will be less likely to function.[848] The measure uses risk adjustment to neutralize the impact of kidney transplant organ characteristics and other factors on clinician performance. The risk adjustment model includes variables related to the transplanted organ, such as whether the donor is living or deceased, and whether the kidney was from a blood type incompatible donor. Deceased donors or donors with incompatible blood types are examples of how a kidney organ may be accepted later in the ranked list of transplant recipients requiring a kidney, and therefore, harder to place. The measure also risk adjusts for patient-level factors, including comorbidities, demographics, disability status, recent use of long-term care, and dual enrollment in Medicare and Medicaid. These risk adjustment variables help ensure that the measure is accounting for higher complexity and higher cost patients, and reduces the likelihood of unintended consequences, such as clinicians choosing not to provide care to higher complexity patients. We will monitor the impact of the Kidney Transplant Management episode-based measure for any unintended consequences that may be identified through public comment or empiric testing during the measure maintenance process.

Comment: A few commenters expressed support for the proposal to adopt and implement the Respiratory Infection Hospitalization episode-based measure. One commenter noted that this measure covers more conditions that can cause a respiratory hospitalization than the original Simple Pneumonia with Hospitalization episode-based measure.

Response: We thank the commenters for their support. We agree that the Respiratory Infection Hospitalization episode-based measure includes a larger patient cohort than the Simple Pneumonia with Hospitalization episode-based measure did, which will allow for more comprehensive assessment of the costs of care related to inpatient hospitalizations for respiratory infections. By expanding the patient cohort, the measure will capture additional MIPS eligible clinicians and patients, resulting in the measure having greater potential impact on the value of care.

Comment: One commenter did not support implementation of the Respiratory Infection Hospitalization episode-based measure in MIPS due to overarching concerns they had with the attribution methodology and actionability of episode-based measures. They stated that the measure may be more appropriate at a systems-level, and that they could support the measure's adoption and use in other Medicare programs instead of MIPS. More specifically, they raised concerns that the measure included services that occur within 30 days of the trigger event and questioned whether hospitalists, who may be attributed the measure, have control over these costs. They also stated that hospital costs are typically fixed by the MS–DRG associated with the hospital stay, so the measure may have limited actionability for MIPS eligible clinicians.

Response: We disagree with the commenters' concerns about the attribution methodology of the Respiratory Infection Hospitalization episode-based measure. As we described in the CY 2025 PFS proposed rule (89 FR 62047 and 62048), the attribution methodology for this measure was developed with input from a TEP, a Clinician Expert Workgroup, and patients, families, and caregivers. The measure only includes the costs of services clinically related to respiratory infection hospitalizations; MIPS eligible clinicians are not assessed on clinically unrelated costs that may occur during the 30-day episode window. We determined that a 30-day episode window is appropriate based on empirical data presented by the measure developer and based on input from the Clinician Expert Workgroup on reasonable timelines for clinicians to influence clinically related costs, such as respiratory infection-specific complications, antibiotic-related complications, and post-acute care. Additionally, while the assigned costs of inpatient hospitalizations that trigger episodes are standardized by MS–DRG, the measure can assess variation in costs based on the additional clinically related services provided during the 30-day episode window, such as the cost of post-discharge care and potential complications or rehospitalization. This

[847] Ashiku L, Dagli C. Identify Hard-to-Place Kidneys for Early Engagement in Accelerated Placement With a Deep Learning Optimization Approach. Transplant Proc. 2023 Jan-Feb;55(1):38–48. doi: *10.1016/j.transproceed.2022.12.005.* Epub 2023 Jan 12. PMID: 36641350.

[848] Organ Procurement & Transplantation Network, Accelerated placement of hard-to-place kidneys. *https://optn.transplant.hrsa.gov/professionals/improvement/improving-organ-usage-and-placement-efficiency/protocols-for-expedited-placement-variance/accelerated-placement-of-hard-to-place-kidneys/.*

measure is attributed to individual MIPS eligible clinicians and groups that provide inpatient E/M services for patients hospitalized for respiratory infections. However, the care that MIPS eligible clinicians provide during and following an inpatient hospitalization can influence the occurrence, frequency, and intensity of services that patients receive during the episode and impact costs of care. For example, appropriate reduction in antibiotic use can reduce costly readmissions for respiratory infections.[849] For more discussion on the potential for reduction in readmissions and appropriate use of antibiotics, we refer readers to the measure rationale available in the Measure Justification Form available for download at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.*

Comment: Commenters expressed concerns with implementing the Rheumatoid Arthritis episode-based measure, noting that the PRMR Recommendation Group voted ''do not recommend'' when considering its implementation in MIPS. Commenters were concerned that this may set a precedent or undermine the PRMR evaluation process.

Response: Each measure that we propose for use in MIPS is considered on a case-by-case basis. We weigh the PRMR recommendations in any decision to propose measures for adoption in MIPS; however, PRMR support is not required for a cost measure to be adopted and implemented into MIPS. As noted previously, cost measures undergo extensive review and testing before we propose to adopt them in MIPS. We proposed the adoption and modification of these cost measures in the CY 2025 PFS proposed rule based on testing results and extensive review from interested parties as part of the measure development and PRMR process. We refer readers to our discussion in the CY 2025 PFS proposed rule (89 FR 62051) for more information regarding this testing and review process.

For the Rheumatoid Arthritis measure, we do not agree with the PRMR Recommendation Group's recommendation as we described in detail in the CY 2025 PFS proposed rule (89 FR 62051 through 62053). Testing conducted during and after measure development demonstrates that the Rheumatoid Arthritis measure is reliable and valid. Additionally, the Rheumatoid Arthritis measure represents a high priority and high-cost area of care with potential for individual MIPS eligible clinicians and groups to improve their performance on the measure.

Finally, we do not agree that a decision to adopt and implement the Rheumatoid Arthritis measure would set a precedent or undermine the PRMR process. The role of the PRMR process is to review potential measures for their use in a CMS program and provide a recommendation to CMS for consideration. We have reviewed the PRMR discussions and recommendations on the Rheumatoid Arthritis measure and considered this feedback in our decision to propose the measure. As previously stated, we consider each measure on a case-by-case basis when determining whether to adopt and implement a measure in MIPS.

Comment: Commenters also reiterated concerns raised during the PRMR public comment period on the Rheumatoid Arthritis measure that current Medicare coverage guidelines, such as fail-first medication requirements and Self-Administered Drug exclusions, limit the types of care that clinicians can provide to rheumatoid arthritis patients, which could also impact cost measurement. One commenter requested that these limiting coverage guidelines be addressed before the episode-based measure can be a successful measurement of rheumatoid arthritis related care. Another commenter more generally requested that CMS review and address specialty society comments made during the PRMR public comment period before adopting the Rheumatoid Arthritis measure.

Response: While we appreciate the commenters' recommendations on broader Medicare coverage guidelines, the measure includes patients who are continually enrolled in Medicare and is stratified by episodes with and without Part D enrollment, so all MIPS eligible clinicians are being assessed on a population with similar Medicare coverage guidelines. These concerns were also raised during the PRMR public comment period, and we do not have concerns about these Medicare coverage guidelines negatively impacting MIPS eligible clinicians' performance on the measure. These guidelines may influence MIPS eligible clinician's practice patterns; however, the measure assesses each MIPS eligible clinician compared to the national average of all other MIPS eligible clinicians attributed the same measure for the same performance period. As such, all MIPS eligible clinicians are being assessed based on similar factors influencing clinicians' practice decisions. As a result, we do not believe that these Medicare coverage guidelines prevent the Rheumatoid Arthritis episode-based measure from successfully measuring cost performance related to the treatment and management of rheumatoid arthritis. We refer readers to section IV.A.4.f.(1)(d) of this final rule for more detailed discussion regarding our scoring methodology for cost measures.

The public comments we received during the PRMR process raised concerns that the measure holds rheumatologists accountable for costs outside of their control, in particular for costly medications that are used in good standards of care. The measure developer and Clinician Expert Workgroup considered what services to include in the measure that would be within the reasonable influence of attributed clinicians. Based on clinical input and empiric analysis, we include Part D drugs in the measure as they are important aspects of care provided for rheumatoid arthritis. The Clinician Expert Workgroup believed that any additional complexity by including Part D was outweighed by the need to capture these costs to appropriately assess clinician performance. The Clinician Expert Workgroup's discussions are available for review in meeting summaries posted on the Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.* Part D costs are standardized to remove price variation from non-clinical factors, such as drug manufacturers and plans. Additionally, the measure sub-groups for episodes for patients with and without Part D enrollment to account for expected differences in cost, such that episodes for patients with Part D enrollment are only directly compared with other episodes for patients with Part D enrollment.

We disagree with the public comments received during the PRMR process stating that the measure will not produce actionable results for MIPS eligible clinicians. Individual MIPS eligible clinicians and groups receive MIPS Performance Feedback for measures on which they are assessed, which they can review to identify potential opportunities to improve future cost performance. For example, MIPS eligible clinicians can review supplemental data reports to help identify differences between the characteristics of the national average episode for the measure and their

[849] Mauro, James, Saman Kannangara, Joanne Peterson, David Livert, and Roman A. Tuma. ''Rigorous Antibiotic Stewardship in the Hospitalized Elderly Population: Saving Lives and Decreasing Cost of Inpatient Care.'' JACAntimicrobial Resistance 3, no. 3 (09, 2021): 1. *https://doi.org/10.1093/jacamr/dlab118.*

attributed episodes, such as whether their episodes have higher than average costs associated with hospitalizations. Additionally, for the Rheumatoid Arthritis measure, there are a number of actions that clinicians can take to provide more efficient care. For instance, the Rheumatoid Arthritis measure includes the cost of hospitalizations and other complications of care, so by reducing the occurrence of potentially avoidable adverse events, clinicians can improve performance on the measure. In addition, peer-reviewed literature notes opportunities to improve the value of care provided to rheumatoid arthritis patients by carefully considering the use of disease-modifying anti-rheumatic drugs (DMARDs).[850] [851] Peer-reviewed literature also indicates that while patients are often prescribed corticosteroids for 6 months or more, guidelines indicate that corticosteroid use should be limited.[852] Chronic glucocorticoid use among rheumatoid arthritis patients is associated with a higher health care costs due to increased occurrence of adverse events (for example, developing diabetes or osteoporosis, cardiovascular events such as thrombotic stroke, myocardial infarction, or death).[853] [854] [855]

Comment: One commenter raised concerns that biosimilar medications are not included in the Rheumatoid Arthritis episode-based measure and the potential implications this would have on the measure's validity.

Response: We thank the commenter for raising these concerns. We agree that biosimilar medications are clinically relevant to rheumatoid arthritis management and believe the costs of biologic and biosimilar disease-modifying anti-rheumatic medications should be included in the Rheumatoid Arthritis episode-based measure. We modified the final specifications for the Rheumatoid Arthritis episode-based measure to include biosimilar medications in addition to biologic medications. For the full list of medications included in the measure, we refer readers to the measure codes list that is available for download at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about*.

Comment: A few commenters recommended that CMS use a specialty attribution exclusion to exclude both ophthalmologists and optometrists from the Rheumatoid Arthritis measure to avoid attributing ophthalmic practices. One commenter stated concerns that the inclusion of ophthalmic medications within the Rheumatoid Arthritis measure could results in clinicians being attributed Rheumatoid Arthritis episodes based on the treatment of ophthalmic complications, rather than treatment of Rheumatoid Arthritis. One commenter further recommended excluding dermatologists.

Response: We thank the commenters for their suggestions; however, we do not believe it is appropriate to apply a specialty attribution exclusion to the Rheumatoid Arthritis episode-based measure for all ophthalmologists, optometrists, and dermatologists. Episode-based measures use care patterns identified in claims data to attribute MIPS eligible clinicians rather than relying on clinician specialties. Input from a TEP and Clinician Expert Workgroup informed the attribution methodology that we proposed for the Rheumatoid Arthritis measure. The Clinician Expert Workgroup advised ophthalmic medications may be used to treat symptoms related to rheumatoid arthritis, and therefore, recommended including these medications as clinically related service costs. However, we agree with the commenter's concerns that the inclusion of ophthalmic medications could result in Rheumatoid Arthritis episodes being attributed to MIPS eligible clinicians prescribing ophthalmic medications for other purposes, but who are not providing broader treatment and management for rheumatoid arthritis. Based on the public comments we received, we have removed ophthalmic medications from the measure specifications prior to implementation of this measure for the CY 2025 performance period/2027 MIPS payment year. We refer readers to the revised measure specifications, which are available here; *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures.*

Comment: One commenter raised concerns about the Rheumatoid Arthritis episode-based measure, stating that the measure does not offer actionable insights for improving costs of care and that it does not differentiate the appropriateness of costs in relation to quality and patient outcomes. They requested CMS reconvene the Clinician Expert Workgroup to reevaluate the validity of the measure, given concerns with cost scoring methodology.

Response: We disagree that the Rheumatoid Arthritis episode-based measure does not offer actionable insights for MIPS eligible clinicians. We have identified many clinical actions that can improve performance on this cost measure based on peer-reviewed literature and discussions with persons and families with lived experiences. These include early diagnosis of rheumatoid arthritis, improving treatment through appropriate use of monitoring tests, appropriate use of medications and reducing medication non-adherence, and improved care coordination to reduce treatment complications. We provide annual MIPS Performance Feedback and patient-level reports, which include information on the services that a MIPS eligible clinician provides and the costs of those services to help inform their care decisions. In response to requests for more information, beginning for the CY 2023 performance period/2025 MIPS payment year, we have also introduced a new supplemental cost report that provides more information for MIPS eligible clinicians to review about their cost measure scores. These reports are a new set of reports that compare a MIPS eligible clinician's costs to the national observed costs for certain types of services. The cost measure assesses costs directly related to treatment choices and the costs of other services, such as clinically related adverse outcomes or complications. With these supplemental cost reports, MIPS eligible clinicians can review differences between the characteristics of the national average episode for a measure and their attributed episodes to determine if there are any billing or care patterns that warrant additional investigation. For example, if MIPS eligible clinicians have higher than average costs associated with hospitalizations, MIPS eligible

[850] Choosing Wisely, ''Don't prescribe biologics for rheumatoid arthritis before a trial of methotrexate (or other conventional non-biologic DMARDs),'' 2013, *https://www.choosingwisely.org/clinician-lists/american-college-rheumatology-biologics-for-rheumatoid-arthritis/*.

[851] Drosos, A. et al., ''Therapeutic Options and Cost-Effectiveness for Rheumatoid Arthritis Treatment,'' *Current Rheumatology Reports,* 22, no. 8 (June 2020): 1–6, *https://doi.org/10.1007/s11926-020-00921-8*.

[852] George, M.D. et al., ''Variability in glucocorticoid prescribing for rheumatoid arthritis and the influence of provider preference on long-term use,'' *Arthritis Care & Research* 73, no. 11 (July 2020): 1597–1605, *https://doi.org/10.1002/acr.24382*.

[853] Black, R.J. et al., ''A Survey of Glucocorticoid Adverse Effects and Benefits in Rheumatic Diseases: The Patient Perspective,'' *Journal of Clinical Rheumatology* 23, no. 8 (December 2017): 416–420, *https://doi.org/10.1097/rhu.0000000000000585*.

[854] Wilson, J.C. et al., ''Incidence and Risk of Glucocorticoid-Associated Adverse Effects in Patients With Rheumatoid Arthritis,'' *Arthritis Care & Research,* 71, no. 4, (April 2019): 498–511, *https://doi.org/10.1002/acr.23611*.

[855] Best, J.H. et al., ''Association Between Glucocorticoid Exposure and Healthcare Expenditures for Potential Glucocorticoid-related Adverse Events in Patients with Rheumatoid Arthritis,'' *Journal of Rheumatology* 45, no. 3 (March 2018): 320–328, *https://doi.org/10.3899/jrheum.170418*.

clinicians could consider practice improvements to reduce the rates of potentially avoidable hospitalizations.

Additionally, MIPS is designed to assess MIPS eligible clinicians' performance on their quality and cost of care (each performance category score generally constituting 30 percent of a MIPS eligible clinician's final score), as well as improvement activities and meaningful use of CEHRT (see section 1848(q)(2)(A), (B) and (q)(5)(E) of the Act). MIPS thereby holistically assesses MIPS eligible clinicians' performance across various aspects of their practice, including both the quality and cost of their care in generally equal measure.

Before proposing the measure for use in MIPS, we tested the measure validity. Testing indicated that the Rheumatoid Arthritis measure reflects the cost directly related to treatment choices and the cost of related adverse outcomes such as downstream emergency department visits, hospitalizations, or post-acute care. For more information on validity testing, we refer readers to the Measure Justification Form available for download here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.* These testing results were made publicly available during the PRMR process in 2023.

Finally, we do not expect that the modifications we proposed for our cost scoring methodology will have any impact on the integrity of the Rheumatoid Arthritis episode-based measure. The cost performance category scoring changes we proposed in the CY 2025 PFS proposed rule (89 FR 62085 through 62088) do not impact the calculation of the Rheumatoid Arthritis episode-based measure or clinicians' average risk-adjusted costs per episode for this measure. Instead, the proposed modifications to the cost performance category's scoring methodology would affect how clinicians' average risk-adjusted costs per episode for all cost measures are benchmarked for MIPS scoring, and assignment of achievement points for each benchmark. We refer readers to section IV.A.4.f.(1)(d) of this final rule for further discussion regarding our proposals to modify scoring of measures in the cost performance category.

Comment: Some commenters expressed concerns about the Prostate Cancer episode-based measure, stating that the highly heterogenous nature of prostate cancer makes it inappropriate for cost measurement. Two commenters stated that the measure does not sufficiently account for the range of severity in prostate cancer patients and significant variation in treatment costs. One of the commenters stated that claims data is insufficient to address disease severity.

Response: We disagree with commenters that the Prostate Cancer measure does not account for prostate cancer severity. The Prostate Cancer measure accounts for severity using several claims-based risk adjustment variables (that is, Androgen Deprivation Therapy (ADT) drugs, chemotherapy, immunotherapy, prostatectomy, Prostate-Specific Antigen (PSA) tests, and radiation). Furthermore, the measure also stratifies (that is, sub-groups) episodes based on whether the patient had a metastatic cancer diagnosis or metastatic cancer drug usage in the year prior to the episode start. This is detailed in the measure specifications available on the Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/.* Testing showed that indicators of high-resource use (for example, chemotherapy and immunotherapy) were strong predictors of episode cost and the sub-groups, in conjunction with the risk adjustment model, adequately account for cost variation. These results are available in the Measure Justification Form available on the Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/.*

While the treatment for prostate cancer can vary substantially, we disagree that this was not accounted for during the development of the measure. The Clinician Expert Workgroup identified that prostate cancer severity can influence the type of treatment and its associated episode costs. As stated previously, the measure risk adjusts and stratifies by metastatic cancer to account for the impact of prostate cancer severity on variation in treatment costs. Furthermore, the current services assigned to the measure are those the Clinician Expert Workgroup determined to be clinically related to the treatment and management of prostate cancer and associated with the attributed clinician's role in managing the patient's care.

The measure's specifications reflect the Clinician Expert Workgroup's consensus on the best approach for accounting for cancer severity given information available in claims. The Clinician Expert Workgroup considered the use of prostate cancer staging information from other sources, such as electronic health records (EHRs) or registries, but these sources lacked current and complete staging information. Ultimately, these methods would not capture the full population of patients included in the measure, making a claims-based approach more feasible and meaningful. If more granular cancer staging information becomes available via claims, we may consider changes to the measure's construction in the future. The Clinician Expert Workgroup's discussions are available for review in meeting summaries posted on the Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.*

Comment: One commenter raised concerns that the majority of the PRMR panel did not support the Prostate Cancer measure. Another commenter raised concerns that the measure was not adequately tested following post-field-testing adjustments and requested CMS refrain from implementing the cost measure until the Clinician Expert Workgroup has been reconvened and testing has been completed on the refined measure that involves the broader oncology community.

Response: We disagree with commenters that the Prostate Cancer measure performance was not adequately tested following post-field-testing adjustments. The Prostate Cancer measure was tested extensively on its importance, scientific acceptability, feasibility, usability, and harmonization following the completion of its development and this testing information was included in the 2023 MUC List [856] and PRMR materials and publicly posted in the Measure Justification Form during PRMR discussions. These results were also noted for readers of the CY 2025 PFS proposed rule (89 FR 62045 through 62049) to reference.

The commenter's statement to involve the broader oncology community was unclear. However, we understand the commenter's reference to a broader oncology community to mean other interested parties involved in oncology care who were not members of the Prostate Cancer Clinician Expert Workgroup. We solicited broad input on the development and refinement of the measure from interested parties though a public comment period, Clinician Expert Workgroups, a TEP, and patients, families, and caregivers as discussed in the CY 2025 proposed rule (89 FR 62044 through 62055). While the PRMR committee did not reach consensus to support the Prostate Cancer measure, the measure testing results support the use of the measure. For example, testing found opportunities for MIPS eligible clinicians to improve cost performance,

[856] Overview of the List of Measures Under Consideration for December 1, 2023, *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

such as substantial variation in performance scores. We calculated the distribution of the measure score for MIPS eligible clinicians that meet the case minimum to determine if there are large gaps in measure scores, and therefore, performance. The 90th percentile score was more than double the 10th percentile score at the TIN level and more than triple at the TIN–NPI level. Clinicians who were in the 90th percentile had much higher average episode costs compared to clinicians who were in the 10th percentile. This suggests there is an opportunity for improving clinician cost performance by closing the gap between the most and least efficient providers.

Testing also showed that the measure far exceeded the 0.4 threshold for mean reliability, which we reaffirmed as the threshold for reliability in the CY 2022 PFS final rule (86 FR 64996). As noted in the CY 2025 PFS proposed rule (89 FR 62052 through 62053), the Prostate Cancer measure had a mean reliability of 0.68 at the TIN level and 0.62 at the TIN–NPI level. This is considered moderate to high reliability. Furthermore, the measure captures a high-cost clinical area, fills a gap in cancer care measurement in MIPS, and enhances the Advancing Cancer Care MVP.

Comment: One commenter expressed concerns regarding potential adverse consequences related to five of the newly proposed episode-based measures affecting clinicians who treat patients from specific backgrounds, particularly Black patients. The commenter stated that the ESRD, CKD, and Kidney Transplant Management measures do not adequately account for differences in disease presentation due to the previous inclusion of race in kidney function calculations, stating that Black patients may have previously received late diagnoses of kidney disease and therefore have higher treatment costs. The commenter raised similar concerns for the Prostate Cancer measure, stating that due to existing differences in disease presentation for Black patients, clinicians could potentially discriminate against Black patients who have more costly, advanced disease with the aim to improve their MIPS score. The commenter also raised equity concerns regarding the Rheumatoid Arthritis measure, suggesting that differences in disease severity and pain level for Black patients compared to other demographics could lead to lower MIPS scores for providers who care for these patients, particularly with the inclusion of Part D medication costs in the measure. Other commenters more generally requested that CMS appropriately accounts for social drivers of health (SDOH) in the episode-based measures.

Response: We thank the commenters for their feedback and agree that it is important to consider SDOH in cost measurement. The 5 new episode-based measures referenced by the commenter include dual Medicare and Medicaid enrollment status in the risk adjustment methodology.

When considering risk adjusting for SDOH, we aim to balance the tension between fairness in performance measurement for clinicians treating vulnerable patients and the risk of perpetuating disparities for these patients if clinicians are held to different standards for different populations. Throughout cost measure development, we have considered several variables to risk adjust for SDOH, including dual Medicare and Medicaid enrollment status, Race/Ethnicity, ICD–10 Z codes, and American Community Survey indices such as Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) index and deprivation index. We considered whether these variables are available for all patients and can be reliably used in risk adjustment, which have been barriers in the past to expanding risk adjustment for SDOH. We determined that dual Medicare and Medicaid enrollment status is still the most appropriate variable to consider for risk adjustment.

We selected this approach in consideration of current peer-reviewed literature on the topic and input from the measure developer, TEP, and Clinician Expert Workgroups. This analysis did consider race/ethnicity factors, however research shows that information found in claims lacks granularity to describe the diversity of the U.S. population, with only five categories available.[857] [858] In addition, the National Quality Forum stated race as ''qualitatively different from other social risk factors because the race variable often reflects a broad range of influences.'' [859] Research also shows that social risk driven by race is often correlated with and partially captured by dual enrollment status, and that dual enrollment status is a powerful predictor of poor outcomes.[860] [861] Given this finding, we are moving forward with using dual Medicare and Medicaid enrollment status as the most appropriate variable to consider for risk adjustment.

However, we recognize the importance of the concerns raised by this commenter and will continue to monitor the episode-based measures for any unintended consequences for Black patients or other vulnerable populations.

Comment: Commenters expressed concern for and opposed the inclusion of Part D prescription drug costs in Medicare cost measures. One commenter explained that the addition of prescription drugs in cost measures would exacerbate current inequities in the Medicare program by unnecessarily penalizing physicians for factors outside of their control (including coverage, formularies, out-of-pocket costs, and transactions outside of physician negotiation). This commenter also stated they were unable to determine the impact of adding Part D drugs to the new episode-based measures due to a lack of information from CMS.

Response: We include Part D costs in many cost measures because they are important drivers of cost. We have included the Part D costs based on input from the TEP and Clinician Expert Workgroup. Per the TEP's guidance, we include Part D costs in measures after considering the following factors: whether we can assess performance without Part D, the amount of cost this represents, and whether there is a sufficient sample size to sub-group by Part D enrollment. The Clinician Expert Workgroups then provide input on which medications to include in the measure that are clinically relevant and within the reasonable influence of attributed MIPS eligible clinicians. Finally, the Part D costs are adjusted to account for expected cost differences. Specifically, Part D costs are standardized so that non-clinical cost variation (such as drug manufacturers and plans) is removed. Additionally, the measure stratifies episodes into distinct sub-groups based on whether a patient

[857] Nguyen, Kevin H., Kaitlyn P. Lew, and Amal N. Trivedi. ''Trends in Collection of Disaggregated Asian American, Native Hawaiian, and Pacific Islander Data: Opportunities in Federal Health Surveys.'' American Journal of Public Health (2022).

[858] Kader, Farah, Lan N. Doan, Matthew Lee, Matthew K. Chin, Simona C. Kwon, and Stella S. Yi. ''Disaggregating Race/Ethnicity Data Categories: Criticisms, Dangers, And Opposing Viewpoints'', Health Affairs Forefront (2022).

[859] National Quality Forum, ''Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement'' (2022). *https://www.qualityforum.org/Publications/2022/12/Risk_Adjustment_Technical_Guidance_Final_Report_-_Phase_2.aspx*.

[860] Office of the Assistant Secretary for Planning and Evaluation. ''Second report to Congress on social risk and Medicare's value-based purchasing programs.'' (2020) *https://aspe.hhs.gov/pdf-report/second-impact-report-tocongress*.

[861] Ibid.

is enrolled in Part D to account for expected differences in costs, and a separate risk adjustment model is run for each sub-group. This results in episodes with and without Part D enrollment having similar risk-adjusted episode costs and measure scores and neutralizes the expected differences in observed episode costs.

Measure testing information on the sub-grouping of episodes with and without Part D enrollment, as well as the impact of medication costs on episodes costs are available in the Measure Justification Form available for download at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*.

Comment: Commenters recommended CMS add specialty exclusions to the chronic condition episode-based measures to prevent inappropriate attribution to clinicians who are providing care to patients with CKD, ESRD, or rheumatoid arthritis but are not managing the patient's chronic condition. One commenter acknowledged CMS's actions to improve attribution of measures but remained concerned that the issues are ongoing and continue to penalize physicians for care outside of their control. Another commenter recommended that new, proposed cost measures should exclude nurse practitioners and physician assistants from attribution where most other MIPS eligible clinicians in their TIN are excluded from the cost measure.

Response: Generally, MIPS eligible clinicians are not excluded from episode-based measure attribution based on specialty; instead, cost measures are attributed to individual MIPS eligible clinicians and groups based on care patterns observable in claims data. Episode-based measures focus on a specific condition or procedure and are constructed so that we only include the costs of services clinically related to that care. The attribution methodology intends to capture MIPS eligible clinicians that influence the care a patient receives for this specific condition or procedure. Clinicians from multiple specialties may contribute to this care, and so the current attribution methodology for episode-based measures does not include specialty exclusions.

As described in the CY 2025 PFS proposed rule (89 FR 62048 through 62050), we continually monitor and reevaluate cost measures adopted into MIPS. However, based on the input that we received from the TEP and Clinician Expert Workgroups and from empiric analyses presented by the measure developer, the measures we proposed in the CY 2025 PFS proposed rule are appropriately specified. Clinician Expert Workgroup discussions and Measure Justification Forms with measure testing results are available for review at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*.

Comment: Several commenters stated the importance of frequent (for example, quarterly) and actionable performance feedback and raised concerns that this was not yet available for cost measures. Commenters were concerned that MIPS eligible clinicians do not know in real time which cost measures are being attributed to them, which patients are being assigned to them, and what costs outside of their practice they are being held accountable for until after the performance period is over. They stated that, without frequent and actionable data, MIPS eligible clinicians cannot make changes to their care.

Response: We currently provide annual MIPS Performance Feedback that includes information on MIPS eligible clinicians' performance for the previous performance period. This feedback typically becomes available during the summer in between the performance period and the MIPS payment year. We provide these reports on an annual basis, as we calculate cost measures following the end of the performance period. We calculate and score the cost measures following the end of the performance period because we need to review all claims that fall within the scope of a cost measure for a given performance period. Specifically, we will score each cost measure attributed to a MIPS eligible clinician (meeting or exceeding the minimum case volume) by assigning achievement points between one and ten based on the MIPS eligible clinician's performance on the cost measure during the performance period compared to the measure's benchmark (§ 414.1380(b)(2)). Each cost measure's benchmark is based on the national averages of all other MIPS eligible clinicians attributed the same measure for the same performance period. These benchmarks are derived from cost data from all individual MIPS eligible clinicians, groups, and virtual groups that met the measure's case minimum for that performance period. MIPS eligible clinicians have episodes of care that begin and end at various times throughout the performance period, so to calculate an accurate comparison across MIPS eligible clinicians, we have historically calculated all scores following the end of the performance period. Calculating the MIPS cost measures during the performance period may provide an incomplete indication of how a MIPS eligible clinician is performing. We refer readers to section IV.A.4.f.(1)(d) of this final rule for more detailed discussion regarding our scoring methodology for cost measures.

Additionally, we post detailed measure specifications that describe the attribution methodology and a list of included services so that MIPS eligible clinicians can anticipate when their Medicare claims for treating a Medicare patient may be captured by a MIPS cost measure.

Finally, we would like to note that MIPS eligible clinicians could be rewarded for improving on their performance on a cost measure in future years based on the improvement scoring methodology, as described in § 414.1380(b)(2)(v).

We are continuing to work towards providing meaningful and timely information on cost measures generally and we recognize the importance of providing this information for measures implemented in MIPS.

Comment: Many commenters recommended that CMS introduce the proposed episode-based measures on an information-only or optional basis to allow for sufficient feedback about the measures and to assess if there are unintended consequences for the measures. Several commenters suggested 2 years as an appropriate minimum length of time. These commenters stated that, in order to fully assess any unintended consequences of the proposed episode-based measures and to evaluate CMS's methodological decisions regarding issues such as health equity, attribution, and inclusion of Part D medication costs, CMS should implement the proposed measures on an informational-only basis.

Response: For cost measures we develop, the cost measure development process (currently 18 months long) provides significant time for testing and public feedback on measure specifications, which we post publicly. As previously stated in the CY 2025 PFS proposed rule (89 FR 62051), cost measures undergo extensive review by clinicians participating in Clinician Expert Workgroups in addition to the multiple opportunities provided for public comment. The measure developer convenes Clinician Expert Workgroups to advise on measure specifications, based on iterative empiric analyses on frequency and impact of related services, patient conditions, and other risk factors. After the measure specifications are drafted, we host a national field testing period, where there is a robust public comment opportunity. Once the measures are fully developed, they undergo the pre-

rulemaking and rulemaking processes, which includes additional testing on the final measure specifications and opportunities for public comment. We strive to balance the development and testing timeline with the importance of being able to develop, adopt, and implement measures to assess cost of care in a timely manner. As we previously stated in the CY 2025 PFS proposed rule (89 FR 62045), we are striving to develop more cost measures to move closer towards the statutory goal of covering 50 percent of expenditures under Medicare Parts A and B, as specified under section 1848(r)(2)(i)(I) of the Act. In addition, as discussed in the CY 2025 PFS proposed rule (89 FR 62045), we seek to develop more cost measures to support our development of MVPs. We need to assess the impact adding a 2-year informational period could have on this policy goal and development process. We will consider the recommendation for an informational-only period for future rulemaking.

Comment: A few commenters expressed concerns about post-field testing transparency in pre-rulemaking cost measure development. These commenters stated there were significant methodological changes made to cost measures after the field testing period. These commenters requested that CMS clearly communicate these post-field testing measure specifications updates to interested parties. The commenters also expressed concern about a lack of available testing on final measure specifications and suggested that CMS publish additional testing results prior to measure proposal. A few commenters also suggested that CMS hold an additional field testing period before the rulemaking process.

Response: We disagree that final measure specifications and testing information is unavailable or that the pre-rulemaking process is not transparent. Following field testing, we reconvene the Clinician Expert Workgroups to discuss the public feedback and additional testing as we work to refine draft measure specifications. A summary of this discussion and the Clinician Expert Workgroups' recommendations are posted publicly on the Cost Measures Information page here: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior*. Based on the field testing, public comments, Clinician Expert Workgroup feedback, and extensive empirical testing from the measure developer, we finalize any refinements to the measure specifications. We then work with the measure developer to conduct thorough testing on the final measures' performance, reliability, and validity. This testing supports submission of the measure for consideration for inclusion in the MUC List. If accepted, the measure and its specifications are shared with the PRMR members to discuss their recommendations for including these measures in MIPS. The testing results, which reflect post-field testing changes to the measure, are posted publicly in the Measure Justification Forms for each measure. In addition, if we propose to adopt the measure via rulemaking, we publish the final specifications for the proposed measures concurrently with the proposed rule. We encourage interested parties to review all measure specifications documents along with the Measure Justification Form for each proposed measure and to provide their feedback via public comment. These materials are published on the Cost Measures Information page for the public's reference: *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/*. Interested parties are welcome to provide feedback on any post-field testing measure specifications updates through the rulemaking process.

While we acknowledge that transparency regarding cost measure development is important, additional field testing periods, beyond those described above, would delay measure implementation beyond the current 18-month process, preventing us from implementing cost measures on a timely basis. We understand that more frequent testing information would be useful, and we will consider this feedback as part of future rulemaking.

Comment: Some commenters requested that CMS ensure close alignment between cost and quality measures to avoid disincentivizing appropriate care.

Response: During episode-based measure development, we consider ways to align cost and quality goals. For example, we may align a cost measure's episode window length or align the overall measure scope with existing quality measures. We work with the Clinician Expert Workgroups and review empirical data from the measure developers on the most appropriate way to do this in the specifications for each cost measure.

Additionally, MIPS is designed to assess MIPS eligible clinicians' performance on their quality and cost of care (each performance category score generally constituting 30 percent of a MIPS eligible clinician's final score), as well as improvement activities and meaningful use of CEHRT (see section 1848(q)(2)(A), (B) and (q)(5)(E) of the Act). Cost measures are used in MIPS alongside quality measures so that MIPS eligible clinicians can be assessed on the value of their care. MIPS thereby holistically assesses MIPS eligible clinicians' performance across various aspects of their practice, including both the quality and cost efficiency of their care in generally equal measure. This goal of assessing value is furthered with the transition to MVPs, which connect measures and activities across MIPS categories on sets of measures relevant to certain types of care. Measures are monitored after implementation for potential unintended consequences, such as evidence of care stinting. However, the measures already safeguard against potential care stinting by including the costs of adverse outcomes.

Comment: Some commenters urged CMS to pursue CBE endorsement for the episode-based measures.

Response: We thank the commenters for their recommendations. We will consider whether to pursue CBE endorsement for the six new episode-based measures in future evaluation cycles. As we discussed in the CY 2025 PFS proposed rule (89 FR 62051) and section IV.A.4.e.(2)(i) of this final rule, we are not required to use only CBE-endorsed measures in MIPS. Additionally, the measures undergo a robust 18-month development cycle, where feedback from public comments, persons with lived experiences, clinician experts, and other interested parties are incorporated into the measure's specifications. The measures undergo an iterative testing process, including empiric analyses to inform measure specification decisions and national field testing where extensive information on measure performance is posted publicly for feedback on potential revisions. As a result, the measure has undergone a high level of scrutiny and received varied input throughout its development, despite not having undergone the CBE endorsement process yet.

After consideration of public comments, we are finalizing the implementation of the six new episode-based measures into MIPS beginning with the CY 2025 performance period/2027 MIPS payment year. The six new episode-based measures are CKD, ESRD, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis, and Respiratory Infection Hospitalization. For the Rheumatoid Arthritis episode-based measure, we are finalizing measures specifications with modifications to the assigned Part D

services: to include biosimilar medications and not include ophthalmic medications. We are finalizing the other new episode-based measures (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Respiratory Infection Hospitalization) as proposed.

(iii) Summary of Proposals To Modify Two Episode-Based Measures Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year

In this section, we summarize our proposal to modify two episode-based measures currently in use in MIPS beginning with the CY 2025 performance period/2027 MIPS payment year. The episode-based measures that we proposed to modify beginning with the CY 2025 performance period/2027 MIPS payment year are listed in the Table 73, including both the original measure names and the modified measure names we proposed.

TABLE 73: Reevaluated Episode-Based Measure Modifications Beginning with CY 2025 Performance Period/2027 MIPS Payment Year

Original Measure Name	Proposed Modified Measure Name	Episode Type
Routine Cataract Removal with Intraocular Lens (IOL) Implantation	Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural
ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI)	Inpatient (IP) Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition

For the purpose of assessing performance of MIPS eligible clinicians in the cost performance category, we finalized, in the CY 2019 PFS final rule (83 FR 59767 through 59773), the Routine Cataract Removal with Intraocular Lens (IOL) Implantation and ST-Elevation Myocardial Infarction (STEMI) Percutaneous Coronary Intervention (PCI) episode-based measures to be included in MIPS beginning with the CY 2019 performance period/2021 MIPS payment year. In the CY 2025 PFS proposed rule (89 FR 62049 through 60253), we proposed to modify the Routine Cataract Removal with IOL Implantation and STEMI PCI measures based on input from interested parties from prior public comment periods and recommendations from Clinician Expert Workgroups.

In addition to new measure titles as set forth in Table 73, we proposed substantive modifications to these measures. While we generally describe the modifications we proposed to these two episode-based measures in this section of this final rule, we refer readers to our discussion in the CY 2025 PFS proposed rule (89 FR 62050 and 62051) for more detailed information regarding the modifications we proposed for each of these measures, and our rationale for these modifications.

We proposed modifications for the modified Cataract Removal with IOL Implantation measure (replacing the Routine Cataract Removal with IOL Implantation Measure) beginning with the CY 2025 performance period/2027 MIPS payment year as follows.

First, we proposed to modify this cost measure by expanding the patient cohort based on changes to the exclusion criteria. Testing has shown that many episodes excluded due to ocular conditions had similar cost profiles, compared to episodes included in the measure, and represented a significant portion of triggered episodes. The measure-specific expert workgroup discussed the appropriateness of the original exclusion criteria and recommended potential revisions. The modified measure includes patients with certain previously excluded ocular conditions, such as glaucoma and macular degeneration, in the measure cohort because of their similar cost profiles. In response to expanding the measure cohort, we also proposed updates to the risk adjustment model to risk adjust for ocular conditions that are no longer excluded but may still impact case complexity and episode costs. These changes are appropriate as they further account for patient heterogeneity in the more clinically diverse patient cohort. However, the modified measure continues to exclude episodes for patients with significant ocular conditions impacting surgical complication rate or visual outcomes because testing did not suggest they had similar enough cost profiles for any expected cost differences to be accounted for through risk adjustment.

Second, we proposed to modify this cost measure's service assignment specifications in two ways, to include: (1) certain clinically related telehealth services, pre-operative testing, emergency department (ED) visits for ocular complaints, and postoperative durable medical equipment (DME); and (2) certain additional clinically related Medicare Part B medication costs that were not initially included in the measure. The previous version of the measure included a smaller subset of these services. However, testing showed that additional clinically related services within these categories occur during Cataract Removal episodes and exclusion of these services from the measure could result in failure to capture important costs. We proposed to include the additional services because this change will retain the original intent of the measure while capturing a more complete picture of cost performance variation. Additionally, we proposed to expand the types of Part B medications assigned to the measure because it will be appropriate to use similar service assignment rules for all clinically related Part B medications.

Further details about the modified Cataract Removal with IOL Implantation measure are available in the measure specifications documents, which are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures.*

We proposed modifications for the modified IP PCI measure (replacing the STEMI PCI measure) beginning with the CY 2025 performance period/2027 MIPS payment year as follows.

First, we proposed to modify this cost measure by expanding the patient cohort based on changes to the triggering logic. The previous version of

the measure narrowly defined a subset of STEMI PCI patients to promote homogeneity of the patient cohort. However, testing demonstrated that PCI episodes with and without STEMI appear to have similar cost profiles and involve similar clinician types. Therefore, it is appropriate to expand the patient cohort in the modified measure to include episodes beyond those with STEMI diagnoses, such as PCI for non-STEMI diagnoses and PCI without either STEMI or non-STEMI diagnoses. As such, we will no longer use ICD–10 diagnosis information to restrict assessment of costs under this measure to only inpatient PCI procedures with a STEMI diagnosis. This change will increase the number of MIPS eligible clinicians and beneficiaries for whom this cost measure will be applicable.

Second, we proposed to modify this cost measure to include additional subgroups to stratify the patient cohort based on diagnosis to account for variations in cost and treatment pathways for inpatient procedures. While there are overall similarities between the diagnosis for inpatient PCI episodes (that is, STEMI, non-STEMI, and other inpatient PCI episodes), there are still expected differences in observed costs between these cohorts. This modification will allow us to assess variation in clinician cost performance rather than expected cost differences due to patient diagnoses. We believe this is appropriate because testing shows differences in observed episode costs among STEMI, non-STEMI, and other inpatient PCI episodes are neutralized via subgrouping and risk adjustment.

Third, we proposed that the modified measure excludes episodes with cardiac arrest and risk adjusts for patients with a history of tobacco use to further address heterogeneity in the patient cohort, as these cases can result in more complex treatment and higher observed costs for reasons outside of the control of the attributed clinician. This was supported by testing on the expanded patient cohort.

Further detail about the modified IP PCI measure is included in the measure specifications documents, which are available at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures.*

We invited comments on the proposals in this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed support for the trigger codes used in the current Routine Cataract Removal with IOL Implantation measure, which we have retained for the modified Cataract Removal with IOL Implantation measure, and urged CMS not to make any additional changes to the trigger logic for routine cataract procedures, given the name change.

Response: We agree that the measure should maintain its current trigger logic methodology, based on extensive discussions with the Clinician Expert Workgroup who similarly recommended not expanding the measure to include additional procedure trigger codes. As a result, we did not propose modifications to the trigger logic for the modified Cataract Removal with IOL Implantation measure. The updated measure name reflects changes to the patient cohort based on revisions to the measure exclusions and risk adjustment methodology.

Comment: Several commenters did not support the updates to the Cataract Removal with IOL Implantation episode-based measure. They raised concerns with the expansion of the measure to include more patients with significant ocular comorbidities and opposed the removal of certain diagnosis codes from the measure's list of exclusions. A couple commenters recommended acute angle-closure glaucoma, capsular glaucoma, glaucoma secondary to eye inflammation or trauma, and other glaucoma codes classified as severe, moderate, or indeterminate severity remain exclusions. Another commenter recommended to continue to exclude diagnoses for pseudoexfoliation glaucoma and syndrome, other age-related cataracts, mature cataracts, and atrophic and exudative Age-Related Macular Degeneration (AMD).

Response: We thank the commenters for their recommendations. We determined that it is appropriate to include these patients within the measure based on empirical analyses and input from the Clinician Expert Workgroup during our reevaluation of the Routine Cataract Removal with IOL Implantation measure.

As part of the initial measure development and the comprehensive reevaluation process, we worked with the clinician experts, including the Clinical Subcommittee during Wave 1 of measure development and the Clinician Expert Workgroup during the comprehensive reevaluation, to review relevant services and patient conditions that may influence the care for the specific condition or procedure. The measure developer and clinician experts considered exclusions for episodes in which there are small patient or case cohorts that demonstrate extreme variability due to clinical heterogeneity, are not feasible for performance improvement, and cannot be mitigated via risk adjustment or service assignment. During reevaluation of the Routine Cataract Removal with IOL Implantation measure, testing showed that nearly half of the episodes meeting the trigger logic were excluded based on the original measure's exclusion criteria, despite excluded episodes for complex eye conditions having very similar observed and risk-adjusted episode cost distributions compared to the episodes include in the measure. Previous analyses also showed that the use of Hierarchical Condition Category (HCC) codes in the measure's standard risk adjustment model successfully accounted for complexity amongst patients with significant ocular comorbidities, further minimizing the need for continuing to exclude them. These testing results do not indicate that the measure will have unintended consequences as a result of no longer excluding episodes for certain ocular conditions. Taking these considerations into account, we agreed with the input from the Clinician Expert Workgroup during the reevaluation of this measure to include episodes with certain ocular conditions (for example, macular degeneration, glaucoma, and Type 2 Diabetes Mellitus with ophthalmic complications) in the measure without adjustment beyond the standard risk adjustment model, while also adding a measure-specific risk adjustor for ocular conditions that impact case complexity. Finally, episodes with significant ocular conditions impacting surgical complication rate and/or visual outcomes remain excluded in the modified measure specifications.

Comment: For the Cataract Removal with IOL Implantation measure we proposed, one commenter recommended excluding episodes for patients with a history of herpes and zoster virus, retinal degeneration, anterior scleritis, posterior polar cataracts, recurrent corneal erosions, punctate keratitis, neurotrophic keratitis, exposure keratoconjunctivitis, filamentary keratitis, lagophthalmos, and exophthalmic conditions to account for high-cost conditions that could be outside a clinician's control.

Response: We thank the commenter for their recommendations, but we do not agree that additional diagnoses should be used to exclude episodes from measure calculation at this time. We will monitor the impact of these diagnosis codes on the Cataract Removal with IOL Implantation measure. Additionally, the measure uses several

methods to minimize the impact of outlier episode costs on measure scores. For more information on how the measure accounts for outlier costs, we refer readers to the Measure Information Form published on the QPP Cost Measures Information page at *https://www.cms.gov/files/zip/2024-06-cy25-pfs-cost-measure-methods.zip.*

Comment: One commenter expressed general support for the inclusion of clinically related services in the Cataract Removal with IOL Implantation measure. However, they recommended exclusion of the costs of lenses and frames, which they consider to be outside of a clinician's control.

Response: We thank the commenters for their support of the assigned services proposed for this modified measure and their recommendation not to include lenses and frames. We continue to believe it is appropriate to include the costs of durable medical equipment (DME) in this measure based on input from the Clinician Expert Workgroup. The Clinician Expert Workgroup supported the inclusion of postoperative DME costs in the Cataract Removal with IOL Implantation measure, as MIPS eligible clinicians may prescribe these for patients after the cataract removal procedure. The Clinician Expert Workgroup's discussions are available for review in meeting summaries posted on the Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.*

Comment: One commenter urged CMS to risk adjust for ICD–10 Z codes for SDOH in the Cataract Removal with IOL Implantation measure.

Response: These codes are not currently available to incorporate into cost measures because of concerns that they are not routinely and consistently coded on Medicare claims. We will continue to monitor ICD–10 Z codes for potential future use in cost measures.

We considered additional risk adjustment for SDOH during the reevaluation of the Routine Cataract Removal with IOL Implantation measure. While ICD–10 Z codes are not a viable option at this time, we tested whether it would be appropriate to risk adjust for dual Medicare and Medicaid enrollment status. We examined the associations between a patient's dual enrollment status and provider performance. Testing demonstrated that most clinicians perform equally well or even significantly better on episodes for patients with dual enrollment status compared to other episodes, which suggests that it is possible for clinicians to mitigate the effect of social risk factors. Additionally, risk adjusting for dual enrollment status does not appear to substantially change the performance ranking for many clinicians. These results support not including a risk adjustment variable for dual enrollment status in the Cataract Removal with IOL Implantation measure at this time. More information about this testing is included in the Measure Justification Form available on the QPP Cost Measures Information page at *https://www.cms.gov/files/zip/2023-wave-1-reevaluated-measure-justification-forms.zip.*

Comment: One commenter expressed support for risk adjusting for certain patient conditions and use of services in the modified Cataract Removal with IOL Implantation measure that were excluded in the original measure. They stated this modification could broaden patient eligibility and help mitigate the impact of outlier cases that skew performance scores.

Response: We agree that the risk adjustment variables added to the Cataract Removal with IOL Implantation measure result in broader eligibility while still accounting for potential differences in cost due to patient-level factors.

Comment: Commenters had mixed feedback on the inclusion of Part B drugs with separate payment status, including non-opioid pain management drugs and drugs with pass-through payment statuses, in the Cataract Removal with IOL Implantation measure. One commenter supported the inclusion of Part B medications with separate payment statuses, when clinically relevant. However, many commenters raised concerns about their inclusion and recommended that Omidria, Dextenza, and IHEEZO not be included in the measure. These commenters stated that their inclusion could disincentivize use of drugs, discourage medication innovation, and bias drug data collected during the pass-through period. Some commenters opposed the inclusion of Part B medications altogether from the measure as to not inadvertently incentivize the use of opioids in routine procedures.

Response: We disagree with the comment that including costs of clinically related Part B medications would necessarily disincentivize their use. Part B medications are included in the original Routine Cataract Removal with IOL Implantation measure, which was reviewed and endorsed by a CBE in Spring 2019.[862] The Clinician Expert Workgroup for the modified Cataract Removal with IOL Implantation measure closely reviewed service assignment rules to determine whether assignment of service categories contributes to the measure's ability to differentiate between clinician performance and is within a clinician's reasonable influence. Once a clinically related service is assigned to an episode, its ability to reduce complications or improve quality of care can be captured in the measure through a reduction in downstream costs of care. In the same way, the inclusion of clinically related Part B costs does not incentivize the use of inappropriately administered medications, as the practice would be reflected in the measure as higher downstream costs of care.

During reevaluation, the Clinician Expert Workgroup for the Cataract Removal with IOL Implantation measure carefully evaluated Part B medication costs and agreed that it is important to have similar service assignment rules for all clinically related drugs with separate payment statuses, including those under pass-through status, as selective inclusion could have unintended consequences. This sentiment was also echoed by public comments received prior to and during the reevaluation process. While clinically related Part B medications can be indicated for use in cataract procedures and result in better quality care and outcomes, clinician experts noted that they could also represent low value care if not used appropriately. The Clinician Expert Workgroup's discussions are available for review in meeting summaries posted on the Cost Measures Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/prior.* Not including these medications would result in important costs not being captured when looking at overall costs of a cataract removal episode.

Comment: One commenter supported the proposed modifications to the STEMI PCI measure under the newly titled IP PCI measure because the modifications intend to provide a more comprehensive, fair, and accurate assessment of costs associated with PCI procedures. The commenter did caution that the expanded patient cohort could introduce added complexity in the measure calculation and that ongoing feedback should be available to monitor the impact of the changes.

Response: We thank the commenter for their support of the IP PCI episode-based measure, reflecting modifications

[862] National Quality Forum, *Cost and Efficiency, Spring 2019 Cycle: CDP Report https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=92292.*

to the STEMI PCI measure. As we explained in the CY 2025 PFS proposed rule (89 FR 62051), we decided to expand the patient cohort for the IP PCI measure beyond STEMI diagnoses based on the empirical data presented by the measure developer and input from the Clinician Expert Workgroup members. To account for the expanded patient cohort and the expected differences in observed costs, the measure is stratified into three sub-groups based on diagnosis and each sub-group uses a separate risk adjustment model. The Clinician Expert Workgroup agreed with using this approach to account for variations in treatment pathways and costs for STEMI and non-STEMI diagnoses.

We also thank the commenter for their recommendation for ongoing feedback to monitor the impact of measure changes. In addition to publicly posting measure specifications that describe each cost measure's scope and stratification, we also release annual QPP Feedback Reports that will include feedback on the modified episode-based measure and publish Public Use Files (PUF) with additional data available for clinicians to review. Additionally, interested parties can contact the Quality Payment Program Service Center to request additional clarifications on the measure specifications. We will continue to monitor the impact of these changes on MIPS eligible clinicians and consider making available additional data about the measure.

Comment: One commenter did not support the proposal to include non-STEMI PCI patients in the modified IP PCI episode-based measure because of the differences between PCI procedures performed for STEMI versus other diagnoses. The commenter recommended developing separate measures for the 2 conditions.

Response: We disagree that it is inappropriate to include diagnoses for both STEMI and non-STEMI conditions in the IP PCI measure. The IP PCI's measure specifications account for expected cost differences between PCI procedures performed for a wider set of diagnoses by creating sub-groups for episodes where there is a diagnosis for STEMI, non-STEMI, or neither STEMI nor non-STEMI. During the reevaluation process, the measure developer and Clinician Expert Workgroup reviewed testing results that showed risk adjustment effectively mitigated cost differences between the three subgroup populations, which is expected based on the design of the risk adjustment model. This approach stratifies episodes into distinct sub-groups, and a separate risk adjustment model is run for each sub-group, resulting in an average observed cost to expected cost ratio that is centered around 1.0 for each subgroup. The observed cost to expected cost ratio is used to calculate the dollar value score for each episode, so the average dollar value score for episodes across each subgroup will be similar. This results in PCI episodes for each diagnosis type having similar risk-adjusted episode costs and measure scores, and neutralizes the expected differences in observed episode costs.

After consideration of public comments, we are finalizing the modifications to two existing episode-based measures in MIPS beginning with the CY 2025 performance period/2027 MIPS payment year, as proposed.

(b) Reliability and Case Minimum

In this section of this final rule, we describe the case minima we proposed for the episode-based measures we proposed to adopt and modify in the CY 2025 PFS proposed rule and are finalizing in section IV.A.4.e.(2) of this final rule, as discussed previously.

Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing meaningful differences between clinicians' performance. However, we continued to caution against using reliability as the sole metric to evaluate a measure because of the tradeoffs between accuracy and reliability, and the role of service assignment in reducing noise. These and other considerations are detailed in the CY 2022 PFS final rule (86 FR 65453 through 65455). We also noted that increasing case minima necessarily reduces the number of clinicians who meet the case minimum for a given measure. Because these are clinically refined measures, we aim to have as many MIPS eligible clinicians as possible to be able to have their costs evaluated by them. Therefore, we considered that a mean reliability of 0.4 represents moderate reliability because it accounts for these considerations and is a sufficient threshold to ensure that the measure is performing as intended when assessed in conjunction with other testing.

We previously established at § 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures and at § 414.1350(c)(4) a case minimum of 10 episodes for procedural episode-based measures in the CY 2019 PFS final rule (83 FR 59773 through 59774). We also established at § 414.1350(c)(6) a case minimum of 20 episodes for chronic condition episode-based measures in the CY 2022 final rule (86 FR 65453 through 65455).

As we described in the CY 2025 PFS proposed rule, we examined the reliability of the eight episode-based measures (six new and two modified) we proposed in this rulemaking, and Table 74 presents the percentage of tax identification numbers (TINs) and TIN/National Provider Identifiers (NPIs) that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our case minimum of 20 for each of the chronic condition and acute inpatient medical condition episode-based measures. At a 20-episode case minimum, the mean reliability for the measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. For the procedural measure, Cataract Removal with Intraocular Lens (IOL) Implantation, we applied the case minimum of 10 episodes. At a 10-episode case minimum, the mean reliability for the measure exceeds 0.4 for both groups and individual clinicians, and all groups and individual clinicians meet the 0.4 reliability threshold.

TABLE 74: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold and TIN and TIN/NPI Mean Reliability

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Prostate Cancer	87.4%	0.68	84.1%	0.62
Rheumatoid Arthritis	95.0%	0.74	97.3%	0.76
Chronic Kidney Disease	88.8%	0.63	82.3%	0.57
End-Stage Renal Disease	92.5%	0.65	90.0%	0.59
Kidney Transplant Management	91.2%	0.64	95.8%	0.68
Respiratory Infection Hospitalization	100.0%	0.74	100.0%	0.53
Cataract Removal with Intraocular Lens (IOL) Implantation	100.0%	0.97	100.0%	0.96
Inpatient (IP) Percutaneous Coronary Intervention (PCI)	100.0%	0.63	100.0%	0.52

Calculating these episode-based measures with these case minimums will accurately and reliably assess the performance of clinicians and clinician group practices. Therefore, we proposed to adopt a case minimum of 20 episodes for the chronic condition (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis) and acute inpatient medical condition (Respiratory Infection Hospitalization and IP PCI) measures and a case minimum of 10 episodes for the procedural measure (Cataract Removal with IOL Implantation) listed in Table 74. For the IP PCI and Cataract Removal with IOL Implantation, these case minimums remain consistent with the case minimums for the original measures (that is, STEMI PCI and Routine Cataract Removal with IOL Implantation) that are currently in use. These proposals are also consistent with our regulation at § 414.1350(c)(4) through (6). We did not propose to modify these regulations establishing the case minima for these types of cost measures.

We invited comments on the proposals in this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the 20-episode case minimum for the new episode-based measures while encouraging CMS to monitor administrative burdens.

Response: We appreciate the commenters' support and agree that this is an appropriate case minimum. We will continue to monitor the impact the episode-based measure case minima may have on MIPS eligible clinicians.

After consideration of public comments, we are finalizing our proposals to adopt a case minimum of 20 episodes for the chronic condition (CKD, ESRD, Kidney Transplant Management, Prostate Cancer, Rheumatoid Arthritis) and acute inpatient medical condition (Respiratory Infection Hospitalization and IP PCI) measures and a case minimum of 10 episodes for the procedural measure (Cataract Removal with IOL Implantation), as proposed.

(c) Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

In accordance with section 1848(r)(2)(H) of the Act, we proposed to revise the operational list beginning with the CY 2025 performance period/2027 MIPS payment year to include 6 new care episode and patient condition groups, based on input from clinician specialty societies and other interested parties, to reflect the new episode-based measures we are finalizing as described in section IV.A.4.e.(2)(ii) of this final rule. We proposed including Respiratory Infection Hospitalization as a care episode group and CKD, ESRD, Kidney Transplant Management, Prostate Cancer, and Rheumatoid Arthritis as patient condition groups. These care episode and patient condition groups serve as the basis for the six new episode-based measures that we are finalizing as described in section IV.A.4.e.(2)(ii) of this final rule for the cost performance category. The codes that define these six care episode and patient condition groups align with the trigger codes of the episode-based measures in section IV.A.4.e.(2)(ii)of this final rule. These specifications are developed with extensive input from interested parties.

Additionally, we proposed to revise the care episode group codes listed to align with the modifications proposed for Cataract Removal with Intraocular Lens (IOL) Implantation and Inpatient (IP) Percutaneous Coronary Intervention (PCI) measures in section IV.A.4.e.(2)(iii) of this final rule.

For context on the statutory requirements for care episode and patient condition groups and changes to the operational list, we refer readers to the CY 2025 PFS proposed rule (89 FR 62054 through 62055).

Our revisions to the operational list are available on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about*.

We invited public comment on our proposals in this section.

We did not receive public comments on these proposals. We are finalizing the revisions to the operational list to include care episode group codes that align with the new and modified episode-based measures, as proposed, beginning with the CY 2025 performance period/2027 MIPS payment year.

(d) Removal Criteria for MIPS Cost Measures

Once adopted, cost measures are retained in the cost performance category measure inventory, except when we specifically proposed to remove a measure. We have identified a need to establish and codify objective criteria that can be used to inform the removal of a cost measure from the MIPS cost performance category. Specifically, when removing the Simple Pneumonia with Hospitalization episode-based measure from the CY 2024 PFS final rule (88 FR 79348 through 79349), we confirmed that, unlike the MIPS quality performance category, the MIPS cost performance category did not have clear guidelines for removing a measure established through the notice-and-comment rulemaking process. Establishing such criteria will allow for more consistency in our evaluation of the cost measures and our decision on whether to propose that a cost measure be removed from the MIPS cost performance category.

Therefore, we proposed to adopt the following factors that can be used to guide the removal of a cost measure:

- Factor 1: It is not feasible to implement the measure specifications.
- Factor 2: A measure steward is no longer able to maintain the cost measure.
- Factor 3: The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- Factor 4: The measure specifications do not reflect current clinical practice or guidelines.
- Factor 5: The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We selected these factors for our proposal because they address instances that we anticipate, based on previous experience, where a cost measure may not be appropriate to maintain in a program, but not limited to these instances. We also worked to align these criteria with the MIPS quality removal considerations and criteria set forth in the CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959), where possible, and, in part, the Hospital Value-Based Purchasing (HVBP) Program's removal factors that are codified in our regulations at 42 CFR 412.164(c)(3). We proposed these specific criteria to encourage a degree of alignment between existing measure removal policies within MIPS and across Medicare programs, where appropriate, for cost measures. For more information on our considerations when determining these removal criteria, we refer readers to the CY 2025 PFS proposed rule (89 FR 62055).

We note that these factors are criteria that will be used as guidance when considering whether to propose to remove a measure, rather than firm requirements. Specifically, there could be instances when a measure meets one or multiple measure removal factors, but will be retained in the cost performance category regardless, if we determine that the benefit of keeping the measure in the cost performance category will outweigh the benefit of removing it. Prior to proposing a measure for removal in accordance with this policy, we will carefully review the specifications of the cost measures by conducting necessary literature reviews, empirical testing, or other information gathering.

Additionally, we proposed to codify this measure removal policy by amending § 414.1350 by adding the cost removal criteria in paragraph (e). Specifically, we proposed at § 414.1350(e) that we may remove a cost measure from MIPS based on one or more of the following factors, provided however that we may retain a cost measure that meets one or more of the following factors if we determine the benefit of retaining the measure outweighs the benefit of removing it.

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.
- The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We invited comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal and agreed with the proposed criteria for removing a cost measure from the program. One commenter stated that these criteria were straightforward and reasonable. One commenter expressed the belief that feasibility should be a pre-requisite to the cost measure removal process.

Response: We thank the commenters for their support and agree that these are reasonable guidelines for removing a cost measure from use.

Comment: Several commenters requested that CMS remove the TPCC measure based on these criteria.

Response: We thank the commenters for their feedback. We will consider the cost measure removal criteria in future years to determine whether the TPCC measure, or any other cost measures, should be proposed for removal.

After consideration of public comments, we are finalizing the cost measure removal criteria as proposed and are finalizing our proposal to codify this cost measure removal policy at § 414.1350(e) as proposed.

(e) Summary of Measures Specified for the Cost Performance Category Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year

The previously established measures for the cost performance category, and those measures being finalized in this rule, specified for the CY 2025 performance period/2027 MIPS payment year and future periods are summarized in Table 75.

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TABLE 75: Summary Table of Previously Established and Finalized Cost Measures for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Performance Periods

Measure Topic	Measure Type	Case Minima	Measure Status
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Cataract Removal with Intraocular Lens (IOL) Implantation	Procedural episode-based	10 episodes	As modified in this rule for use for the CY 2025 Performance Period and beyond
Colon and Rectal Resection	Procedural episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Elective Outpatient Percutaneous Coronary Intervention (PCI)	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Elective Primary Hip Arthroplasty	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Femoral or Inguinal Hernia Repair	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and
Hemodialysis Access Creation	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Knee Arthroplasty	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Lumpectomy, Partial Mastectomy, Simple Mastectomy	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Melanoma Resection	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Revascularization for Lower Extremity Chronic Critical Limb Ischemia	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Screening/Surveillance Colonoscopy	Procedural episode-based	10 episodes	Currently in use for the CY 2025 Performance Period and beyond
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Inpatient (IP) Percutaneous Coronary Intervention (PCI)	Acute inpatient medical condition episode-based	20 episodes	As modified in this rule for use for the CY 2025

Measure Topic	Measure Type	Case Minima	Measure Status
			Performance Period and beyond
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Lower Gastrointestinal Hemorrhage *(at group level only)*	Acute inpatient medical condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Psychoses and Related Conditions	Acute inpatient medical condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Respiratory Infection Hospitalization	Acute inpatient medical condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond
Sepsis	Acute inpatient medical condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Asthma/Chronic Obstructive Pulmonary Disease (COPD)	Chronic condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Chronic Kidney Disease (CKD)	Chronic condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond
Depression	Chronic condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Diabetes	Chronic condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
End-Stage Renal Disease (ESRD)	Chronic condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond
Heart Failure	Chronic condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Kidney Transplant Management	Chronic condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond
Low Back Pain	Chronic condition episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Prostate Cancer	Chronic condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond
Rheumatoid Arthritis	Chronic condition episode-based	20 episodes	As finalized in this rule for use for the CY 2025 Performance Period and beyond

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Measure Topic	Measure Type	Case Minima	Measure Status
Emergency Medicine	Care Setting episode-based	20 episodes	Currently in use for the CY 2025 Performance Period and beyond
Medicare Spending Per Beneficiary Clinician	Population-based	35 episodes	Currently in use for the CY 2025 Performance Period and beyond
Total Per Capita Cost	Population-based	20 beneficiary months	Currently in use for the CY 2025 Performance Period and beyond

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), and the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351). We also refer readers to § 414.1305 for the definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

In the CY 2025 PFS proposed rule (89 FR 62055 through 62059) we proposed two changes to the traditional Merit-based Incentive Payment System (MIPS) and the MIPS Value Pathways (MVPs) improvement activities policies for the CY 2025 performance period/2027 MIPS payment year. First, we proposed to eliminate the weighting of improvement activities. Second, we proposed to reduce the number of activities to which clinicians are required to attest to achieve a full score in the improvement activities performance category. We also proposed to codify at § 414.1355 the seven improvement activity removal factors, which were adopted in the CY 2020 PFS final rule (FR 84 62988 through 62990) to establish the criteria used to identify improvement activities for potential modification or removal from the improvement activities Inventory. In addition, we proposed changes to the improvement activities Inventory for the CY 2025 performance period/2027 MIPS payment year and future years as follows: adding two new improvement activities; modifying two existing improvement activities; and removing eight previously adopted improvement activities.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

We refer readers to the CY 2025 PFS proposed rule (89 FR 62056) for details about the annual Call for Improvement Activities.

(ii) Codification of Improvement Activity Removal Factors

In the CY 2018 Quality Payment Program proposed rule (82 FR 30056), we solicited comments on the criteria that may be used to identify improvement activities for potential removal from the improvement activities Inventory, citing that, over time, certain improvement activities should be considered for removal to ensure the Inventory is robust and relevant (84 FR 40764). In the CY 2020 PFS final rule (84 FR 62988 through 62990), we established seven removal factors to identify improvement activities for potential modification or removal from the improvement activities Inventory. In the CY 2025 Quality Payment Program proposed rule (89 FR 62056),We proposed to codify at § 414.1355 the following existing seven improvement activity removal factors:

- Factor 1: Activity is duplicative of another activity.
- Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.
- Factor 3: Activity does not align with current clinical guidelines or practice.
- Factor 4: Activity does not align with at least one meaningful measure area.
- Factor 5: Activity does not align with the quality, cost, or Promoting Interoperability performance categories.
- Factor 6: There have been no attestations of the activity for 3 consecutive years.
- Factor 7: Activity is obsolete.

We note that these factors are criteria that are used as guidance in determining removal of an activity, but their use is at our discretion. For example, there may be instances when an activity meets one or multiple activity removal factors but may be retained in the improvement activities performance category Inventory, because the benefit of retaining the improvement activity outweighs the benefit of removing it. We believe that codifying these removal factors will provide transparency and consistency with removals of improvement activities from the Inventory by requiring that elements of each activity are objectively reviewed and justification for removal is clearly identified.

We received comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for our proposal to codify these seven improvement activity removal factors, citing that this would provide clarity when providing justification for changes to the Inventory. A few commenters requested that CMS provide a detailed rationale for why certain improvement activities are removed.

Response: We appreciate commenters' support. For detailed information about the rationale for activity removals, we refer commenters to Table C of Appendix 2 of this final rule.

Comment: Multiple commenters requested that CMS follow a policy of retaining activities when the benefits of retaining the activity outweigh the benefits of removing them. They recommended that we err on the side of

retaining activities if they continue to offer clinical relevance and benefit to their patient populations. One commenter asked CMS to consider clinical professional society guidelines and practices as well as quality measurement standards when creating removal factors so that all types of practitioners have improvement activities available to them.

Response: We appreciate these suggestions. In our efforts to streamline and refine the improvement activities Inventory, we have and will continue to fully examine each activity for clinical relevance and applicability prior to proposing to remove the improvement activity. The removal or modification of an improvement activity from the Inventory will occur through notice-and-comment rulemaking. Commenters will have an opportunity to provide their input during the notice-and-comment rulemaking process.

Comment: A few commenters had concerns regarding Activity Removal Factor 7 (activity is obsolete) and its consideration of activities that are commonly reported and are thus ''overutilized'' and ''achieved.'' One commenter argued that an activity that is frequently reported by clinicians demonstrates the activity's importance to improving patient care. Another commenter requested that we clearly define ''obsolete'' and clarify how the value of the activity across varying specialties is evaluated.

Response: For Activity Removal Factor 7, we consider an activity ''obsolete'' when it is no longer available or can no longer be completed by eligible clinicians as an improvement activity. In vetting and establishing this Removal Factor, we employed a commonly used definition of ''obsolete'' as in 'out of date.' In the context of the Quality Payment Program, this means an activity that no longer reflects current clinical best practices, that is no longer available for implementation (*e.g.,* when a program or initiative upon which an activity depends has been ended or closed), and/or that, because of the nature of the activity, cannot be attested to year after year with a reasonable expectation of clinical quality improvement year after year. For example, in Appendix 2 of the CY 2024 PFS final rule, we finalized the removal of ''Consulting Appropriate Use Criteria (AUC) Using Clinical Decision Support (CDS) when Ordering Advanced Diagnostic Imaging'' (IA_PSPA_29) under removal factor 7 because the AUC CDS program ended and it was no longer possible to attest to this activity. This criterion also applies to activities for which the required actions are completed once or a finite number of times and that, because of the nature of the activity, cannot be repeated year after year to improve clinical care. Once the requirements of an activity are met, continuing to attest to the activity that has already been completed is not considered meeting the intent of improving clinical care. For example, in Appendix 2 of this final rule, we are finalizing the removal of ''Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record'' (IA_EPA_1) under Removal Factor 7. A clinician or group practice meets the requirements of this activity if they complete the establishment of expanded hours of access to the patient medical record, alternative methods for accessing patient information, and/or a process for providing rapid access to patient information during urgent care or transition management. However, continuing to maintain this access year after year does not significantly improve care year after year. This improvement activity is obsolete because EHR systems that provide 24/7 access and health exchange of patient data by clinicians and groups have largely been adopted and, therefore, the goal of this improvement activity has largely been achieved.

Comment: One commenter expressed concern over Activity Removal Factor 1 (activity is duplicative of another activity), indicating that they disagree with a removal criterion that indicates that activities are duplicative of quality measures.

Response: We agree with the commenter that alignment between the various MIPS performance categories is often a benefit, not a weakness, as it promotes harmonization around key care improvement goals while reducing burden. Activity Removal Factor 1 identifies when multiple improvement activities in the Inventory overlap in their requirements, goals and/or clinical scope and can justifiably be removed or modified. This removal factor is beneficial in streamlining the Inventory so that all activities are unique and clinically relevant without being redundant.

Comment: One commenter requested additional clarification regarding how activities will be identified for removal under Activity Removal Factor 2 (there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice). Specifically, the commenter expressed concern that ''stronger relationship to quality care'' is not clearly defined and therefore could have unintended consequences of removing activities that are critical to certain specialties. The commenter also asked how this removal factor differs from Activity Removal Factor 1 (activity is duplicative of another activity). If the activity considered for removal is not duplicative of an existing activity, it may have an important role.

Response: For Activity Removal Factor 1, we evaluate and identify two or more improvement activities that require the same or similar actions to be completed in order to achieve clinical practice improvement in the same clinical area. For Activity Removal Factor 2, we evaluate activities within each subcategory and activities that pertain to similar clinical areas to identify whether one activity may yield a stronger relationship to clinical practice improvement. Even when activities are not duplicative, some activities may promote a higher level of clinical practice improvement in a clinical area than others. Over the last several performance years, we have observed that some activities have not remained aligned with the latest clinical practice standards, have not incorporated the latest national priorities, and/or have activity requirements that are no longer substantive enough to promote a sufficient level of clinical practice improvement in today's health care environment. As we review activities and refine the Inventory, this removal factor will enable us to retain the most robust and clinically meaningful improvement activities.

After consideration of comments, we are finalizing the codification of seven improvement activity removal factors at§ 414.1355, as proposed.

(iii) Changes to the Improvement Activities Inventory

We refer readers to the CY 2025 PFS proposed rule (89 FR 62056 through 62057) for details about proposed changes to the improvement activities Inventory.

We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvement Activities&py=2023#measures* for a complete list of the current improvement activities.

We proposed to add two new improvement activities, modify two existing improvement activities, and remove eight previously adopted improvement activities for the CY 2025 performance period/2027 MIPS payment year and future years. We refer readers to Appendix 2 of the CY 2025

PFS proposed rule (89 FR 62571) for more details.

In response to stakeholder feedback, we are making efforts to streamline the Inventory over the coming rulemaking cycles to include only the most robust and clinically meaningful improvement activities. The removal and modification of 10 total activities is an initial step toward our goal of reducing the size of the Inventory and helping to ensure that it includes only the most meaningful activities that have a clear path to clinical practice improvement, while the two proposed new activities would help fill gaps we have identified in the Inventory.

We proposed two new improvement activities in the Population Management subcategory (89 FR 62057). One new activity, IA_PM_24, titled ''Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake'' will allow MIPS eligible clinicians to receive credit for establishing a process or procedure to increase rates of lung cancer screening. While lung cancer is a leading cause of cancer-related deaths in the U.S., lung cancer screening is under-utilized.[863] [864] [865] [866] This activity aims to increase this screening and improve associated outcomes. Another activity, IA_PM_25, titled ''Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk'' will allow MIPS eligible clinicians to receive credit for implementing a standardized, evidence-based cardiovascular disease risk assessment and care management plan in their practices. This activity is informed by the results of the CMS Innovation Center Million Hearts Model, which included initial atherosclerotic cardiovascular disease (ASCVD) assessment as well as cardiovascular care management. ASCVD assessment and care management were shown to contribute to improved identification and treatment of patients at risk for ASCVD;[867] this activity expands on the work of the Million Hearts Model by (1) increasing flexibility in requirements, allowing more clinician specialties to participate; increased flexibility in risk assessment will fit the needs of attesting clinicians and their patient populations; and (2) requiring the use of structured documentation of risk factors and associated treatment plans with the aim of addressing all risk factors directly.

We proposed two modifications to improvement activities focused on strengthening the activities to better promote more meaningful clinical practice improvement (89 FR 62057). We proposed to modify IA_PM_26 (formerly IA–ERP_6), titled ''Vaccine Achievement for Practice Staff—COVID–19, Influenza, and Hepatitis B,'' and its validation criteria to revise its target goals, and to expand its focus and promote the vaccination of staff for COVID–19 as well as Influenza and Hepatitis B. Adjusting the target goals for this activity aligns with the latest Centers for Disease Control and Prevention (CDC) recommendations,[868] and feedback received over the last 2 years indicates that this could increase its utilization. Additionally, we proposed to expand the focus of this activity to include influenza and hepatitis B to highlight the importance of staff vaccination for vaccine-preventable diseases prevalent today. We also proposed to change the activity's subcategory, from Emergency Response & Preparedness to Population Management, to emphasize that staff vaccination is a long-term strategy in reducing morbidity and mortality rates for these diseases.

We proposed to modify IA_BE_4, currently titled ''Engagement of patients through implementation of improvements in patient portal,'' and its validation criteria to limit the activity to new implementations of a patient/caregiver portal and encourage the measure's adoption by clinicians who do not currently utilize this health information exchange technology. We proposed to modify this activity's name, description, and its validation criteria to better align with current practices. This activity was originally created during a time of transition to EHRs to encourage electronic information exchange. It has become standard practice to use patient portals; therefore, the activity is no longer driving improvement among clinicians who have already implemented patient portals.

We separately proposed to remove eight existing activities, presented in Table 76:

[863] American Cancer Society. (2021) Can Lung Cancer Be Found Early?, *https://www.cancer.org/cancer/lung-cancer/detection-diagnosis-staging/detection.html*.

[864] NIH National Cancer Institute. Cancer Stat Facts: Lung and Bronchus Cancer. (2022). *https://seer.cancer.gov/statfacts/html/lungb.html*.

[865] Fedewa, S.A., Bandi, P., Smith, R.A., Silvestri, G.A., & Jemal, A. (2022). Lung Cancer Screening Rates During the COVID–19 Pandemic. Chest, 161(2), 586–589. *https://doi.org/10.1016/j.chest.2021.07.030*.

[866] National Cancer Institute (2023). Lung Cancer Screening. *https://progressreport.cancer.gov/detection/lung_cancer*; accessed May 2023, last updated March 2024.

[867] American College of Cardiology (n.d.). Million Hearts Cardiovascular Disease Reduction Model (Million Hearts Model). *https://www.cms.gov/priorities/innovation/data-and-reports/2023/mhcvdrrm-finalannevalrpt-fg*.

[868] Centers for Disease Control and Prevention (2024). Vaccines & Immunizations. Last Updated April 2024. *https://www.cdc.gov/vaccines/index.html*.

TABLE 76: Improvement Activities Inventory: Proposed Removals

Proposed Removals Titles	*Removal Criteria (Factor)*
EPA_1 Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record	Factor 7, activity is obsolete
PM_12 Population empanelment	Factor 7, activity is obsolete
CC_1 Implementation of use of specialist reports back to referring clinician or group to close referral loop	Factor 1, activity is duplicative; Factor 5, activity does not align with quality, cost, or promoting interoperability performance categories
CC_2 Implementation of improvements that contribute to more timely communication of test results	Factor 7, activity is obsolete
ERP_4 Implementation of a Personal Protective Equipment (PPE) Plan	Factor 7, activity is obsolete
ERP_5 Implementation of a Laboratory Preparedness Plan	Factor 7, activity is obsolete
BMH_8 Electronic Health Record Enhancements for BH data capture	Factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice
PSPA_27 Invasive Procedure or Surgery Anticoagulation Medication Management	Factor 1, activity is duplicative

We refer readers to Appendix 2 to this final rule for details on the proposed revisions to the improvement activities Inventory, the comments we received on these activities, our responses to those comments, and the final disposition of each proposal.

In addition to the comments on individual activities we received, which are addressed in Appendix 2 to this final rule, we received comments on our reporting and scoring proposals as well as policies around the maintenance of the improvement activities Inventory. The following is a summary of these comments and our responses.

Comment: One commenter recommended that CMS consider the relative effort of activities when evaluating the IA inventory as a whole. Another commenter asked that we continue to add new activities when appropriate to ensure that a diversity of activities with a manageable effort level are available for all clinicians.

Response: We appreciate commenters' suggestions on ways to maintain an Inventory of activities that are diverse, robust, and meaningful. We agree with this approach to review and assess each activity on a regular basis for relevance and effectiveness in promoting clinical practice improvement while adding new activities that incorporate varying aspects of clinical care that may not already be addressed. As we work to streamline the Inventory, the overall number of improvement activities from which MIPS eligible clinicians can choose is reduced; however, each retained activity highlights a unique and vital aspect of clinical practice improvement, and therefore every activity remaining in the Inventory would be considered a high priority activity.

Comment: Several commenters requested that CMS give a one-year notice before removing an activity so that practices have enough time to plan for changes. For example, activities proposed for removal in the CY 2025 PFS proposed rule should not be removed from the program until the 2026 performance year. Since the final rule does not come out until roughly a month before the start of the applicable performance year, and practices need ample time to plan for any changes, particularly when reporting a different activity would require a financial investment or increased resource allocation.

Response: We appreciate this comment. A blanket delay of the removal of all eight activities as proposed would not be necessary. At least four of the eight proposed activity removals still offer a significant opportunity to streamline the Inventory by eliminating activities that have been determined to be less substantive. We also believe that the reduction in the number of activities to report offsets any burden on clinicians to select alternate activities to report for CY 2025.

After consideration of comments, we are finalizing as proposed the addition of two new activities, the modification of one activity, and the removal of four activities in the improvement activities Inventory for the CY 2025 performance year/2027 MIPS payment year and subsequent years. We are also finalizing the delay removal of four activities and modification of one activity until the CY 2026 performance year/2028 MIPS payment year to allow clinicians time to plan and budget for selecting alternate activities to report. We refer readers to Appendix 2 of this final rule for details on the finalized revisions to the improvement activities Inventory.

(iv) Improvement Activity Scoring and Reporting Policies

In the CY 2025 Quality Payment Program proposed rule (89 FR 62059), We proposed two scoring and reporting policy changes for the improvement activities performance category effective for the CY 2025 performance period/

2027 MIPS payment year and subsequent years. First, we proposed to eliminate the weighting of improvement activities in order to simplify scoring of the category, as well as complement our ongoing efforts to refine and improve the Inventory. In the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), we codified at § 414.1380(b)(3) the scoring policies for the improvement activities performance category. We established there that clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic health professional shortage areas (HPSAs)) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity. We established a differentially weighted model for the improvement activities performance category with two categories, medium and high, to provide flexible scoring and because there are no nationally recognized standards or definitions for these activities (81 FR 28210). Weights were assigned based on the level of effort and resources needed to complete each activity, as well as alignment with current national public health priorities and programs such as the Quality Innovation Network-Quality Improvement Organization (QIN/QIO).

We have subsequently determined that the benefit to categorizing activities as high or medium weighted has greatly diminished. Over the last several years of the Quality Payment Program, we have made refinements and enhancements to the improvement activities Inventory by adding new activities to incorporate newly identified opportunities for clinical improvement and by modifying existing activities to support changes in practice standards, while also eliminating activities that are duplicative or that no longer promote a sufficient level of clinical improvement. In this and subsequent rulemaking cycles, we are focusing our efforts on streamlining the Inventory to retain the highest priority activities that offer the strongest promotion of clinical practice improvement. As the Inventory is streamlined, each retained activity highlights a unique and vital aspect of clinical practice improvement, and therefore every activity remaining in the Inventory would be considered a high priority activity.

Second, we proposed to further simplify improvement activity reporting requirements by reducing the number of activities to which clinicians are required to attest to achieve a full score in the improvement activities performance category. We proposed that MIPS eligible clinicians who participate in traditional MIPS would be required to report two activities. In addition, we proposed that MIPS eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing would now be required to report one activity. We proposed that these policies would be effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years.

We also proposed that MVP participants would be required to report one activity. In the CY 2022 PFS final rule (86 FR 65412 through 65413), we established that MVP Participants submitting MVPs report fewer improvement activities than eligible clinicians reporting traditional MIPS to incentivize and support MVP adoption. As we stated in the CY 2022 PFS final rule (86 FR 65412), we continue to believe that reduced reporting requirements are necessary to support the adoption of and reduce the burden for implementation of MVPs.

We proposed to lower the number of activities that MIPS eligible clinicians are required to complete in order to obtain a full score to adjust for the ongoing reduction of activities in the Inventory as well as to support eligible clinicians with simplified reporting as they engage in fewer but more demanding activities. While our efforts to streamline the Inventory may result in a lower overall number of improvement activities MIPS eligible clinicians can choose from, the retained activities in the Inventory would be the highest priority activities that offer the strongest promotion of clinical practice improvement. This proposal is also responsive to commenters who, in the past, have requested that the number of required activities be reduced and that more activities be highly weighted (81 FR 77182). The activity removals and modifications being proposed would result in an Inventory of activities that are meaningful, timely, and rigorous. While decreasing the number of required activities would simplify reporting, MIPS eligible clinicians would still be required to participate in meaningful activities that yield significant practice improvement.

We requested comments on our proposals to remove weighting and reduce the number of activities that clinicians are required to attest to achieve a full score in the improvement activities performance category.

Specifically, we requested comments on our proposal to revise § 414.1380(b)(3) to read that, beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 20 points for each improvement activity, while non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 40 points for each improvement activity. Therefore, to receive a score of 40 points, or full credit, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) must report two improvement activities, while non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs must report one improvement activity.

We also requested comments on our proposal to revise § 414.1365(c)(3) to state that, beginning with the CY 2025 performance period/2027 MIPS payment year, MVP participants receive 40 points for each improvement activity. Therefore, to receive a score of 40 points, or full credit, MVP participants would be required to report one improvement activity.

We received comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for our proposal to eliminate improvement activity weights. Many believed that this change would simplify reporting and greatly reduce administrative burden and complexity of scoring. Other commenters found activity weights were not beneficial, indicating that in some cases, the activity weight does not necessarily correlate with the activity's value to clinicians or to patient care. A few commenters praised this change of weighting all improvement activities equally because it promotes fairness across different practice settings and aligns with our efforts to make the Quality Payment Program more accessible. One commenter encouraged CMS to identify additional simplifications to make the process of reporting even less burdensome.

Response: We appreciate commenters' support.

Comment: A few commenters recommended that CMS balance the

need for reduced reporting burden with the continued goal of driving meaningful quality improvements and not overlooking critical aspects of care. One commenter highlighted that improvement activities which are weighted as high typically reflect more significant or innovative improvements than activities that are weighted as medium, and, if weighting is eliminated, it may be more challenging to distinguish between practices making substantial improvements and those meeting only minimal requirements. Another commenter believed that incentivizing clinicians for choosing to report high value activities may drive clinical improvements more effectively. One commenter stated that removing the distinction between medium and high-weighted activities may reduce the motivation for clinicians to engage in activities with the highest impact as well as reduce the robustness of the improvement activities performance category.

Response: We appreciate these comments and will continue to assess and take such concerns into consideration as we refine the Inventory. As we streamline the Inventory, each retained activity highlights a unique and vital aspect of care and will offer a meaningful level of clinical practice improvement. We believe that, with the elimination of activity weighting, clinicians will invariably be participating in activities that offer the highest level of clinical improvement, as every retained activity in the Inventory will ultimately be considered a high-priority activity. As we move forward, we will continue to explore ways to incentivize clinicians to engage in actions that yield the highest level of practice improvement.

Comment: Many commenters expressed support for the reduction in the number of activities to which clinicians must report. A few commenters also commended CMS for continuing to alleviate the reporting burden for small practice, rural, in a provider-shortage area, or non-patient facing clinicians by reducing the number of required activities.

Response: We appreciate commenters' support of our changes to simplify reporting as well as our commitment to reducing reporting burden for eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing.

Comment: One commenter requested that CMS award bonus points to clinicians that report additional improvement activities in a performance year to encourage pursuit of more than the minimum. Another commenter requested that CMS consider ways to provide cross-category credit for investments in quality that are captured through both quality measures and improvement activities.

Response: We appreciate these comments. Our current policy focus is to consider reporting changes that align with both MIPS and MVP. We noted in the CY 2019 PFS final rule (83 FR 59851) that bonus points were created as transition policies, which were not meant to continue through the life of the program. As we move to MVPs, we are simplifying our scoring by ending transition policies that were established in the initial years of the program. As we are in the eighth year of the Quality Payment Program and we are reducing (not increasing) the reporting requirements for the improvement activities performance category, we are not able to provide bonus points for improvement activities at this time. As we consider policies that support MVP adoption by current MIPS participants, we will continue to assess and explore ways to incorporate incentives via future rulemaking. We will continue to identify cross-category efficiencies as we refine the Inventory for both MIPS and MVP.

Comment: One commenter recommended that the requirements for improvement activity reporting be aligned across MIPS and MVPs to reduce complexity, enhance consistency across the program, and ensure fairness for participants.

Response: We appreciate this comment and will continue to consider reporting changes that align with both MIPS and MVPs. At this time, we continue to believe that reduced reporting requirements are necessary to support the adoption of and reduce the burden for implementation of MVPs. Finalizing the policy that MVP participants may report fewer improvement activities than eligible clinicians reporting traditional MIPS will incentivize and support MVP adoption. We will also continue to seek ways to further simplify reporting across both MIPS and MVPs.

Comment: A few commenters requested that CMS require clinicians to report only one improvement activity instead of two. Those commenters argued that even practices that don't qualify as small practices, especially those in multispecialty settings, struggle to find two appropriate improvement activities that apply to the majority of the group, and, as the improvement activity Inventory continues to be streamlined, large multi-specialty groups may be forced to implement improvement activities that are not meaningful. One commenter expressed the belief that there should be parity in reporting requirements regardless of whether or not a clinician is patient-facing in order to remove complexity. Another commenter argued that participants may still face challenges in meeting these new reduced requirements, especially compared to MVP participants who will only need to report one improvement activity.

Response: As we consider policies that support MVP adoption by current MIPS participants, we will assess and explore ways to incorporate incentives via future rulemaking. At this time, we continue to believe that reduced reporting requirements for MVP participants are necessary to support the adoption of and reduce the burden for implementation of MVPs. We do not believe that the current and future Inventory is not sufficient and MIPS participants should be able to identify two activities to implement that will be both meaningful and not overly burdensome. We also note that flexibilities for special statuses such as Non-patient facing are a feature of the Quality Payment Program overall. Section 1848(q)(2)(C)(iv) of the Act requires the Secretary, in specifying improvement activities, to give consideration to the circumstances of professional types who typically furnish services that do not involve face-to-face interaction with a patient. In the CY 2017 Quality Payment Program final rule (81 FR 77041 through 77049), we discuss the definition of a non-patient facing MIPS eligible clinician as well as the establishment of exceptions due to many non-patient facing MIPS eligible clinicians not having sufficient improvement activities applicable and available to report under MIPS. We will continue to identify opportunities to reduce reporting burden for both MIPS and MVPs, particularly for multispecialty practices and clinicians in other settings who do not classify as a small practice, rural practice, or Non-patient facing.

After consideration of comments, we are finalizing these scoring and reporting policy changes as proposed.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the Promoting Interoperability performance category (and in past rulemaking, we referred to

it as the advancing care information performance category).

For our previously established policies regarding the Promoting Interoperability performance category, we refer readers to the regulation at 42 CFR 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), and CY 2024 PFS final rule (88 FR 79308 through 79312 and 88 FR 79351 through 79365).

(b) Current Definition of CEHRT for the Quality Payment Program

In the CY 2024 PFS final rule (88 FR 79307 through 79312), we finalized revisions to the definition of CEHRT for the Quality Payment Program at 42 CFR 414.1305. In the CY 2024 PFS final rule (88 FR 79309 and 79310), we amended the definition of CEHRT to be more flexible in response to changes proposed by the Office of the National Coordinator for Health Information Technology (ONC) [869] in the ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' (HTI–1) proposed rule (88 FR 23746 through 23917). Specifically, we amended our definition of CEHRT at § 414.1305 to ensure references to ONC's definition of Base EHR at 45 CFR 170.102 and its health IT certification criteria at 45 CFR 170.315 were responsive to any changes ONC makes to its definition and criteria at any time. Instead of requiring that CEHRT meet only the ''2015 Edition Base EHR definition,'' we added that it also may meet the ''subsequent Base EHR definition'' as defined at 45 CFR 170.102. We also amended our definition of CEHRT to provide that the CEHRT must also be certified to the ONC health IT certification criteria ''as adopted and updated'' in 45 CFR 170.315. This approach is consistent with the policies subsequently finalized in the HTI–1 final rule (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In consideration of the updates finalized in the CY 2024 PFS final rule and the HTI–1 final rule, we refer to ''ONC health IT certification criteria'' throughout this final rule where we previously would have referred to ''2015 Edition health IT certification criteria.'' These revisions to the definition of CEHRT in § 414.1305 ensure that updates to the definition of Base EHR in 45 CFR 170.102, and updates to applicable ONC health IT certification criteria in 45 CFR 170.315, are incorporated into the CEHRT definition without additional regulatory action by CMS. For ease of reference, Table 80 sets forth the ONC health IT certification criteria required to meet the Promoting Interoperability performance category objectives and measures.

In the CY 2024 PFS final rule (88 FR 79408 through 79414), we also finalized changes to the CEHRT definition at § 414.1305 for Advanced APMs requiring use of EHR technology certified under the ONC Health IT Certification Program that meets the ONC Base EHR definition at 45 CFR 170.102 and any such ONC health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM, for the year, considering factors such as clinical practice area, promotion of interoperability, relevance to reporting on applicable quality measures, clinical care delivery objectives of the APM, or any other factor relevant to documenting and communicating clinical care to patients or their health care providers in the APM. This CEHRT definition affords Advanced APMs the ability to tailor additional CEHRT use requirements to those features or capabilities that are clinically relevant to the APM and its participants, rather than referring to the same criteria associated with measures in the Promoting Interoperability performance category of MIPS (88 FR 79413).

We highlight certain updates to ONC health IT certification criteria finalized in the ONC HTI–1 final rule that impact certification criteria referenced under the CEHRT definition. ONC adopted the certification criterion ''Decision support interventions'' (DSI) in 45 CFR 170.315(b)(11) to ultimately replace the ''Clinical decision support (CDS)'' certification criterion in 45 CFR 170.315(a)(9) included in the Base EHR definition (89 FR 1236). The finalized DSI criterion ensures that Health IT Modules certified to 45 CFR 170.315(b)(11) must, among other functions, enable a limited set of identified users to select (that is, activate) certain evidence-based decision support interventions and Predictive DSI (as the latter term is defined in 45 CFR 170.102) (89 FR 1241) and support user access to specified ''source attributes''—categories of technical performance and quality information—for both evidence-based and Predictive DSI (89 FR 1236). ONC further finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS certification criterion in 45 CFR 170.315(a)(9) or being certified to the revised DSI criterion in 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that a Health IT Module must be certified to the DSI certification criterion in 45 CFR 170.315(b)(11) in order to meet the Base EHR definition, and the adoption of the CDS certification criterion in 45 CFR 170.315(a)(9) will expire on January 1, 2025 (89 FR 1281).

In the HTI–1 final rule, ONC also finalized other updates related to ONC health IT certification criteria referenced in the CEHRT definition. ONC finalized January 1, 2026, as the date when updates discussed below would take effect; accordingly, health IT developers must update and provide certified Health IT Modules to their customers consistent with the Maintenance of Certification requirements in 45 CFR 170.402(b)(3) by this date, including the following updates:

- ONC updated the ''Transmission to public health agencies—electronic case reporting'' criterion in 45 CFR 170.315(f)(5) to specify the use of consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion on and after January 1, 2026 (89 FR 1228).
- ONC adopted the United States Core Data for Interoperability (USCDI) version 3 in 45 CFR 170.213(b) and finalized that USCDI version 1 in 45 CFR 170.213(a) will expire on January 1, 2026 (89 FR 1211 and 1224). This change impacts ONC health IT certification criteria that reference the USCDI, including the ''Transitions of care'' certification criteria (45 CFR 170.315(b)(1)(iii)(A)(*1*) and (*2*)), ''Clinical information reconciliation and incorporation—Reconciliation'' (45 CFR 170.315(b)(2)(iii)(D)(*1*) through (*3*)); and ''View, download, and transmit to 3rd party'' (45 CFR 170.315(e)(1)(i)(A)(*1*)) (89 FR 1214).
- ONC updated the ''Demographics'' certification criterion (45 CFR 170.315(a)(5)), including renaming the

[869] On July 29, 2024, notice was posted in the **Federal Register** that the Office of the National Coordinator for Health IT would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

criterion to ''Patient demographics and observations'' (89 FR 1295 and 1296).

• ONC updated the ''Standardized API for patient and population services'' certification criterion in 45 CFR 170.315(g)(10) including finalizing references to newer versions of standards referenced in the criterion, such as the US Core IG 6.1.0 (89 FR 1285) and the SMART App Launch Implementation Guide Release 2.0.0 (89 FR 1292).

For complete information about the updates to ONC health IT certification criteria finalized in the HTI–1 final rule, we refer readers to the text of the final rule (89 FR 1192) as well as resources available on ONC's website.[870]

(c) Potential Future Update of the SAFER Guides Measure

(i) Background

ONC developed the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. ONC provided the SAFER Guides, including the High Priority Practices SAFER Guide, as a tool to help organizations at all levels conduct self-assessments to optimize the safety and use of EHRs.[871] In the CY 2022 PFS final rule (86 FR 65475 through 65477), we adopted the SAFER Guides measure under the Protect Patient Health Information objective beginning with the CY 2022 performance period/2024 MIPS payment year. For the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year, MIPS eligible clinicians were required to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide[872] at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement. MIPS eligible clinicians were not scored based on their answer to the attestation, or their level of implementation of each of the practices. However, failure to attest to this measure would result in earning a score of zero for the Promoting Interoperability performance category for failing to meet the minimum reporting requirements.

In the CY 2024 PFS final rule (88 FR 79354 through 79356), we modified the SAFER Guides measure. Beginning with the CY 2024 performance period/2026 MIPS payment year, this modified measure requires MIPS eligible clinicians to conduct, and attest ''yes'' to having completed, an annual self-assessment of their CEHRT, using the High Priority Practices SAFER Guide. We remind readers that the SAFER Guides measure only requires completion of a self-assessment and does not require MIPS eligible clinicians to implement fully each of the practices identified in their self-assessment.

(ii) Status of Updates to SAFER Guides

As summarized in the CY 2024 PFS final rule (88 FR 79354 through 79356), we received comments in response to our proposal to modify the SAFER Guides measure, including many comments recommending that we collaborate with ONC to update the SAFER Guides, noting that the SAFER Guides were last updated in 2016 (88 FR 59264). In response to these comments, we noted that, while the current SAFER Guides reflect relevant and valuable guidelines for safe practices with respect to current EHR systems, we would consider exploring updates in collaboration with ONC. We reminded readers to visit the CMS resource library website at *https://www.cms.gov/regulations-guidance/promoting-interoperability/resource-library* and the ONC website at *https://www.healthit.gov/topic/safety/safer-guides* for resources on the content and appropriate use of the SAFER Guides (88 FR 59262). We also noted that future updates to the SAFER Guides would be provided with accompanying educational and promotional materials to notify participants, in collaboration with ONC, when available (88 FR 59265).

In the proposed rule and this final rule, we seek to make readers aware that efforts to update the SAFER Guides are currently underway. We anticipate that updated versions of the SAFER Guides may become available as early as CY 2025. We would consider proposing a change to the SAFER Guides measure, as soon as feasible, potentially beginning in the CY 2026 performance period/2028 MIPS payment year to permit use of updated versions of the SAFER Guides at that time. We encourage MIPS eligible clinicians to become familiar with the updated versions of the SAFER Guides when they become available and consider them as they implement appropriate EHR safety practices.

(d) Modification of the Definition of Meaningful EHR User for Healthcare Providers That Have Committed Information Blocking

The Department of Health and Human Services (HHS) final rule ''21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking'' (hereafter referred to as the Disincentives final rule), was displayed for public inspection by the Office of the Federal Register on June 26, 2024, and appeared in the **Federal Register** on July 1, 2024 (89 FR 54662 through 54718). The final rule implements the provision of the 21st Century Cures Act specifying that a healthcare provider, determined by the HHS Office of the Inspector General (OIG) to have committed information blocking, shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In the Disincentives final rule, we finalized that a MIPS eligible clinician (other than a qualified audiologist) will not be considered a meaningful EHR user in a performance period if the OIG refers, during the calendar year of the performance period, a determination that the MIPS eligible clinician committed information blocking as defined at 45 CFR 171.103. Information blocking, in the case of a health care provider, as defined in 45 CFR 171.102, is a practice that is likely to interfere with the access, exchange, or use of electronic health information, except as required by law or specified in an information blocking exception in 45 CFR part 171, subpart B, C, or D, and that the health care provider knows is unreasonable and is likely to interfere with access, exchange, or use of electronic health information. Furthermore, we finalized amendments to the definition of ''meaningful EHR User for MIPS'' at § 414.1305 to state that a MIPS eligible clinician (other than a qualified audiologist) is not a meaningful EHR user for a performance period if the OIG refers a determination that the MIPS eligible clinician committed information blocking, as defined at § 171.103, during the calendar year of the performance period (89 FR 54699). We also finalized amending the requirements at § 414.1375(b) to specify that a MIPS eligible clinician must be a meaningful EHR user for MIPS (as defined at § 414.1305) to earn a score for MIPS Promoting Interoperability performance category (89 FR 54695 through 54699). Under the final policies, a MIPS eligible clinician that OIG determines has committed information blocking would

[870] For more information, see *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

[871] *https://www.healthit.gov/topic/safety/safer-guides.*

[872] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

not be a meaningful EHR user, and therefore would be unable to earn a score (instead earning a score of zero) for the Promoting Interoperability performance category.

Additional regulatory provisions were finalized at 45 CFR part 171, subpart J, related to the application of disincentives (89 FR 54675).

We note that, as finalized, the revised definition of ''meaningful EHR user for MIPS'' at § 414.1305 and the revisions to § 414.1375(b) became effective when the final rule took effect on July 31, 2024. For additional background and information, we refer readers to the discussion in the ''21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking'' proposed rule (88 FR 74957 through 74962), as well as the Disincentives final rule.

(e) Future Goals of the Promoting Interoperability Performance Category

(i) Future Goals with Respect to Fast Healthcare Interoperability Resources® (FHIR) APIs for Patient Access

In partnership with ONC, we envision a future where patients have timely, secure, and easy access to their health information through the health application of their choice. We are working with ONC to enable this type of access to health information by requiring the use of APIs that utilize the Health Level Seven International® (HL7) FHIR standard. We are working with ONC and other Federal partners to improve timely and accurate data exchange, partner with industry to enhance digital capabilities, advance adoption of FHIR, support enterprise transformation efforts that increase our technological capabilities, and promote interoperability.

In the CY 2021 PFS proposed rule (85 FR 50303), we described our future vision for the Promoting Interoperability performance category and stated that we will continue to consider changes that support a variety of HHS goals, including supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. We also described plans to continue to align the Promoting Interoperability performance category with policies finalized in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (85 FR 25642), including finalization of a new certification criterion for a standards-based API using FHIR, among other health IT topics.

ONC finalized the HTI–1 final rule (89 FR 1192), effective March 11, 2024, to further implement the 21st Century Cures Act, among other policy goals. ONC finalized revisions to the ''Standardized API for patient and population services'' certification criterion at 45 CFR 170.315(g)(10). It also adopted the HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use version 6.1.0 at 45 CFR 170.215(b)(1)(ii), which provides the latest consensus-based capabilities aligned with the USCDI Version 3 [873] data elements for FHIR APIs. The HTI–1 final rule also created the Insights Condition and Maintenance of Certification requirements (Insights Condition) within the ONC Health IT Certification Program to provide transparent reporting on certified health IT (89 FR 1199). This Insights Condition will require developers of certified health IT subject to the requirements to report on measures that provide information about the use of specific certified health IT functionalities by end users. One such measure calculates the number of unique individuals who access their electronic health information overall and by different methods such as through a standardized API for patient and population services (89 FR 1313 and 1314).

By adopting these new and updated standards, implementation specifications, certification criteria, and conditions of certification, provisions in the HTI–1 final rule advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. We aim to further advance the use of FHIR APIs through policies in the Promoting Interoperability performance category to advance interoperability, encourage the exchange of health information, and promote innovative uses of health IT. We also hope to gain insights into the adoption and use of FHIR APIs by MIPS eligible clinicians due to the ONC Health IT Certification Program's Insights Condition. We believe maintaining our focus on promoting interoperability, alignment, and simplification would reduce healthcare provider burden while allowing flexibility to pursue innovative applications that improve care delivery. For additional background and information, we refer readers to the discussion in the HTI–1 final rule on this topic (89 FR 1192).

[873] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3.*

(ii) Improving Cybersecurity Practices

The Promoting Interoperability performance category encourages the advancement of EHR safety by promoting appropriate cybersecurity practices through the Security Risk Analysis and SAFER Guides measures. On February 14, 2023, the National Institute of Standards and Technology (NIST) published updated guidance for health care entities implementing requirements of the Health Insurance Portability and Accountability of 1996 (HIPAA) Security Rule (45 CFR part 160 and subparts A and C of 45 CFR part 164). The guidance, NIST SP 800–66r2, provides information and resources to HIPAA-covered entities to improve their cybersecurity risk practices.[874] We also wish to alert readers of additional HHS resources and activities regarding cybersecurity best practices as recently summarized in an HHS strategy document that provides an overview of HHS recommendations to help the health care sector address cyber threats.[875] HHS has also recently published a website detailing recommended cybersecurity performance goals.[876] We intend to consider how the Promoting Interoperability performance can promote cybersecurity best practices for MIPS eligible clinicians in the future.

(iii) Improving Prior Authorization Processes

We recently released the CMS Interoperability and Prior Authorization final rule, which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758). The final rule aims to enhance health information exchange and access to health records for patients, healthcare providers, and payers, and improve prior authorization processes. In the final rule, we finalized the addition of a new measure, the ''Electronic Prior Authorization'' measure, under the HIE objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8909 through 8927).

(f) Requirements for the Promoting Interoperability Performance Category for the CY 2025 Performance Period/ 2027 MIPS Payment Year

[874] *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

[875] *https://aspr.hhs.gov/cyber/Documents/Health-Care-Sector-Cybersecurity-Dec2023-508.pdf.*

[876] *https://hphcyber.hhs.gov/performance-goals.html.*

(i) Objectives and Measures for the CY 2025 Performance Period/2027 MIPS Payment Year

For ease of reference, Table 77 lists the objectives and measures for the Promoting Interoperability performance category required for the CY 2025 performance period/2027 MIPS payment year. We note that we did not propose any changes to previously established objectives, measures, and other requirements for the Promoting Interoperability performance category in the proposed rule.

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TABLE 77: Objectives and Measures for the Promoting Interoperability Performance Category for the CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	Any MIPS eligible clinician who: 1. is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; or 2. Any MIPS eligible clinician who does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or healthcare provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange	HIE Bi-Directional Exchange: Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	engaging in exclusionary behavior when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA MIPS eligible clinicians would attest to the following: ● Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. ● Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician:	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
access to their health information.	1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	The MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and	Electronic Case	N/A (measure is	N/A (measure is	The MIPS eligible clinician:

Objective	Measure	Numerator	Denominator	Exclusion
Clinical Data Exchange	Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	Yes/No and requires an affirmative attestation to fulfill)	Yes/No and requires an affirmative attestation to fulfill)	1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2. Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period:
Public Health and Clinical Data Exchange	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	None
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	None
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	None
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or	Security Risk Assessment: Conduct or review a security risk analysis in accordance with the	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	None

Objective	Measure	Numerator	Denominator	Exclusion
maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.	requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.			
Protect Patient Health Information	SAFER Guides High Priority Practices Guide: Conduct an annual assessment of the High Priority Practices Guide SAFER Guides	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	N/A (measure is Yes/No and requires an affirmative attestation to fulfill)	None

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(ii) Scoring Methodology for the CY 2025 Performance Period/2027 MIPS Payment Year

Table 78 reflects the scoring methodology for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year.

TABLE 78: Scoring Methodology for the CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required but will not be assigned points. Failure to submit an affirmative ("yes") attestation for these two measures will result in a zero score for the Promoting Interoperability performance category.
In addition, MIPS eligible clinicians must submit an affirmative ("yes") attestation regarding ONC direct review, and an affirmative ("yes") attestation that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3). Failure to submit an affirmative ("yes") attestation to fulfill these requirements will result in a zero score for the Promoting Interoperability performance category.

(iii) Exclusion Redistribution

Many required measures have exclusions associated with them as shown in Table 77. If a MIPS eligible clinician believes that an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum points available in Table 78 do not include the points that will be redistributed if a MIPS eligible clinician claims an exclusion for a specific measure. For ease of reference, Table 79 shows how points will be redistributed among the objectives and measures specified for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE 79: Exclusion Redistribution for CY 2025 Performance Period/2027 MIPS Payment Year

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required but will not be assigned points. Failure to submit an affirmative ("yes") attestation for these two measures will result in a zero score for the Promoting Interoperability performance category.
In addition, MIPS eligible clinicians must submit an affirmative ("yes") attestation regarding ONC direct review, and an affirmative ("yes") attestation that they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT, as required by § 414.1375(b)(3). Failure to submit an affirmative ("yes") attestation to fulfill these requirements will result in a zero score for the Promoting Interoperability performance category.

(iv) ONC Health IT Certification Criteria

For ease of reference, Table 80 lists the objectives and measures for the Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. We refer readers to the CY 2024 PFS final rule (88 FR 79307 through 79312) for our discussion of and amendments to the definition of CEHRT at § 414.1305.

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TABLE 80: Promoting Interoperability Performance Category Objectives and Measures and ONC Health IT Certification Criteria

Objective	Measure	Certification Criteria (CY 2025 Performance Period/2027 MIPS Payment Year) in Title 45 of the CFR
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.

Objective	Measure	Certification Criteria (CY 2025 Performance Period/2027 MIPS Payment Year) in Title 45 of the CFR
Protect Patient Health Information	Security Risk Assessment	The requirements are a part of CEHRT specific to each certification criterion.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

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(g) Request for Information (RFI) Regarding Public Health Reporting and Data Exchange

In the CY 2025 PFS proposed rule (89 FR 62072 through 62075), we sought comment on a series of goals and principles for the Promoting Interoperability performance category's Public Health and Clinical Data Exchange objective, particularly to support timely sharing of information with public health agencies that also reduces administrative burden for MIPS eligible clinicians.

We received many comments on this RFI regarding public health reporting and data exchange, and we thank the commenters for responding to our request for information. Although we will not be addressing in this final rule the comments received in response to this RFI, we value the input received and will take the comments into consideration to help us consider potential future policies to enhance public health reporting and data exchange. We will continue to collaborate with the CDC and ONC to explore how the Promoting Interoperability performance category could advance public health infrastructure through more advanced use of health IT and data exchange standards and consider the feedback received for future rulemaking.

f. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(6)(A) of the Act specifies that, to then determine a MIPS payment adjustment factor for each MIPS eligible clinician for an applicable MIPS payment year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. We refer readers to section IV.A.4.g.(2) of this final rule for further discussion of the performance threshold, and our calculation of MIPS payment adjustment factors, and our proposals with respect thereto.

Section 1848(q)(2)(A) of the Act provides that the Secretary must assess each MIPS eligible clinician with respect to four performance categories in determining each MIPS eligible clinician's final score: quality, resource use (referred to as ''cost''), clinical practice improvement activities (referred to as ''improvement activities''), and meaningful use of certified EHR technology (referred to as ''Promoting Interoperability''). Section 1848(q)(2)(B) of the Act describes the measures and activities that must be specified under each performance category, including the quality performance category and cost performance category. Section 1848(q)(3) of the Act provides that we must establish performance standards with respect to the measures and activities specified under the four performance categories for a performance period, considering historical performance standards, improvement, and the opportunity for continued improvement. To calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act provides that we must develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards we have established with respect to applicable measures and activities specified for each performance category, using a scoring scale of 0 to 100.

In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for the CY 2025 performance period/2027 MIPS payment year, the scoring weights for each performance category are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

For the CY 2025 performance period/2027 MIPS payment year, we proposed in the CY 2025 PFS proposed rule to update our scoring methodologies to respond to statutory requirements and impacts observed in performance data. Specifically, we proposed to—

- Establish defined topped out benchmarks for certain topped out measures for clinicians impacted by limited measure choice;
- Establish Complex Organization Adjustment for eCQMs reported by Virtual Groups and APM Entities.
- Score Medicare CQMs using flat benchmarks for their first two performance periods in the program.
- Modify the benchmarking methodology for scoring measures in the cost performance category;
- Adopt a new cost measure exclusion policy;
- Eliminate the weighting of activities in the improvement activities performance category; and
- Reduce the number of activities to which clinicians are required to attest.

We did not propose any changes to scoring policies for the Promoting Interoperability performance category.

We refer readers to section IV.A.4.e.(3)(b)(iv) of this final rule for discussion of scoring proposals in the Improvement Activities performance category.

We refer readers to section IV.A.4.f.(1)(d) of this final rule for discussion of proposals for scoring the cost performance category.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY

2021, CY 2022, and CY 2023 PFS final rules, and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR65490 through 65509, and 87 FR 70088 through 70091). In the CY 2024 PFS final rule, we finalized updates to our scoring flexibilities policy at § 414.1380(b)(1)(vii)(A) (88 FR 79368 through 79369).

(i) Scoring for Topped Out Measures in Specialty Measure Sets With Limited Measure Choice

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2023 PFS final rule (81 FR 77282 through 77287, 82 FR 53721 through 53727, 83 FR 59761 through 59765, and 88 FR 70090 through 70091), and § 414.1380(b)(1)(iv) for our established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). We define topped out measures in § 414.1305 differently for process measures and non-process measures. A topped out process measure means a measure with a median performance rate of 95 percent or higher. A topped out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.01 and the 75th and 90th percentile are with 2 standard errors. For MIPS eligible clinicians electing to report on measures where they expect to perform well, we anticipated many measures would have performance distributions clustered near the top. (81 FR 77282). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement nor, more broadly, do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies to identify and cap the scoring potential of such measures. Additionally, we established practices for the removal of such measures, such as establishing the topped out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary.

The topped out measure lifecycle is described in the CY 2018 PFS final rule (82 FR 53721 and 53727). We established at § 414.1380(b)(1)(iv)(B) that we would cap scoring for topped out measures at 7 points in the second consecutive year that it is identified as topped out. If a measure has been identified as topped out for 3 consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern where removal of topped out measures would leave clinicians with fewer than 6 applicable measures to report and that such removal in those instances would impact some specialties more than others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

The topped out scoring cap and the topped out measure lifecycle were established with the intention to drive continued quality improvement by providing clinicians with the ability to plan for optimal quality measurement and reporting and by providing measure developers time to develop and submit alternative measures for use in the program (82 FR 53727). However, the pace of measure development has not matched the rate at which topped out measures would ideally be removed under the established topped out lifecycle policy. Since the CY 2017 performance period/2019 MIPS payment year, the MIPS final list of quality measures has decreased from 271 to 198 including the removal of 34 topped out measures that had reached the end of the topped out measure lifecycle.

We have received feedback from interested parties and independently verified that clinicians reporting specialty sets in which there is high presence of topped out measures receiving the 7-point cap are often facing both limited measure choice and limited scoring opportunities. Analysis of data from the CY 2022 performance period/2024 MIPS payment year showed that only 7 percent of quality measure submissions were for topped out measures. However, of those submissions, clinicians representing five specialties accounted for 54 percent of the submissions of topped out measures that contributed to the final score. When we analyzed the data from the CY2022 performance period/2024 MIPS payment year, we found that clinicians in these specialties were facing limited measure choice, with an overrepresentation of topped out measures among their measure selection. Some such topped out measures have been retained in the program to ensure specialists will have applicable measures in the absence of more robust measure development.

We acknowledge that certain clinician specialists have limited measure choice and that their opportunities to maximize their MIPS performance score may be particularly affected by the current topped out measure scoring policy. We appreciate that, as the performance threshold increases, it may become more difficult for these clinician specialists to maximize their MIPS performance score and secure positive payment adjustments for reasons entirely outside of their control, primarily the topped-out measure scoring cap. To determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a ''prior period'' specified by the Secretary. In the CY 2024 PFS final rule, we finalized the performance threshold at a score of 75 points for the CY 2024 performance period/2026 MIPS payment year at § 414.1405(b)(9)(iii) (88 FR 79319). We have finalized in section IV.A.4.g.(2)(c) of this final rule to maintain the performance threshold at 75 points for the CY 2025 performance year/2027 MIPS payment year. As the number of topped out measures a clinician reports increases, a clinician who must report topped out measures will see their maximum potential quality performance category score decrease, and the clinician must score as close to perfect as possible on the topped out measures to mitigate the effect of the 7-point cap on the clinician's final score. Affected clinicians face additional difficulty should they be subject to additional scoring policies, including reweighting of performance categories and reporting quality measures that lack benchmarks. Reweighting of the Promoting

Interoperability, cost, or both performance categories increases the weighting of the quality performance category in the final score from 30 percent to 55 or 85 percent.

We want to address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps consistent with our desire to facilitate fairer scoring of all specialties. For this reason, we proposed in the CY 2025 PFS proposed rule that beginning with the CY 2025 performance period/2027 MIPS payment year CMS could remove the 7-point cap for certain topped out measures that we would select based on the methodology discussed below. This will allow clinicians who practice in specialties impacted by limited measure choice to be scored according to defined topped out measure benchmarks that do not cap scores at 7 measure achievement points. Table 81 is an illustrative example of the proposed defined topped out measure benchmark.

TABLE 81: Example Proposed Defined Topped Out Measure Benchmark

Measure Achievement Points	Performance Rate
1-1.9	84-85.9%
2- 2.9	86-87.9%
3-3.9	88-89.9%
4-4.9	90-91.9%
5-5.9	92-93.9%
6-6.9	94-95.9%
7-7.9	96-97.9%
8-8.9	98-99.9%
10	100%

As discussed above, given that clinicians reporting specialty measure sets with limited measure choice are disproportionately hindered by the 7-point topped out measure scoring cap, we would, in accordance with the methodology proposed in the CY 2025 PFS proposed rule (89 FR 62079) focus on identifying the topped out measures within specialty measure sets which clinicians with limited measure choice report. We proposed to identify the measures for which we would apply the defined topped out measure benchmark on a yearly basis. Measures receiving the defined topped out measure benchmarks would be proposed and adopted through notice-and-comment rulemaking concurrent with our adoption of the MIPS final list of quality measures.

This proposed performance standard would aim, for clinicians with limited measure availability, to continue to require high performance, but would not cap scoring potential for exceptional performers and would offer better scoring opportunities for those performing below the median in the distribution than under our current policy. Under the proposed topped out measure benchmarking methodology, those achieving high performance rates would be rewarded for high performance. Scores between 9–9.9 were intentionally left out. We considered inclusion of scores in the 9th decile, but ultimately excluded them to necessitate exceptional clinical quality performance to achieve maximum scores. As originally proposed, we believed this approach would ameliorate the challenge of reporting on measures with a scoring cap while maintaining a high performance standard for topped out measures.

In addition to addressing the scoring limit of the cap, we also proposed to address the scoring limits caused by the heavily skewed distribution of topped out measures. Previously, because median clinician performance was heavily skewed towards the top of distribution for many topped out measures the second highest achievable decile after the 7th decile may be the 3rd or 4th decile. We therefore proposed to specify a topped out measure benchmark that would set an even performance standard. Such a benchmark policy would facilitate clinician efforts to improve clinical quality among clinicians for whom improvement is still possible. The proposed distribution would allow those performing at or above the 97th percent to achieve a score of 7.5 measure achievement points or greater to reward high performance and encourage clinical quality improvement for those who perform below the median.

We proposed a methodology that would be used to conduct an analysis annually to determine which specialty measure sets are impacted by limited measure choice and which measures should be subject to the scoring cap exemption. Our analysis would evaluate all specialty measure sets by collection type to assess the impact of limited measure choice considering the influence of several scoring considerations including the number of capped topped out measures, the number of measures in the specialty set without historical benchmarks, and the scoring potential to meet or exceed the performance threshold. We would then consider each capped topped out measure in the corresponding specialty measure sets on a case-by-case basis for application of the defined topped out measure benchmark. Additionally, annual consideration of which measures would have the defined topped out measure benchmark applied would consider any changes to the availability of applicable measures and changes in the topped out status of measures that previously had the defined topped out measure applied. A measure would not have a defined topped out measure benchmark applied until it was identified as topped out for 2 consecutive performance periods, the point at which point the 7-point cap would be applied. If suppression of a measure or removal of a benchmark impacts a measure scored according to the defined topped out measure benchmark, it would not be proposed again for the application of the defined topped out measure benchmark and the performance standard would return to the standard scoring policy at § 414.1380(b)(1)(i).

Measures that are identified as topped out for 3 consecutive performance periods may still be proposed for

removal through notice-and-comment rulemaking and extremely topped out measures, those with an average mean performance within the 98th to 100th percentile range, could also still be proposed for removal in the next rulemaking cycle, regardless of whether or not they are in the midst of the topped out measure lifecycle (83 FR 59763). If a measure that is scored according to a defined topped out measure benchmark later shows extremely topped out status, it would be subject to this policy. Any such measure removal would continue to occur through notice-and-comment rulemaking. While we aim to be responsive to those facing limited measure choice, we do not believe that measures with topped out performance have the same value in the program as measures that are not topped out, and they should be scored accordingly in instances where doing so does not unfairly limit a clinician's scoring opportunity. We believe these parameters identify those most impacted by limited measure choice while continuing to encourage high clinical quality measure performance.

This proposal is consistent with our current topped out measure lifecycle, program goals, and historical approaches to scoring scenarios with limited measure choice. In the CY 2017 Quality Payment Program final rule, we exempted measures reported via the CMS Web Interface from the 7-point measure cap. The CMS Web Interface requires that MIPS eligible clinicians submitting via the CMS Web Interface must submit all measures included in the CMS Web Interface (81 FR 77116). Their lack of ability to select alternative measures made the application of the 7-point measure cap inappropriate. Instead, we finalized a proposal at § 414.1380(b)(1)(ii)(A) to use benchmarks from the corresponding year of the Shared Saving Program as the Shared Savings Program incorporates a methodology for measures with high performance into the benchmark (82 FR 53721). The defined topped out measure benchmark similarly aims to score clinicians facing limited measure choice on topped out measures using a methodology that adjusts for high performance.

We considered several policy options to address topped out measure scoring for clinicians facing limited measure choice. These included removing all topped out measures at the end of the topped out measure lifecycle, exempting all topped out measures in specialty measure sets from application of the 7-point cap, applying a denominator reduction for those scoring 7 out of 10 measure achievement points on topped out measures in specialty measure sets, and adopting a new reweighting policy for the quality performance category for clinicians impacted by limited measure choice that score below the performance threshold. These approaches would not appropriately address the barriers to fair scoring posed by limited measure choice, nor would they incentivize and reward improvement in clinical quality measure performance. Additionally, these alternatives would introduce additional scoring complexity and in one case, require clinicians' additional submission of a reweighting application to access potential benefits. The proposed approach of applying defined topped out measure benchmarks for certain topped out measures selected in accordance with the methodology set forth above avoids the additional complexity of the other approaches by building on historical and current quality measure scoring policies to topped out measures that does not require additional steps to access and is applicable as we transition to MVPs.

For the reasons stated above, we proposed in the CY 2025 PFS proposed rule to add § 414.1380(b)(1)(iv)(C) to state that beginning with the CY 2025 performance period/2027 MIPS payment year, measures impacted by limited measure choice as specified in paragraph (b)(1)(ii)(E) are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B). We proposed a conforming change to § 414.1380(b)(1)(iv)(B).

We also proposed to add § 414.1380(b)(1)(ii)(E) to state that, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice. Measures included in the list would be scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 7.5 measure achievement points. Accordingly, we also proposed to update § 414.1380(b)(1)(ii) to state that except as provided in paragraphs (b)(1)(ii)(B) through (F), benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. We also proposed to make conforming changes to this section to include a previous inadvertent omission of paragraph (b)(1)(ii)(D) in addition to the proposed new exceptions in paragraphs (b)(1)(ii)(E) and (F) corresponding to policies discussed in sections IV.A.4.f.(1)(b)(i) and IV.A.4.f.(1)(c)(i) respectively.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the 7-point cap for topped out measures that have been impacted by limited measure choice. These commenters believed that this proposal would expand clinicians' and specialists' ability to participate in the program and not penalize them for factors outside of their control. Several commenters also stated this proposal will help level the playing field for specialists and help them achieve a quality score that is more representative of the care they provide. Further, several commenters noted that the proposal would provide fairer and more accurate performance assessments, support consistent high-quality care, encourage continuous quality improvement, and address challenges posed by high-performing measures. Further, several commenters stated that this proposal would be advantageous for certain specialties, such as anesthesiology, oncology, pathology, and radiology. A few commenters also appreciated CMS' willingness to recognize the challenges faced by specialties, especially given the fact that the pace of measure development has been slower than anticipated.

Response: We thank commenters for their support.

Comment: Several commenters offered suggestions on how to clarify or improve on the proposed Topped Out Measure Benchmark and methodology. A few commenters requested that CMS clarify why it chose to tie a performance rate in the 97th percentile to 7.5 measure achievement points. These commenters further questioned if 7.5 points represent 10 percent of the current year's performance threshold, similar to CMS' cost measure scoring proposal. They also noted that CMS should align this proposal with the cost category proposal and assign a point value that increases over time in alignment with any increases to the MIPS performance threshold. Additionally, a few commenters offered recommendations on the proposed Topped Out Measure Benchmark. A few commenters recommended that CMS allow for 9–9.9 measure achievement points for a performance rate of 99–99.9 percent. One commenter recommended that CMS omit the first decile rather than the ninth and did not believe CMS

adequately justified why it removed the ninth percentile. Another believed that the benchmarking methodology should be modified to a lower limit of 25 percent, instead of 84 percent.

Response: At § 414.1305 we define topped out measures. A topped out process measure is a measure with a median performance rate of 95 percent or higher. A topped out non-process is a measure where the Truncated Coefficient of Variation is less than 0.01 and the 75th and 90th percentile are with 2 standard errors. Extremely topped out measures are defined as measures where the mean performance rate is between 98 and 100 percent. We tied a performance rate of 97 percent to 7.5 points to assure that clinicians reporting measures for which the defined topped out measure benchmark is applied could meet the performance threshold which is similar to the cost measure benchmarking methodology discussed in section IV.A.4.f.(1)(d)(ii)(B) of this final rule. We will continue to align the defined topped out measure benchmark with the performance threshold as updates are made.

We agree that CMS should include the 9th decile. Originally, we thought exclusion would emphasize the importance of high performance to achieve high scores. After further consideration, we have determined that the omission of the 9th decile would unnecessarily penalize clinicians facing limited measures choice. Assigning clinicians with a performance rate of 84 percent to the lowest decile holds clinicians to the higher performance standards necessary to perform well on a topped out measure. Omitting the 9th decile would doubly penalize clinicians, which is unnecessary due to the aforementioned abbreviated higher performance standard. Therefore, we are finalizing the define topped out measure benchmark to include the 9th decile corresponding to a performance rate from 99 to 99.9 percent. The defined topped out measure benchmarks seek to alleviate concerns that clinicians with limited measure choice forced to report on a high proportion of topped out measures cannot meet the performance threshold, while still requiring high performance to score well on measures with topped out performance. Therefore, it is not appropriate to lower the first decile to a performance rate of 25 percent.

Comment: A few commenters requested clarification from CMS on the proposal. One commenter sought guidance on whether the proposal would apply to quality measures in an MVP. Another commenter sought clarification on how broadly the proposal would be applied, especially for specialties that have greater weight placed on their quality score and may be exempt from the Promoting Interoperability and Cost categories. One commenter inquired about how CMS would define ''limited measure sets'' and if it is solely based on CQM/eCQM availability or if it also is inclusive of QCDR measures.

Response: To identify measures subject to this proposal, we would review each specialty measure set by collection type and identify if the prevalence of topped out measures within such a set hinders a clinician's ability to successfully participate in the MIPS quality performance category. For discussion on our approach for determining topped out measures impacted by limited measure choice and subject to the defined topped out measure benchmark, please see section IV.A.4.f.(1)(b)(ii) of this final rule. As discussed in section IV.A.4.f.(1)(b)(ii), those reporting specialty measure sets are those most likely to be impacted by limited measure choice. If a measure is identified for application of the defined topped out measure benchmark, that benchmark would be used across MIPS. If it is in use in an MVP, the defined topped out measure benchmark would be applied there as well. Additionally, reporters reporting the measure outside of the entire specialty measure set as part of their six required quality measures would be scored according to the defined topped out measure benchmark. The policy is designed to help those most impacted by limited measure choice, but application of the benchmark applies to all who report it. QCDR measures were not included in this scope as they are governed by another policy at § 414.1400(b)(4)(iii)(C) stating that CMS may revoke a measure's second year approval if identified as topped out.

Comment: Several commenters expressed concern with the proposal to remove the 7-point cap for topped out measures that have been impacted by limited measure choice and recommended CMS remove the cap on all topped out measures. A few commenters believed that the proposal falls short of addressing the overall challenges with the way benchmarks for all measures are currently established. A few commenters also stated that universal application of this policy would ensure that no clinicians are negatively impacted by the current scoring cap while also avoiding challenges related to accurately identifying which measures should be subject to this policy. For example, one commenter specifically mentioned that specialties like podiatry would be disadvantaged as they have more than 10 measures in their specialty set, the majority of which are cross-cutting measures. One commenter encouraged CMS to think more broadly about ''limited measure choice,'' recognizing that many specialists and subspecialists also experience limited choice and there is an inadequate selection of measures for multispecialty TINs. One commenter believed that limiting the proposal to a select set of measures is confusing and arbitrary. One commenter raised concerns that the proposal restricts the number of achievable measures for physicians, which could lead to fewer scoring opportunities and a higher likelihood of penalties. Another commenter noted that the proposal may place unrealistic expectations and pressure on providers, because they may find it challenging to consistently meet such high performance thresholds. Further, one commenter suggested that when selecting measures under this proposal, CMS should view performance rates for traditional MIPS independently from MVPs while another commenter requested that CMS remove the 7-point cap for a specified timeframe to ensure stability for clinicians. One commenter encouraged CMS to identify ways to evaluate topped out measures more granularly, highlighting that they may represent an opportunity for improvement among clinicians who do not currently report them. Another commenter suggested that CMS should monitor the impact of the proposal to address any complexity or unintended consequences.

Response: We thank commenters for their feedback. As the program evolves, we will continue to evaluate our scoring methodology to support fair and equitable scoring that promotes clinical quality improvement. Our current topped out measure policy at § 414.1380(b)(1)(iv) was established to incentivize clinicians to strive to for continued improvement taking into consideration areas where continued improvement is still needed. The topped out measure scoring cap has been a useful tool in communicating that there is limited opportunity for continued improvement. Measures with topped out performance, indicate that there is already reasonable expectation of high clinical quality performance. Clinicians not facing limited measure availability can choose to report on measures for which there is opportunity to score above seven points. Clinicians facing the most limited measure choice, do not have this option. For the CY 2025 performance period/2027 MIPS

payment year, the defined topped out measure policy provides relief for the clinicians most impacted by limited measure choice. Our methodology seeks to identify those most impacted by limited measure choice that current topped out measure policies would leave unable to avoid negative adjustments and includes instances where reweighting of other performance categories would result in a higher weight of the quality performance category. This policy looks at specialty measure sets to identify measures because reporters often have fewer than 6 measures from which to choose. Specialties, such as podiatry, have specialty measure sets that include topped out measures, but have an opportunity to reach the performance threshold based on the available measures in the specialty measure set and avoid harsh negative payment adjustments. We will monitor the impact of this proposal. Additionally, we will evaluate our larger benchmarking policy and consider scoring alternatives that do not include scoring caps.

This proposal does not restrict the number of achievable measures for clinicians but rather provides those with a limited availability of quality measures relevant to their practice the ability to avoid significant negative payment adjustments solely based on the limited availability. It is important to maintain high performance standards for the topped out measures identified under this policy as historical data shows that there is a reasonable expectation of high performance. The defined topped out measure benchmark will score those already performing well accordingly and provides those below the median performance rates the opportunities to receive scores not impacted by the large performance skews in the distribution that typically omits deciles in the middle ranges. Our benchmarking methodology does not distinguish the performance rates between traditional MIPS and MVPs. Therefore we would not distinguish between traditional MIPS and MVPs for application of the defined topped out measure benchmarks. We will not remove the cap for a specified timeframe. Measure performance can change year over year and a measure that shows topped out performance in one year can change in the next. Therefore, application of the topped out measure policies including the defined topped out measure benchmark will be done on a yearly basis. We will continue to find ways to evaluate topped out measures to ensure we provide clinicians with fair scoring opportunities on measures meaningful to their practices. We will continue to monitor the impact of this policy and the status of topped out measures and amend them through notice and comment rulemaking in the future, if necessary.

Comment: Several commenters offered general recommendations to CMS concerning topped out measures. One commenter stressed the importance of developing new measures to drive improvements in care while another recommended that CMS work with interested parties to identify ways to maintain topped out measures in the program so that CMS can continue to track performance. Another commenter noted that topped out measures should not be removed in specialty measure sets, because it penalizes specialties with limited reporting options and discourages them from investing in the development of new measures. Further, one commenter recommended that CMS consider a process for revisiting topped out measures that have been removed from the quality inventory, as it could encourage renewed focus on patient outcomes that have been deprioritized in prior years.

Response: We agree that development of new measures is essential to resolving the problem of limited measure choice. We encourage clinicians to engage in the measure development process. For more information on how to get involved in the measure development process, we direct stakeholders to visit *https://mmshub.cms.gov/*. Where necessary, we maintain topped out measures in MIPS beyond the four-year timeline for removal described in the CY 2018 PFS final rule (83 FR 59761), often to ensure that specialty clinicians have appropriate measures to report. We encourage clinicians to participate in our notice-and-comment rulemaking measure inventory process to ensure we maintain measures that are meaningful to their practices. For measures that are topped out, we encourage measure stewards to revise the measures to add more stringent or next-step criteria to make the measure more robust, thereby building on the original quality measure assessment to drive further quality care and likely changing the measure's topped out status. Additionally, whether a clinician or a group is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. Once quality actions have become a standard of care, the focus of quality assessment shifts to areas where a gap exists. We do not believe it would be appropriate to reintroduce quality measures that have been removed from the program.

After consideration of public comments, we are finalizing our proposal with modification. We are modifying the language at § 414.1380(b)(1)(ii)(E) to state, beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. Unlike our proposal, this revised language will include the 9th decile in the scoring range to corresponding scores with a performance rate of 99 percent.

(ii) Approach for Determining Topped Out Measures Impacted by Limited Measure Choice and Subject to the Defined Topped Out Measure Benchmark and the List of Measures That Will Be Subject to the Defined Topped Out Measure Benchmark for the CY 2025 Performance Period/2027 MIPS Payment Year

In the CY 2025 PFS proposed rule, we proposed that we would annually determine and publish a list of topped out measures that will have the 7-point cap removed and be subject to the proposed defined topped out measure benchmark. To identify which topped out measures would be added to the list, we proposed that we would review each specialty measure set by collection type and identify if the prevalence of topped out measures within such a set hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we would analyze the ability of clinicians reporting the specialty measure sets under review to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. As stated, the analysis would be conducted for each specialty measure set and will be further broken down by collection type. At the collection type level, each measure will be assigned points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100

percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points would be added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each measure set would be compared to the analysis threshold, which is currently 75 percent of available quality achievement points, based upon number of available measures. Any measure sets that are not able to meet or exceed the threshold will be flagged as 'at-risk.' Additional factors that we will take into consideration would include whether:

- A measure within the specialty measure set is considered a cross cutting measure;
- A measure within the specialty measure set is a broadly applicable measure, which we would consider to be a measure included in three or more specialty sets; and
- There are more than ten measures, by collection type, available in the specialty set.

Table 82 contains the list of measures that meet the criteria specified above and for which we proposed to apply the defined topped out measure benchmark for the CY 2025 performance period/2027 MIPS payment year. Specialty measure sets impacted by limited measure choice include those for Pathology, Anesthesiology, Diagnostic Radiology, and Radiation Oncology.

TABLE 82: Proposed topped out measures impacted by limited measure choice and subject to defined topped out measure benchmark for the CY 2025 performance period/2027 MIPS Payment Year

Measure ID	Collection Type	Measure Title
143	eCQM, MIPS CQM	Oncology: Medical and Radiation – Pain Intensity Quantified
249	Medicare Part B Claims, MIPS CQM	Barret's Esophagus
250	Medicare Part B, MIPS CQM	Radical Prostatectomy Pathology Reporting
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medical Studies
364	MIPS CQM	Optimized Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens
397	Medicare Part B, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions
406	MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
424	MIPS CQM	Perioperative Temperature Management
430	MIPS CQM	Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy
436	MIPS CQM	Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
463	MIPS CQM	Prevention of Post-Operative (POV) – Combination Therapy (Pediatrics)
477	MIPS CQM	Multimodal Pain Management

We solicited comment on the proposed approach that we would use each year to identify the list of measures subject to the defined topped out measure benchmark, as well as the proposed list of topped out measures impacted by limited measure choice and subject to defined topped out measure benchmark for CY 2025 performance period/2027 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed approach for determining topped out measures that would not be subject to the 7-point cap. Commenters noted that the proposed approach would address concerns that providers are being unfairly penalized for MIPS scoring due to a dearth of measures to report.

Response: We thank commenters for their support.

Comment: Several commenters expressed concern or did not support the proposed approach for determining topped out measures, citing limited quality or specialty-specific measure choice as a result of measures being topped out and putting specialists, particularly subspecialists, at a disadvantage due to limited measure availability. One commenter did not

support the topped out measure methodology, because they believed that the proposed quantitative level does not consider clinical relevance of the measure or volume of Medicare services it impacts.

Response: For the CY 2025 performance period/2027 MIPS payment year, we set 75 percent as the quantitative level according to the performance threshold of 75 points discussed in section IV.A.4.g.(2)(c) of this final rule. We will continue to set the quantitative level for identifying topped out measures subject to the defined topped out measure benchmark in relation to the performance threshold to ensure clinicians with limited choice will not be penalized as it rises. This is an effective first step in addressing the scoring constraints of limited measure choice. Additionally, we consider clinical relevance in the maintenance of the quality measure inventory and regularly maintain topped out measure in MIPS based on their relevance to participants. We encourage interested parties to engage in the development of measures that are meaningful to their practice. For more information, see visit *https://mmshub.cms.gov/*. Additionally, we will continue to revisit our scoring policies and propose policies that alleviate concerns about scoring and measure selection constraints.

Comment: Many commenters offered recommendations to CMS on additional topped out measures that CMS should include in the proposed list of topped out measures that would be subject to the topped out measure benchmark. Several commenters recommended that CMS include all the measures in the MIPS Hospitalist Specialty Set in the list of proposed topped out measures for the CY 2025 performance period. These commenters believed that the hospitalist specialty measure set should be included, because out of four measures in the set, three of them are capped at 7 points. A few commenters recommend that CMS remove the 7-point cap for QCDR measures that are topped out, citing that the 7-point cap for QCDR measures will disproportionately impact specialists and subspecialists. One commenter specifically recommended the topped out measure policy should extend to QCDR measures, such as anesthesiologist measure sets that are approaching or have approached topped out measure status. A few commenters recommended developing new measures for radiology given the lack of other measures and current gaps. Further, a few commenters requested that CMS reevaluate the occupational therapy (OT) and physical therapy (PT) specialty set measures, citing that these measures are increasingly being topped out.

Response: Topped out measures in the Hospitalist and occupational therapy (OT) and physical therapy (PT) specialty sets were not proposed for application of the defined topped out measure benchmark because they are cross-cutting or broadly applicable. QCDR measures were not included in the scope of this policy because they are governed by policy at § 414.1400(b)(4)(iii)(C) stating that CMS may revoke a measure's second year approval if identified as topped out. We encourage interested parties to engage in the development of measures that are meaningful to their practice. For more information, see visit *https://mmshub.cms.gov/*.

(iii) Complex Organization Adjustment for Virtual Groups and APM Entities

Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of Certified Electronic Health Record Technology (CEHRT) and qualified clinical data registries. Section 1848(q)(5)(B)(ii)(II) of the Act provides that the Secretary shall treat such clinicians as satisfying the clinical quality measures reporting requirement described in section 1848(o)(2)(A)(iii) of the Act if they report such measures through the use of such EHR technology for a given performance period.[877] In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end electronic reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting.

In the CY 2022 PFS final rule, we finalized our proposal to end measure bonus points for end-to-end electronic reporting. We noted that as we move to MVPs we are simplifying scoring by removing many of the transition policies that we established in the early years of the program in order to develop a stronger MVP program and promote alignment between MIPS and MVPs. As stated in previous rulemaking, we are working to develop ways to encourage the use of CEHRT for electronic reporting without offering measure bonus points. We stated that we believed that we could fulfill the statutory requirement at section 1848(q)(5)(B)(ii)(I) of the Act to encourage the usage of CEHRT, through other means. Accordingly, over the past few years, we have reduced the availability and limited who can submit data for the Medicare Part B claims collection type to only small practices noting that the Medicare Part B claims collection type is not an electronic means of submission.

Satisfying quality reporting requirements is not equally attainable for each MIPS eligible clinician or entity in the Quality Payment Program. As the Quality Payment Program and its components (MIPS and Advanced APMs) has matured, reliance on and subsequent requirements necessitating the use of CEHRT have increased (88 FR 79331). Virtual groups and APM Entities may experience administrative and technological barriers to electronic reporting, including challenges aggregating patient data from multiple TINs, data deduplication, and interoperability between different health IT/EHR systems. In the CY 2018 Quality Payment Program final rule, commenters indicated that data aggregation across multiple TINs for virtual groups would be burdensome for rural and small practices and that this burden could be prohibitive for virtual groups' successful participation in MIPS (82 FR 53610). Commenters stated that the requirement for virtual groups to aggregate data from individual clinicians could be a potential barrier for virtual group participation and would likely be error prone (82 FR 53610). Commenters noted that the potential penalty for failure to overcome technical challenges in data aggregation was, at that time, a 5 percent decrease to the payment adjustment for TINs that are already operating on small margins (82 FR 53610). Commenters noted that the aggregation of data across various TINs using health IT systems may be logistically difficult and complex, as groups and health IT systems have different ways of collecting and storing data and stated that data aggregation across various systems for measures and activities under each performance category may not be possible if qualified registries do not have the option to assist virtual groups (82 FR 53610). Additionally, commenters stated that practices already have an issue of not being able to deduplicate patient data across different health IT systems/multiple EHRs and indicated that virtual groups need clear guidelines regarding how to achieve accurate reporting (82 FR 53613).

[877] Section 1848(o)(2)(A)(iii) of the Act requires a meaningful EHR user to demonstrate to the satisfaction of the Secretary that the eligible professional, among other things, has not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of the certified EHR technology.

Furthermore, commenters expressed concerns that registries supporting virtual group reporting would be opening themselves to potential penalties as a result of technical challenges in data aggregation across multiple EHR systems (82 FR 53610). The commenters indicated that registries may not be able to support virtual group reporting due to legal and operational complexity. Certain registries have internal data governance standards, including patient safety organization requirements, that they must follow when contracting with single TIN participants that may complicate their ability to support virtual group reporting due to necessary legal agreements between solo practitioners and small groups within a virtual group (82 FR 53611). Commenters requested that CMS provide guidance to registries regarding how to handle data sharing among virtual groups with respect to patient safety organization requirements and provide guidance regarding the expectations for registries supporting virtual group reporting (82 FR 53611).

APM Entities are organizations that participate in CMS's various APMs, including the Medicare Shared Savings Program and CMS Innovation Center models. APM Entities face similar organizational challenges reporting eCQMs because of their complex structures, new and innovative partnerships under their respective APMs, and utilization of multiple EHR technologies across participants (88 FR 79097). For ACOs in the Shared Savings Program, and ACOs and other large organizations in CMS Innovation Center models, these issues are further exacerbated by scale and patient volume, as discussed in more detail further in this section. In the CY 2023 PFS proposed rule, commenters noted for ACOs participating in the Shared Savings Program reporting all payer/all patient eCQMs/MIPS CQMs there are issues related to meeting all-payer data requirements, data completeness requirements, and data aggregation (87 FR 69837). ACOs also noted the financial burden of aggregating, deduplicating, and exporting eCQM data across multiple TINs and EHRs (88 FR 79097). In addition, as summarized in the CY 2024 PFS final rule, commenters noted that the current state of data standards and interoperability do not yet fully enable Shared Saving Programs ACOs to meet the eCQM reporting requirements successfully and encouraged CMS to continue working with providers to facilitate the transition to all-payer/all-patient measures even as/if the provider or ACO chooses to report Medicare CQMs (88 FR 79107). In the CY 2024 PFS final rule (88 FR 79098), we stated that our long-term goal continues to be to support Shared Savings Program ACOs in the adoption of all payer/all patient measures and transition to digital quality measurement reporting. These challenges also can be faced by other large APM Entities participating in CMS Innovation Center models.

Additionally, APM Entities in CMS Innovation Center models, regardless of size, are participating in innovative payment and delivery designs through which they may forging new partnerships among different providers and provider types to provide care to attributed beneficiaries to meet the APM's care delivery requirements. For example, the Making Care Primary (MCP) Model includes several payment innovations to support participants in delivering advanced primary care and aims to strengthen coordination between patients' primary care clinicians, specialists, social service providers, and behavioral health clinicians, ultimately leading to chronic disease prevention, fewer emergency room visits, and better health outcomes. The model will operate through three progressive tracks, with the first track being designed for organizations with no prior value-based care experience. Additionally, the model includes State partnerships and multi-payer alignment objectives. Participation in this model will involve forming new relationships to provide whole-person care to beneficiaries, which is likely to necessitate bridging data across multiple technologies and involve new and complex administrative burdens in the provision of this advanced primary care.

Based on our assessment and understanding over the past 2 years, we have learned that there are complexities and challenges for virtual groups and APM Entities in adopting all-payer/all-patient collection types, and as a result, the widespread adoption of the all-payer/all patient collection types requires further time and support. We have come to understand that further support is needed for complex organizations. As an example, Shared Saving Program ACOs provide a high volume of services, particularly those related to preventative screening measures. An internal analysis of performance year 2022 submission data indicates that Shared Savings Program ACOs reported on 33 times more denominator eligible patients for eCQM 001—Diabetes: HbA1c Poor Control (≤9 percent), 53 times more denominator eligible patients for eCQM 134—Preventative Care and Screening: Screening for Depression and Follow-Up Plan, and 25 times more denominator eligible patients for eCQM 236—Controlling High Blood Pressure than other MIPS reporters. In performance year 2022, one ACO reported on over 700,000 denominator eligible beneficiaries for a single eCQM.

The requirement to aggregate patient data collected across multiple health records into a single data stream before sending to CMS poses administrative challenges and the need for additional resources for virtual groups and APM Entities, including Shared Savings Program ACOs. Additionally, data deduplication is resource intensive and requires the development of new workflows to ensure accuracy. Stakeholders have also noted that patient files exist in multiple, disparate EHRs since each EHR system may collect and store data differently. This is important as moving to reporting eCQMs requires building new processes to fill data gaps and ensure data accuracy and causes participants often to customize workflows for data processing, such as using Quality Reporting Document Architecture (QRDA) I (individual patient) and QRDA III (measured entity's aggregate) data submission approaches for quality reporting. EHR vendors have also expressed concerns regarding the need for more time to develop new features that can facilitate eCQM reporting processes. Some interested parties have also voiced concerns that clinician specialty or patient population could yield lower quality scores when reporting eCQMs and create resistance to switching to this collection type.

We noted in the CY 2024 PFS final rule that a few commenters agreed that Medicare CQMs would address most of ACOs' concerns regarding all payer/all patient reporting in the Shared Saving Program, such as difficulties reporting for those ACOs with a higher proportion of specialty practices or groups with multiple EHRs, beneficiaries with no primary care relationship, and shouldering a greater burden when matching and deduplicating patient records (88 FR 79101). Other commenters noted Medicare CQMs reduce concerns about specialists reporting on primary care focused measures. Commenters shared that Medicare CQMs were responsive to several key concerns raised by Shared Savings Program ACOs regarding feasibility of implementing eCQMs/MIPS CQMs, including equity concerns (88 FR 79101). However, we maintain that consistent with section 1848(q)(5)(B)(ii)(I) of the Act we support

and encourage providers as they perform any necessary bridging of data across multiple technologies, which can involve new and complex administrative burdens.

To account for the organizational complexities faced by Virtual Groups and APM Entities, including ACOs in the Shared Savings Program, we proposed to establish a Complex Organization Adjustment beginning in the CY 2025 performance period/2027 MIPS Payment Year. Virtual Group and APM Entities would receive 1 measure achievement point for each submitted eCQM that meets the data completeness at § 414.1380(b)(1)(iii) and case minimum requirements at § 414.1340. Each reported eCQM may not receive more than 10 measure achievement points and the total achievement points (numerator) may not exceed the total available measure achievement points (denominator) for the quality performance category. The Complex Organization Adjustment for a Virtual Group or APM Entity may not exceed 10 percent of the total available measure achievement points in the quality performance category. The adjustment would be added for each eCQM measure submitted at the individual measure level.

Adding one point for each eCQM would help complex organizations to overcome barriers to reporting eCQMs while not masking overall quality performance. By limiting the Complex Organization Adjustment to Virtual Groups and APM Entities, we can limit scoring inflation and target this intervention to those facing challenges to eCQM implementation. Moreover, while acknowledging the Complex Organization Adjustment is a recognition of current challenges to eCQM reporting we believe that adoption of approaches to the exchange and aggregation of quality data enabled by Fast Healthcare Interoperability Resources (FHIR) Application Programing Interfaces (APIs) will reduce or eliminate the barriers posed by organizational complexities to eCQM reporting and will revisit and end this Adjustment as uptake of capabilities for quality data aggregation and exchange using FHIR APIs increases, requirements surrounding the use of FHIR APIs for quality data change are established, or other barriers posed by organizational complexity are otherwise reduced. This adjustment differs from the previous end-to-end electronic reporting bonus in that it does not merely award measure achievement points for reporting but provides an adjustment for clinicians facing complex organizational barriers for adopting the eCQM collection type.

We proposed to add § 414.1380(b)(1)(vii)(C) to provide that, beginning in the CY 2025 performance period/2027 payment year, a virtual group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) and the data completeness requirement at § 414.1340. Each measure may not to exceed 10 measure achievement points. The total adjustment to the Virtual Group or APM Entity's quality performance category score under this paragraph may not exceed 10 percent of the total available measure achievement points. Accordingly, we proposed to update § 414.1380(b)(1)(vii) to state a MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) and Complex Organization Adjustment in paragraph (b)(1)(vii)(C). The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) is added to that result. The quality performance category score cannot exceed 100 percentage points.

We solicited comment on our proposal to implement a Complex Organization Adjustment for virtual groups and APM Entities, including ACOs in the Shared Savings Program.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed complex organization adjustment for virtual groups and APM entities. These commenters believed that this would promote eCQM adoption and address the unique challenges that virtual groups and APM entities experience in reporting eCQMs. One commenter also believed that the proposal would help ease the transition for ACOs as they familiarize themselves with eCQM reporting tools and implement new processes to improve performance on eCQMs. Another commenter supported the proposal on the condition that CMS maintain the option to report Medicare CQMs.

Response: We thank commenters for their support.

Comment: Many commenters recommended that CMS expand the complex organization adjustment to all MIPS participants reporting eCQMs and any clinician or practice that uses multiple EHRs or practices at multiple sites rather than restricting the policy to virtual groups and APM entities. These commenters noted that individual clinicians and group practices also face challenges in reporting eCQMs and aggregating data across disparate EHR platforms. Therefore, these commenters believed that these entities should also receive the adjustment. One commenter requested clarification on the proposed complex organization adjustment, specifically requesting that CMS provide a transparent definition of ''complex organization'' and information on how an organization is determined to be a complex organization. A few commenters specifically discussed the proposal's potential impacts on small practices. These commenters recommended that CMS expand the adjustment to small practices as they face disproportionate barriers to reporting of eCQMs. Another commenter encouraged CMS to ensure that the costs of complying with the requirements are not disproportionately borne by APM participants in small practices who may struggle to cover the costs associated with aggregating patient data across systems. A few commenters recommended that the proposed complex organization adjustment should be broadened beyond eCQM reporting and also offered to entities reporting Medicare CQMs and MIPS CQMs.

Response: At this time, we are defining complex organizations as virtual groups and APM Entities including Shared Saving Program ACOs. In order to facilitate their participation in the Quality Payment Program, these organizations' compositions require structures that are complex or are participating in innovative payment models that require flexibility in forming their structures, posing the challenges to data aggregation, deduplication and interoperability across multiple EHRs/health IT vendors. This differs from other types of organizations that do not by nature necessitate these complex, innovative compositions. This adjustment is to offset the challenges associated with adoption of eCQMs because of the organizational complexity required by definition of virtual groups and APM Entities and is therefore not appropriate for other types of participants or collection types such as MIPS CQMs or Medicare CQMs. Small practices in MIPS currently receive a small practice bonus of 6 measure achievement points added to the quality performance category if they submit at least one

measure in the performance category. Small practices that are APM Entities or virtual groups would receive the small practice bonus in addition to the Complex Organization Adjustment. We will continue to monitor the interaction of these policies as well their impacts on small practices.

Comment: A few commenters expressed concern about the proposed complex organization adjustment. These commenters believed that the complex organization adjustment is insufficient to offset the significant challenges that APM entities, specifically ACOs, continue to face. Additionally, commenters expressed skepticism that the proposal would increase eCQM reporting since it does not address underlying concerns related to data interoperability and aggregation. A few commenters recommended that CMS address the underlying technology infrastructure and interoperability concerns that virtual groups, ACOs, and other entities experience. Further, a few commenters stated that scoring adjustments do not address barriers to aggregating and reporting data across multiple EHRs nor do they solve concerns with data validity and reliability when reporting eCQMs. These commenters also stated that adding bonus points to quality scores makes it difficult to track and improve quality over time. Another commenter had concerns that the adjustment would not fully address difficulties encountered by large physician groups, particularly if the 10-point cap per measure is too limiting.

Response: We thank commenters for their feedback. In response to comments that the proposal does not solve the underlying concerns with data validity and reliability when reporting eCQMs we acknowledged in our proposal that the requirement to aggregate patient data collected across multiple health records into a single data stream before sending to CMS poses administrative challenges and the need for additional resources for virtual groups and APM Entities, including Shared Savings Program ACOs. We also acknowledged that data deduplication is resource intensive and requires the development of new workflows to ensure accuracy. We will continue to work with interested parties to resolve this issue. In adding one point for each eCQM would help complex organizations to overcome structural barriers to reporting eCQMs. In limiting the application to virtual groups and APM Entities and capping the adjustment to 10 percent of the total achievable points in the quality performance category, the Complex Organization Adjustment will serve to help these participants overcome barriers to eCQM reporting while reducing scoring inflation. We will monitor the impact of this policy and make amendments where necessary. Additionally, MIPS CQMs will be available to report in the APP Plus measure set for an additional two years as discussed in section III.G.4.b.(2)(b). of this final rule. Furthermore, we believe that the adoption of approaches leveraging FHIR APIs for quality data aggregation and exchange will reduce or eliminate the barriers posed by organizational complexities to eCQM reporting and will revisit and end this Adjustment as uptake of FHIR APIs for these purposes increases, requirements surrounding the use of FHIR APIs are established, or other barriers posed by organizational complexities are otherwise reduced.

After consideration of public comments, we are finalizing our proposal to add § 414.1380(b)(1)(vii)(C) to provide that, beginning in the CY 2025 performance period/2027 payment year, a virtual group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) and the data completeness requirement at § 414.1340. Each measure may not to exceed 10 measure achievement points. The total adjustment to the virtual group or APM Entity's quality performance category score under this paragraph may not exceed 10 percent of the total available measure achievement points. Additionally, we are finalizing our proposal to update § 414.1380(b)(1)(vii) to state a MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) and Complex Organization Adjustment in paragraph (b)(1)(vii)(C). The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) is added to that result. The quality performance category score cannot exceed 100 percentage points

(c) Scoring the Quality Performance Category Through MIPS for ACOs in the Shared Saving Program

(i) Score for Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

In section III.G.4.c.(2)(c) of this final rule we proposed to score Shared Savings Program ACOs reporting Medicare CQMs in the APP Plus quality measure set using flat benchmarks for their first 2 performance periods in MIPS. Consistent with this discussion, we proposed to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type will be scored using flat benchmarks for their first 2 performance periods in MIPS. We solicited comment on our proposal to score Medicare CQMs using flat benchmarks for their first two performance periods in MIPS.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We refer readers to section III.G.4.c.(2)(c) of this final rule for a summary of comments and our responses.

After consideration of public comments, we are finalizing the addition of § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type will be scored using flat benchmarks for their first 2 performance periods in MIPS.

(d) Cost Performance Category Score

(i) Scoring the Cost Performance Category Background

As discussed previously, to calculate a final score for each MIPS eligible clinician for the performance period of an applicable MIPS payment year, section 1848(q)(5)(A) of the Act requires that we must develop a methodology for assessment of the total performance of each MIPS eligible clinician, according to the performance standards we have established in accordance with section 1848(q)(3) of the Act, with respect to applicable measures and activities specified for each performance category. For the final score, we must use a scoring scale of 0 to 100.

We refer readers to § 414.1380(b)(2) for our policies regarding scoring for the cost performance category and to previous rules where these policies were finalized, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), the CY 2019 PFS final rule (83 FR 59856), the CY 2021 PFS final rule (85 FR 84877 through 84880), the CY 2022 PFS final rule (86 FR 65507 through 65509), the CY 2023 PFS final rule (87 FR 70091 through 70093), and the CY 2024 PFS final rule (88 FR 79369 through 79373).

In the CY 2025 PFS proposed rule (89 FR 62083 through 62088), we proposed to: (1) modify the benchmark

methodology for scoring measures specified for the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year; and (2) adopt a new cost measure exclusion policy beginning with the CY 2025 performance period/2027 MIPS payment year.

(ii) Benchmark Methodology for Scoring the Cost Performance Category

(A) Background on Methodology for Scoring the Cost Performance Category

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. Under § 414.1380(b)(2), we score each MIPS eligible clinician [878] on each cost measure attributed to them in accordance with § 414.1350(b) so long as the MIPS eligible clinician meets the minimum case volume specified under § 414.1350(c) to be scored on that cost measure. Cost performance category measures are attributed to MIPS eligible clinicians through, and scored based on, claims data; we do not require MIPS eligible clinicians to submit any additional data on cost measures to CMS (§ 414.1325(a)). We have codified our cost performance category scoring policies at § 414.1380(b)(2).

Specifically, we finalized at § 414.1380(b)(2) that we will score each cost measure attributed to a MIPS eligible clinician (meeting or exceeding the minimum case volume) by assigning achievement points between one and ten based on the MIPS eligible clinician's performance on the cost measure during the performance period compared to the measure's benchmark. We award the achievement points (including partial points) based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. The MIPS eligible clinician's cost performance category score (to be added to the final score) is the sum (not to exceed 100 percent) of: (1) the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and (2) the cost improvement score, as determined under § 414.1380(b)(2)(iv) (§ 414.1380(b)(2)(iii)). We will not calculate a cost performance category score if the MIPS eligible clinician is not attributed any cost measures for the performance period because the MIPS eligible clinician has not met the minimum case volume as specified at § 414.1350(c) for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the MIPS eligible clinician (§ 414.1380(b)(2)(v)).

As set forth at § 414.1380(b)(2)(i), we determine cost measure benchmark ranges based on all MIPS eligible clinicians' performance on each attributed cost measure during the performance period. We determine a benchmark for a cost measure only if at least 20 MIPS eligible clinicians are attributed and meet the minimum case volume for that measure, as specified at § 414.1350(c). If we cannot determine a benchmark for a cost measure because an insufficient number of MIPS eligible clinicians had the measure attributed to them (that is, less than 20 MIPS eligible clinicians meet the minimum case volume), then we will not assign any score for the measure for any MIPS eligible clinician (§ 414.1380(b)(2)(i) and (v)). We refer readers to our prior rulemakings, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), for a detailed discussion of our previously finalized policies for determining a benchmark for each cost measure and then assignment of achievement points based on comparison of a MIPS eligible clinician's performance to that established benchmark.

Specifically, under our current scoring policy at § 414.1380(b)(2) and benchmark methodology, MIPS eligible clinicians with the lowest average cost per episode or beneficiary would be in the top decile (Decile 10) and receive the highest number of available achievement points (10). On the other end of the spectrum, MIPS eligible clinicians with the highest average cost per episode or beneficiary would be in the bottom decile (Decile 1) and receive the lowest number of achievement points (1). More information about how average cost per beneficiary or per episode are calculated and translated to MIPS achievement points is available in the 2023 MIPS Cost User Guide.[879]

Table 83 provides an example of using benchmark deciles along with partial achievement points to assign achievement points for a sample cost measure under our current methodology. The following formula is used to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(measure score, expressed as a dollar amount—bottom of benchmark decile range)/(top of benchmark decile range—bottom of benchmark decile range)] = Cost Measure Achievement Points.[880]

[878] The term MIPS eligible clinician is defined in § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. A cost measure therefore may be attributed to a group that includes at least one MIPS eligible clinician and the group may therefore be scored on the cost performance category as a whole. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

[879] *https://qpp.cms.gov/resources/document/fac61617-20ef-4d31-9f0f-4a0e76620ca3.*

[880] Ibid.

TABLE 83: Example of Using Benchmark Deciles and Partial Points to Assign Achievement Points for Performance on the Screening/Surveillance Colonoscopy Cost Measure

Benchmark Decile	Cost per Episode	Percentile	Possible Points
Benchmark Decile 1	$1330.65-$1126.35	99th	1.0–1.9
Benchmark Decile 2	$1126.34-$1062.93	90th	2.0-2.9
Benchmark Decile 3	$1062.92-$1025.75	80th	3.0-3.9
Benchmark Decile 4	$1025.74-$997.78	70th	4.0-4.9
Benchmark Decile 5	$997.77-$969.73	60th	5.0-5.9
Benchmark Decile 6	$969.72-$940.03	50th	6.0-6.9
Benchmark Decile 7	$940.02-$904.83	40th	7.0-7.9
Benchmark Decile 8	$904.82-$860.44	30th	8.0-8.9
Benchmark Decile 9	$860.43-$779.69	20th	9.0-9.9
Benchmark Decile 10	$779.68 and lower	10th	10

In the CY 2021 PFS final rule (85 FR 84877 through 84880), we finalized at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year. We noted that such an approach would allow us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year (see section 1848(q)(5)(E)(i)(II) of the Act) while reducing the impact of experiencing an increase in the weight of the cost performance category too much in any single year and providing clinicians with an eased gradual and incremental transition starting with the 2023 MIPS payment year. Since then, MIPS eligible clinicians have raised concerns about cost performance category scoring having a negative impact on their final MIPS score. Multiple factors have likely contributed to clinician concerns. First, there has been an increase in weight for the cost performance category over time. Specifically, due to the COVID–19 Public Health Emergency (COVID–19 PHE) which ended on May 11, 2023, we reweighted the cost performance category's score to zero percent of the final score for many MIPS eligible clinicians. We announced on April 6, 2020 that, due to the COVID–19 PHE, we would apply our extreme and uncontrollable circumstances reweighting policies described at § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide and extend the deadline to submit an application for reweighting the quality, cost, improvement activities or Promoting Interoperability reporting categories for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 and 19278). Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described under § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the COVID–19 PHE.[881] [882] As a result, the CY 2022 performance period/2024 MIPS payment year was the first MIPS payment year that the cost performance category score generally constituted 30 percent of MIPS eligible clinicians' final scores (section 1848(q)(5)(E)(i)(II) of the Act). Second, the number of cost measures has increased over time, and therefore, more MIPS eligible clinicians are being measured on the cost performance category and on new measures.

Additionally, based on our calculation of cost performance category scores for the CY 2022 performance period/2024 MIPS payment year, we observed lower scores for the cost performance category than for the quality performance category, even though they each generally constitute 30 percent of the final score. Recent analyses of CY 2022 performance period/2024 MIPS payment year data have identified the unweighted mean cost performance category score was 59 out of 100, while the unweighted mean score for the quality performance category was 74 out of 100. We also note that the unweighted mean scores were 95 out of 100 for the improvement activities performance category and 94 out of 100 for the Promoting Interoperability performance category.

There are several factors that may have contributed to a significantly lower score in the cost performance category, compared to the other categories. First, measures in the cost performance category are scored against a benchmark determined based on average performance of all MIPS eligible clinicians during that same performance period (§ 414.1380(b)(2) introductory text and (b)(2)(i)) rather than a benchmark determined based on historical data, which is used, wherever possible, for non-administrative claims-based quality measures in the quality performance category. Benchmarks determined based on historical data for the quality performance category provide MIPS eligible clinicians with helpful performance targets in advance of or during the performance period. Meanwhile, the performance period benchmarks for the cost performance category do not provide MIPS eligible clinicians with information about performance targets before or during the performance period. However, in the CY 2025 PFS proposed rule, we stated that using benchmarks based in the performance period is a better approach for the cost performance category than using benchmarks based on historical data because different payment policies may apply during the historical period than during the performance period, which may affect the cost of care for patients treated by MIPS eligible clinicians.

Second, in traditional MIPS (compared to MVP reporting), MIPS eligible clinicians are scored on each cost measure for which they are attributed and meet the established case minimum and a benchmark can be calculated. In the quality performance category, if a MIPS eligible clinician

[881] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/816/2020%20Cost%20Quick%20Start%20Guide.pdf.*

[882] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1298/2021%20MIPS%20Cost%20Quick%20Start%20Guide.pdf.*

reports more than the required number of quality measures, we use the highest scored outcome measure and then the next highest scored measures to reach a total of 6 scored quality measures to calculate the clinician's MIPS quality performance category score. The current cost benchmark methodology uses a decile range based on linear percentile distributions and assigns 5.0 to 6.9 achievement points to clinicians with cost measure scores within the 50th to 60th percentiles (Table 83).

For the example cost measure presented in Table 83, the cost measure median, the 50th percentile, is $969.72. If a MIPS eligible clinician's average cost per episode for the measure is $1,104 (about $135 above the median), the MIPS eligible clinician's cost falls within Benchmark Decile 2, for which the MIPS eligible clinician may receive between 2.0 and 2.9 achievement points. We then use the following formula to determine the number of partial points awarded to the MIPS eligible clinician:

Benchmark Decile # + [(measure score, expressed as a dollar amount—bottom of benchmark decile range)/(top of benchmark decile range—bottom of benchmark decile range)] = Cost Measure Achievement Points.[883]

Based on this partial points calculation formula, the clinician would receive 0.3 partial points, resulting in a cost measure score of 2.3 out of 10 achievement points for the Screening/Surveillance Colonoscopy cost measure under this example.

This score may have the effect of lowering the MIPS eligible clinician's final score, as discussed previously. If the MIPS eligible clinician is only attributed and scored on this single cost measure and does not receive a cost improvement score, then their score for the cost performance category would be based on the cost measure's score of 2.3 out of 10 achievement points. Their score for the cost performance category would be 0.23 (2.3/10 = 0.23), equal to the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points under § 414.1380(b)(2)(iii)(A). Based on the final score calculation under § 414.1380(c), the contribution of the cost performance category score to the final score for this MIPS eligible clinician would be equal to the cost performance category score multiplied by the cost performance category weight (30 percent if the MIPS eligible clinician has not received any reweighting).

To illustrate how this cost performance category score could lower the final score, if this MIPS eligible clinician received perfect scores in each of the other three performance categories, based on the final score calculation under § 414.1380(c) and the respective performance category weights when all four performance categories are scored without reweighting, we would use the formula as described below. For this example, we have not included the complex patient bonus.

MIPS Final score = [(60/60 × 30 percent for quality) + (2.3/10 × 30 percent for cost) + (40/40 × 15 percent for improvement activities) + (100/100 × 25 percent for Promoting Interoperability)] × 100 = 76.9.[884]

In this example, a MIPS final score of 76.9 for the MIPS eligible clinician is just above the 2024 MIPS payment year performance threshold of 75. Therefore, under the current cost scoring methodology, a MIPS eligible clinician scoring near the median on a cost measure would need to score perfectly (or nearly perfectly) within the other three performance categories to receive a final score slightly above the performance threshold and to avoid a negative payment adjustment. The unweighted cost performance category score of 23 out of 100 noticeably lowers the MIPS eligible clinician's MIPS final score.

(B) Modification to Scoring Methodology for the Cost Performance Category Beginning with CY 2024 Performance Period/2026 MIPS Payment Year

In light of the concerns identified with our current cost scoring policies, we proposed to modify the methodology for scoring the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year (89 FR 62085 through 62087). The proposed cost scoring methodology would be based on standard deviation, median, and an achievement point value that is derived from the performance threshold. Specifically, for a MIPS eligible clinician whose average costs attributed under a cost measure would be equal to the median cost for all MIPS eligible clinicians that had the measure attributed them, we would assign an achievement point value equal to 10 percent of the performance threshold. For example, for the CY 2024 performance period/2026 MIPS payment year, the median would have an achievement point value of 7.5, based on a performance threshold of 75 as finalized at § 414.1405(b)(9)(iii). For each cost measure, the cut-offs for benchmark ranges would be calculated based on standard deviations, expressed in dollars, from the median.

The benchmark ranges, the median, and the performance threshold-derived achievement point values aligned with the median would be dynamic and responsive to changes in average costs per episode or beneficiary assessed by cost measures and performance thresholds for each CY performance period/MIPS payment year. The performance threshold-derived point values could change based on the performance threshold established for each performance period/MIPS payment year. The standard deviations from the median used to determine cutoffs for benchmark ranges for each year would be reviewed for any necessary updates on an annual basis based on performance across MIPS eligible clinicians within the cost performance category and the performance threshold established for the performance period/MIPS payment year. We would perform analyses when the performance threshold changes to set the benchmark ranges. To determine the benchmark ranges, we would adhere to the following principles: (1) center the majority of average costs per episode or beneficiary around the performance threshold-derived point value; (2) determine benchmark ranges according to the statistical distribution curve of the average cost per episode or beneficiary; and (3) distribution of achievement points for cost measures should be reflective of overall program performance. We refer readers to Table 84 for an example of how the proposed cost scoring methodology could be implemented for a specific cost measure when the performance threshold is set to 75.

[883] *https://qpp.cms.gov/resources/document/fac61617-20ef-4d31-9f0f-4a0e76620ca3.*

[884] In simplified terms, the MIPS Final score = (30 points for quality) + (6.9 points for cost) + (15 points for improvement activities) + (25 points for Promoting Interoperability) = 76.9 final score points.

TABLE 84: Example of Implementation of the Proposed Cost Scoring Methodology for Assignment of Achievement Points for Performance on the Screening/Surveillance Colonoscopy cost measure

Benchmark Range	Points	Proposed Methodology for Bottom of Benchmark Range ($)	Example Benchmark Ranges
Benchmark Range 1	1 - 1.9	Median cost + (2.75 x standard deviation)	$1341.93 - $1308.10
Benchmark Range 2	2 - 2.9	Median cost + (2.5 x standard deviation)	$1308.09 - $1.274.26
Benchmark Range 3	3 - 3.9	Median cost + (2.25 x standard deviation)	$1274.25 - $1240.43
Benchmark Range 4	4 - 4.9	Median cost + (2 x standard deviation)	$1240.42 - $1172.75
Benchmark Range 5	5 - 5.9	Median cost + (1.5 x standard deviation)	$1172.74 - $1105.08
Benchmark Range 6	6 – 6.9	Median cost + (1 standard deviation)	$1105.07 - $1037.40
Benchmark Range 7	7 - 7.9	Median cost + (0.5 x standard deviation)	$1037.39 - $902.05
Benchmark Range 8	8 - 8.9	Median cost - (0.5 x standard deviation)	$902.04 - $834.38
Benchmark Range 9	9 - 9.9	Median cost - (1 x standard deviation)	$834.37 - $766.70
Benchmark Range 10	10	Median cost - (1.5 x standard deviation)	$766.69 and below

Continuing with the example of the Screening/Surveillance Colonoscopy cost measure, now presented in Table 84 as an example of implementation of the proposed cost scoring methodology, the median (50th percentile) cost would remain $969.72. Under the proposed cost scoring methodology, for the CY 2024 performance period/2026 MIPS payment year, a MIPS eligible clinician with a cost per episode equal to the median cost of all cases attributed to all MIPS eligible clinicians would receive 7.5 achievement points out of 10 possible achievement points.

Using the same example as previously presented in section IV.A.4.f.(1)(d)(ii)(A) of this final rule, we would apply the proposed cost scoring benchmark methodology as shown in Table 84 to a MIPS eligible clinician with an average cost per episode for this measure that is $1,104 (about $135 above the median). Based on the analysis of data in this example, the standard deviation for the Screening/Surveillance Colonoscopy cost measure would be $135.35. This value for the standard deviation would then be used to calculate the benchmark ranges in Table 69 by plugging in this value for the standard deviation for each benchmark range. For example, ''Median cost + (1 × $135.35)'' would be calculated for ''Median cost + (1 standard deviation)'' for the bottom of Benchmark range 6. As shown with the example in Table 84, under our proposed cost scoring methodology, the MIPS eligible clinician's average cost per episode of $1,104 would fall within Benchmark Range 6 for the Screening/Surveillance Colonoscopy cost measure, for which the MIPS eligible clinician may receive between 6.0 and 6.9 achievement points.

Under our proposal to modify the cost performance category's scoring methodology for individual cost measures, we would continue to use our established formula to assign partial achievement points:

Benchmark Range # + [(measure score, expressed as a dollar amount—bottom of benchmark range)/(top of benchmark range—bottom of benchmark range)] = Cost Measure Achievement Points.

As a result, using the example shown in Table 84, under our proposed cost scoring methodology, the MIPS clinician would receive 6.02 cost measure achievement points (6 + [($1,104—$1,105.07)/($1,037.40—$1,105.07)] = 6.02). The assignment of 6.02 achievement points under the proposed cost scoring methodology would be closer to the performance threshold equivalent of 7.5 than the assignment of 2.3 achievement points under the current cost scoring methodology, as discussed in our previous example in section IV.A.4.f.(1)(d)(ii)(A) of this final rule.

In this example, the MIPS eligible clinician's score for the cost performance category would be 0.602 (6.02/10 = 0.602), equal to the total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points at § 414.1380(b)(2)(iii)(A). Based on the final score calculation at § 414.1380(c), the contribution of the cost performance category score to the final score for this MIPS eligible clinician would be equal to the cost performance category score multiplied by the cost performance category weight (30 percent if the MIPS eligible clinician has not received any reweighting).

If this MIPS eligible clinician received perfect scores in each of the other three performance categories, based on the final score calculation at § 414.1380(c) and the respective performance category weights when all four performance categories are scored without reweighting, we would use the formula as described below. For this example, we have not included the complex patient bonus.

MIPS Final score = [(60/60 × 30 percent for quality) + (6.02/10 × 30 percent for cost) + (40/40 × 15 percent for improvement activities) + (100/100 × 25 percent for Promoting Interoperability)] × 100 = 88.06.[885]

This MIPS final score of 88.06 for the MIPS eligible clinician would be well above the 2024 MIPS payment year performance threshold of 75. The cost performance category score of 60.2 out of 100 would not noticeably lower the MIPS eligible clinician's MIPS final score.

This proposed modification in our scoring methodology for cost measures would align the assignment of achievement points for cost measures so that clinicians with costs near the measure's 50th percentile (median) would not receive a disproportionately low score. Based on our analyses utilizing data from the CY 2022 performance period/2024 MIPS payment year, this proposed methodology would increase the mean cost performance category score (unweighted) for clinicians with a cost performance category score from 59 out of 100 to 72 out of 100 (an increase of

[885] In simplified terms, the MIPS Final score = (30 points for quality) + (18.06 points for cost) + (15 points for improvement activities) + (25 points for Promoting Interoperability) = 88.06 final score points.

13 points).[886] Further, this proposed cost scoring methodology would increase the means for each cost measure score by amounts ranging from 0.04 to 2.52 points. Our analysis showed that, under our proposed methodology, with this increase to the mean cost performance category score, the mean final score would increase by 3.89 points for MIPS eligible clinicians assessed on at least one cost measure and receiving a cost performance category score. Under our analysis, our scoring methodology would not negatively impact MIPS eligible clinicians whose average costs for a specific cost measure are around the median.

Specifically, our analysis supports our intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians who deliver care at an average cost near the median costs for all MIPS eligible clinicians attributed the measure would receive scores at, or very close to, the performance threshold-derived score. Additionally, this proposed modification would address MIPS eligible clinicians' concerns that cost measure scoring negatively impacts their final scores more than other performance categories, including disparate negative effects for MIPS eligible clinicians who are scored on the cost performance category compared to clinicians not scored on the cost performance category.

To codify this policy, we proposed to modify § 414.1380(b)(2) to specify that achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in (89 FR 62087). We also proposed to specify that CMS assigns partial points based on where the MIPS eligible clinician's performance falls between the top and the bottom of the benchmark ranges. The terms ''decile'' and ''percentile distribution'' are currently used at § 414.1380(b)(2) to describe the scoring methodology used to award achievement points and assign partial points. However, under the proposed methodology, the term ''decile'' no longer accurately describes how the benchmark ranges would be constructed. The more general term ''benchmark range'' accurately describes both the current and the proposed cost scoring methodology, and we therefore proposed to modify § 414.1380(b)(2) to use ''benchmark range'' in lieu of ''decile'' and ''percentile distribution.'' We did not propose any modifications to the remainder of the language currently at § 414.1380(b)(2), which provides that, for each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark.

We also did not propose any modifications to the language currently at § 414.1380(b)(2)(i), generally governing if and how CMS determines a cost measure's benchmark. However, we proposed to codify our current cost scoring policy, previously finalized in the CY 2017 QPP final rule (81 FR 77308 through 77311), with modification by adding language at § 414.1380(b)(2)(i)(A). We proposed to specify at § 414.1380(b)(2)(i)(A) that, for the 2019 through 2025 MIPS payment years, CMS determines cost measure benchmark ranges based on linear percentile distributions (89 FR 62087).

We also proposed to codify our proposed benchmarking methodology at § 414.1380(b)(2)(i)(B) (89 FR 62087). We proposed to specify at § 414.1380(b)(2)(i)(B) that, beginning with the 2026 MIPS payment year, for each cost measure, CMS determines 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations and that CMS awards achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. We also proposed to codify at § 414.1380(b)(2)(i)(B) that, beginning with the 2026 MIPS payment year, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure.

We received public comments on this proposal. The following is a summary of the comments we received on the proposed modification to the cost scoring methodology and our responses.

Comment: Many commenters supported the proposal to modify the cost scoring methodology starting with the CY 2024 performance period/2026 MIPS payment year. These commenters stated their belief that the modifications will improve fairness, help address cost performance category scoring transparency and predictability, mitigate significant variations in cost scores for minimal differences in performance, ensure the performance category remains focused on lowering costs, and result in a positive impact on cost scores. A few commenters agreed that setting the median performance period cost for each measure at 10 percent of the performance threshold (7.5 points for the CY 2024 performance period/2026 MIPS payment year) will result in cost measure scores more closely aligning with actual and expected MIPS performance without negatively impacting final MIPS scores. A few commenters stated that the proposed modification would ensure fairer comparison, allowing for more accurate and equitable performance assessment across diverse health care settings. A few commenters expressed appreciation that the proposed modification would better align cost and quality performance category scores, prevent the cost performance category from more negatively impacting final MIPS scores than the other performance categories, and prevent disproportionate negative impacts on those who receive cost performance category scores. One commenter stated their belief that the proposed scoring changes will help address the difficulties associated with parsing out cost data for improvement efforts. One commenter stated their belief that the use of standard deviations from the median to determine benchmark ranges should better align measure scores with statistically significant differences.

Response: We thank the commenters for their support.

Comment: While many commenters supported the proposed modifications to our cost scoring methodology, many of these commenters requested that CMS implement the cost scoring methodology modification starting with an earlier performance period than we proposed (before the CY 2024 performance period/2026 MIPS payment year). The commenters believed the current cost scoring methodology to be problematic and therefore recommended applying the proposed cost scoring methodology to earlier MIPS payment years to prevent low cost performance category scores from leading to lower MIPS final scores in those previous MIPS payment years. Several commenters stated their belief that problems with the cost performance category started with the CY 2022 performance period/2024 MIPS payment year, when CMS began to score the category once again following the COVID–19 pandemic and the cost performance category weight increased

[886] In the CY 2025 PFS proposed rule (89 FR 62086), we stated that this proposed methodology would increase the mean cost performance category score (unweighted) for clinicians with a cost performance category score from 59 out of 100 to 71 out of 100 (an increase of 11.9 points). In between the publishing of the CY 2025 PFS proposed rule (89 FR 62086) and this final rule, updated modeling for our regulatory impact analysis (RIA) was performed, and we have revised to 72 out of 100 (an increase of 13 points) in this final rule to align with the updated RIA modeling.

to 30 percent. These commenters recommended that CMS should therefore apply this policy retroactively starting with the CY 2022 performance period/2024 MIPS payment year or the CY 2023 performance period/2025 MIPS payment year. The commenters stated their belief that retroactive application of this policy is necessary because MIPS eligible clinicians scored in the cost performance category for previous years are at a disadvantage compared to clinicians not scored on cost measures, such as certain specialties or those participating through MIPS APMs. One commenter expressed their belief that applying the policy retroactively is consistent with section 1871(e)(1)(A)(ii) of the Act that provides statutory authority to retroactively apply a substantive change in regulation when failure to do so would be contrary to the public interest.

Response: We acknowledge the commenters' recommendation to implement the proposed modified policy for scoring cost measures earlier than we proposed, beginning with the CY 2022 performance period/2024 MIPS payment year or CY 2023 performance period/2025 MIPS payment year. Understanding MIPS eligible clinicians' concerns with our cost measure scoring policy as previously discussed, we proposed to apply modifications to our scoring policy as soon as feasible, beginning with the CY 2024 performance period/2026 MIPS payment year (89 FR 62085 through 62087).

In the interest of finality in our MIPS payment adjustment factor determinations (especially given the budget neutrality requirement for our calculations in aggregate in section 1848(q)(6)(F) of the Act), we are unable to reopen determinations for the 2024 MIPS payment year or 2025 MIPS payment year after this final rule becomes effective. For the CY 2022 performance period/2024 MIPS payment year, we have finalized our calculation of, and are currently applying to Medicare Part B payments, the MIPS payment adjustment factors for each MIPS eligible clinician. Changing those payment rates to apply our proposed modified cost measure scoring policy would require extensive reprocessing of claims, which is not feasible. For the CY 2023 performance period/2025 MIPS payment year, we already completed our initial calculations of MIPS final scores and payment adjustment factors based on our MIPS policies in effect for that performance period/MIPS payment year. Section 1848(q)(7) of the Act requires that we finalize and notify all MIPS eligible clinicians of their final MIPS payment adjustment factors for the 2025 MIPS payment year no later than 30 days prior to January 1, 2025, prior to the effective date of this final rule. Applying new, modified scoring policies after we have finalized our calculations for the performance period/MIPS payment years, even as we identify and seek to apply improvements for future MIPS payment years, is not feasible.

While some MIPS eligible clinicians may benefit from application of this modified cost measure scoring policy to earlier MIPS payment years, others may not. Further, MIPS eligible clinicians generally rely on the finality of our calculation and application of MIPS payment adjustment factors to their Medicare Part B claims during the MIPS payment year.

Comment: Several commenters requested that, if the proposed scoring policy cannot be applied retroactively, CMS reweight the cost performance category for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year. One commenter stated their belief that CMS has statutory authority (section 1848(q)(5)(F) of the Act) and regulatory authority (§ 414.1380(c)(2)(i)(A)(2) and § 414.1380(c)(2)(i)(A)(9)) to reweight the cost performance category when there are not sufficient measures or flaws in the cost scoring methodology that make it impossible to reliably calculate a score for measures to adequately capture and reflect performance.

Response: We decline this request to reweight the cost performance category on these bases for the CY 2022 performance period/2024 MIPS payment year or the CY 2023 performance period/2025 MIPS payment year. In the CY2025 PFS proposed rule (89 FR 62085 through 62087), we proposed to modify our methodology for assigning achievement points for a MIPS eligible clinician's performance on cost measures relative to the measure's benchmark (that is, the average performance of all MIPS eligible clinicians attributed the same cost measure during the same performance period) to better align the achievement points with our performance threshold. We did not note any issues with individual cost measures, their respective specifications, or the reliability of the cost measure data that would warrant reweighting under these statutory and regulatory authorities on the basis of this proposed modification to our cost measure scoring policy.

We did previously conduct an empirical analysis of all cost measures for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year to determine if any of the cost measures had been significantly impacted by the COVID–19 PHE to warrant individual measure exclusion or reweighting of the cost performance category. Our empirical analysis identified that only the Simple Pneumonia with Hospitalization measure warranted exclusion from our calculation of MIPS eligible clinicians' scores under the cost performance category. We otherwise did not identify a basis for reweighting the cost performance category for all MIPS eligible clinicians for the CY 2022 performance period/2024 MIPS payment year and the CY 2023 performance period/2025 MIPS payment year. We refer readers to our fact sheets for more information about these analyses and our findings at: *https://qpp.cms.gov/resources/document/b0889301-2116-4844-99f7-3f56f8a3de22* (for the CY 2022 performance period/2024 MIPS payment year) and *https://qpp.cms.gov/resources/document/689a740a-5b23-47e6-8b7d-c448d6d68085* (for the CY 2023 performance period/2025 MIPS payment year). Based on our analysis, it would not be appropriate to reweight the cost performance category.

Comment: A few commenters encouraged CMS to ensure that there are adequate risk adjustments made for high-risk cases and flexibility for specialties with inherent cost challenges. Specifically, one commenter suggested using states or regions, specialty status, and practice size to inform peer groups and consider geographical variability and specialty practice differences that are not addressed by using the national cost averages.

Response: We thank the commenters for their recommendation to include risk adjustments in cost scoring. We agree that it is important for cost measures to include adequate risk adjustment. All MIPS cost measures include risk adjustment for patient-level factors and other variables. We refer readers to the QPP Explore Measures page (*https://qpp.cms.gov/mips/explore-measures?tab=costMeasures*) for more information about the cost measures currently in use in MIPS, including the risk adjustment methodology for each measure. We will continue to risk adjust at the specific cost measure level as discussed in the CY 2025 PFS proposed rule (89 FR 62047) and in section IV.A.4.e.(2)of this final rule. At this time, we will not make additional adjustments as part of cost performance

category scoring. The measures used within the cost performance category are constructed to identify the differences in clinician services provided and specialties as much as possible.

Comment: A few commenters urged CMS to evaluate and publish the results of CMS' future analyses of the impact of the cost scoring modification as they are concerned that not every cost measure has a normal distribution which could lead to unexpected and undesirable results and to ensure equity. One commenter requested that CMS offer robust support for physicians adapting to the new cost scoring methodology.

Response: We thank the commenters for their recommendation to monitor and publish the impact of the cost scoring methodology modification. Our analysis supports our intended goal for the proposed modification to the scoring methodology: MIPS eligible clinicians who deliver care at an average cost near the median costs for all MIPS eligible clinicians attributed the measure would receive scores at, or very close to, the performance threshold-derived score. Additionally, this proposed modification would address MIPS eligible clinicians' concerns that cost measure scoring negatively impacts their final scores more than other performance categories, including disparate negative effects for MIPS eligible clinicians who are scored on the cost performance category compared to clinicians not scored on the cost performance category. We release annual QPP Feedback Reports that include feedback and publish Public Use Files with additional data available for clinicians to review. We would continue to monitor the impact of these scoring changes on MIPS eligible clinicians and consider making available additional data.

In response to the request that CMS offer support for adjusting to the new cost scoring methodology, we note that clinicians would not need to do anything different under this new cost scoring methodology since CMS automatically scores cost measures using claims data. Additionally, we will make available educational materials to inform MIPS eligible clinicians about the new cost scoring methodology modifications and their anticipated impact.

Comment: A few commenters, while supportive of the proposal, expressed their belief that it does not resolve core issues of the cost performance category, which they believe are: lack of clinical relevancy to many clinicians; lack of timely feedback for improving performance; the lengthy process for developing new measures; and the need for changes to the attribution logic of certain measures. A few commenters requested that CMS provide timely and detailed performance feedback throughout the performance period (quarterly or at a minimum bi-annually) for cost measures to allow clinicians to track and improve performance during the performance period.

Response: We note that the proposed modifications to the cost scoring methodology are intended to address cost scoring concerns, as previously discussed. While we appreciate the additional feedback, the other issues raised are outside of the scope of our proposals for this rulemaking. We will consider this feedback as we continue to work to improve the cost performance category overall.

Regarding the commenters' request for timely and detailed feedback for MIPS eligible clinicians on their performance in the cost performance category, we currently provide annual MIPS Performance Feedback that includes information on MIPS eligible clinicians' performance for the previous performance period. This feedback typically becomes available during the summer in between the performance period and the MIPS payment year, which is as soon as feasible. We provide these reports on an annual basis, as we calculate cost measures following the end of the performance period. This is because MIPS cost measure scores are based on national averages and are calculated using benchmarks that are derived from cost data from all MIPS eligible clinicians, groups, and virtual groups that met the measure's case minimum for that performance period. MIPS eligible clinicians have episodes of care that begin and end at various times throughout the performance period, so to calculate an accurate comparison across clinicians, CMS has historically calculated all scores following the end of the performance period. Calculating the MIPS cost measures during the performance period may provide an incomplete indication of how a MIPS eligible clinician is performing. We are continuing to work towards providing meaningful and timely information on cost measures generally and we recognize the importance of providing this information for measures implemented in MIPS.

Additionally, we post detailed measure specifications that describe the attribution methodology and a list of included services so that MIPS eligible clinicians can anticipate when they are treating a Medicare patient that may be captured by a MIPS cost measure.

Finally, we note that MIPS eligible clinicians could be rewarded for improving on their performance on a cost measure in future years based on the improvement scoring methodology, as described in § 414.1380(b)(2)(iv).

Comment: One commenter did not support the proposed modification to the cost scoring methodology and stated their belief that keeping the current cost scoring methodology is a better option to ensure half of MIPS eligible clinicians perform well and the other half of clinicians perform poorly on the cost performance category. The commenter stated that it was their understanding that, in order to create meaningful incentives, the goal of MIPS is for roughly half of the industry to pass and the other half to fail.

Response: The proposed cost scoring methodology is intended to prevent MIPS eligible clinicians delivering care at an average cost near the median cost for all MIPS eligible clinicians attributed a measure from being negatively impacted and to address concerns that the current cost measure scoring methodology disproportionately lowers final scores for clinicians more than other performance categories, creating disparate negative impacts for those scored on the cost performance category compared to those who are not.

Since the proposed methodology utilizes the median, around half of the clinicians would receive cost measure scores at or above the performance threshold equivalent. Both the current and proposed methodologies calculate the range of national average costs for all MIPS eligible clinicians attributed the cost measure and assign achievement points based on how the individual MIPS eligible clinician's attributed costs compare to that national range. The proposed methodology modifies the assignment of those achievement points such that MIPS eligible clinicians performing near the median for a cost measure would be more likely to receive a neutral score consistent with the performance threshold than a negative score, which they would be more likely to receive under the current scoring methodology. Some MIPS eligible clinicians will still perform well while other MIPS eligible clinicians will still perform poorly on the cost performance category. However, under the proposed methodology, the MIPS eligible clinicians performing near the median for a cost measure will be treated more neutrally, rather than grouped together with those performing poorly. This proposal likewise would not impact the budget neutrality of the MIPS payment adjustments; it would only address issues with the cost

performance category scoring so that those scored on cost are not disadvantaged compared to those not scored on cost.

After consideration of public comments, we are finalizing our proposals to modify our scoring methodology for the cost performance category beginning with the CY 2024 performance period/2026 MIPS payment year, as proposed. Specifically, we are finalizing that, beginning with the 2026 MIPS payment year, for each cost measure, we will determine 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations, and we will award achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. We also are finalizing as proposed that, beginning with the 2026 MIPS payment year, we will award achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure. We are also finalizing as proposed that achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in and that we will assign partial points based on where the MIPS eligible clinician's performance falls between the top and the bottom of the benchmark ranges.

We are also codifying this modified scoring policy as proposed at § 414.1380(b)(2) and 414.1380(b)(2)(i)(B). We are also finalizing our proposed amendment to the regulation text at § 414.1380(b)(2) to use the term ''benchmark range'' in lieu of ''decile'' and ''percentile distribution.'' We did not propose any modifications to the remainder of the language currently at § 414.1380(b)(2), which provides that, for each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. We are also finalizing as proposed to codify our current cost scoring policy by adding at § 414.1380(b)(2)(i)(A) that, for the 2019 through 2025 MIPS payment years, we determine cost measure benchmark ranges based on linear percentile distributions.

(iii) Adoption of Additional Cost Measure Exclusion Policy

(A) Background on Cost Measure Exclusion Policy

We refer readers to § 414.1380(b)(2)(v)(A) and the CY 2022 PFS final rule (86 FR 65507 through 65509) for our previously established policy for excluding a single cost measure from a MIPS eligible clinician's score for the cost performance category. As described at § 414.1380(b)(2)(v)(A), we established that, beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. We also established at § 414.1380(b)(2)(v)(A) that ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. We specified at § 414.1380(b)(2)(v)(A) that significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

As described in the CY 2022 PFS final rule (86 FR 65507 through 65509), we finalized the policy at § 414.1380(b)(2)(v)(A) to provide scoring flexibility in instances where changes during a performance period impede the effective measurement of cost. We identified that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions that are beyond the control of individual MIPS eligible clinicians and groups. We noted that this flexibility would allow us to ensure that clinicians are not impacted negatively when performance is affected not due to the care provided, but due to external factors. We noted that we would determine whether such external changes impede the effective measurement of cost by considering factors including: The extent and duration of the changes, and the conceptual and empirically tested relationship between the changes and each measure's ability to accurately capture clinician cost performance (86 FR 65508). Empirical testing could include assessing whether there are rapid or unprecedented changes to patient case volume or case mix, and the extent to which this could lead to misleading or inaccurate results (86 FR 65508).

(B) Permit Exclusion of a Cost Measure When Impacted by Errors and When Significant Changes Occur Outside of the Performance Period

In the CY 2022 PFS final rule, for the quality performance category, we modified the quality measure exclusion policy at § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' (86 FR 65492) and to include the omission of codes or inclusion of inactive or inaccurate codes to provide that for each measure submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. Currently, for the cost performance category, we do not include ''errors'' in addition to ''significant changes'' within our cost measure exclusion policy at § 414.1380(b)(2)(v)(A). To provide CMS with greater flexibilities to be responsive to any errors or significant changes outside of the control of MIPS eligible clinicians that negatively impact the ability of specific cost measure(s) to assess clinician performance, we proposed in the CY 2025 PFS proposed rule (89 FR 62087 and 62088) to add a new cost measure exclusion policy at § 414.1380(b)(2)(v)(B) similar to the quality measure exclusion policy. Additionally, to further align our measure exclusion policies among the performance categories, we proposed to include ''errors'' for the cost performance category. Specifically, we proposed that, beginning with the 2027 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the individual MIPS eligible clinician's or group's cost performance category score.

For purposes of this cost measure exclusion policy at § 414.1380(b)(2)(v)(B), we proposed to define ''significant changes or errors'' as changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance (89 FR 62088). While we proposed to include ''errors'' within this policy for the cost performance category, as the quality performance category already

does, the list of what ''significant changes or errors'' includes would differ by performance category to capture differences in how cost measures and quality measures are calculated and measured. For instance, unlike quality measures for which MIPS eligible clinicians generally must submit data to CMS, cost measures are calculated by CMS solely based on administrative claims data; and, therefore, should not be impacted by reporting errors. However, cost measures could be impacted by CMS calculation errors. Further, under our proposed cost measure exclusion policy, errors would be external to the care provided, and such that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Under our proposed exclusion policy for cost measures, significant changes or errors would include, but not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. Additionally, the proposed exclusion policy would not automatically result in cost measure exclusion. Instead, we would determine whether there is a negative impact from the significant change or error when deciding if a cost measure would be excluded.

Specifically, we proposed that, before applying the proposed cost measure exclusion policy, we would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. It is important to clarify that a change or error would not automatically result in measure exclusion, but instead, that we would need to determine whether there is a negative impact from the change or error that would affect cost measure scoring.

Because significant changes or errors can have an ongoing impact on a measure beyond a single performance period, we proposed that the new cost measure exclusion policy at § 414.1380(b)(2)(v)(B) would allow us to exclude cost measures when such changes and errors occur outside of the performance period, but otherwise affect the performance period. For example, if a cost measure is impacted by a coding change or guidance that requires substantive changes to a measure, we may not be able to modify the measure within one performance period. In such circumstances, we may want to exclude the cost measure for the affected performance periods due to the ongoing impact on the measure. We would ensure that if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting one or more performance periods delivering misleading or inaccurate results, then the affected cost measure could be excluded from the individual MIPS eligible clinician's or group's cost performance category score. The cost measure should be able to be excluded regardless of when we become aware of the issue, when the significant change came into effect, or when the error first occurred. Therefore, we proposed that this cost measure exclusion policy would address data used to calculate a score for a cost measure being impacted by significant changes and errors affecting a performance period, even if they do not occur during the performance period and also to codify this policy at § 414.1380(b)(2)(v)(B) (89 FR 62088).

We proposed that this cost measure exclusion policy would be effective beginning with the CY 2025 performance period/2027 MIPS payment year so this policy would be in place as soon as feasible.

This proposal would specify that, beginning with the 2027 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure would be excluded from the MIPS eligible clinician's or group's cost performance category score. We proposed to specify that ''significant changes or errors'' are changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We also proposed to specify that significant changes or errors would include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. We proposed that CMS would empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We also proposed to codify this new cost measure exclusion policy at § 414.1380(b)(2)(v)(B).

We received public comments on this proposal. The following is a summary of the comments we received on the proposal to adopt a new cost measure exclusion policy and our responses.

Comment: A few commenters supported the proposed cost measure exclusion policy as they believe it will prevent unfair cost performance category scores. One commenter appreciated that CMS's proposed cost measure exclusion policy recognizes the inherent difficulties in attribution for cost in the MIPS program, especially for lower volume Medicare specialists such as obstetrics.

Response: We thank the commenters for their support. In the CY 2025 PFS proposed rule (89 FR 62087 and 62088), we proposed the new cost measure exclusion policy to provide greater flexibilities to be responsive to any errors or significant changes outside of the control of MIPS eligible clinicians that negatively impact the ability of specific cost measure(s) to assess clinician performance. This cost measure exclusion policy would not address any potential concerns with attribution of cost measures in MIPS.

Comment: A few commenters supported the new cost measure exclusion policy but requested that CMS finalize and apply the policy earlier than we proposed, beginning with the CY 2023 performance period/2025 MIPS payment year or the CY 2024 performance period/2026 MIPS payment year. A few commenters expressed their belief that there are cost measures in use for the CY 2023 performance period/2025 MIPS payment year for which this exclusion policy should be applied because they have concerns about the data and measure specifications used to calculate these measures.

Response: We acknowledge the commenters' recommendation to implement the proposed cost measure exclusion policy earlier than we proposed. As previously discussed, we proposed to adopt and apply this cost measure exclusion policy as soon as feasible, beginning with the CY 2025 performance period/2027 MIPS payment year. We will not apply this policy for the CY 2023 performance period/2025 MIPS payment year. In the interest of finality in our MIPS payment adjustment factor determinations (especially given the budget neutrality requirement for our calculations in aggregate in section 1848(q)(6)(F) of the Act), we are unable to reopen determinations for the CY 2023 performance period/2025 MIPS

payment year after this final rule becomes effective. We have completed our initial calculations of MIPS final scores and payment adjustment factors based on our MIPS policies in effect for that performance period/MIPS payment year. Section 1848(q)(7) of the Act requires that we finalize and notify all MIPS eligible clinicians of their final MIPS payment adjustment factors for the 2025 MIPS payment year no later than 30 days prior to January 1, 2025, prior to the effective date of this final rule. Applying new, modified policies after we have finalized our calculations for the performance period/MIPS payment year, even as we identify and seek to apply improvements for future MIPS payment years, is not feasible. The CY 2024 performance period/2026 MIPS payment year is not impacted by these same barriers as the measures have not yet been scored. Therefore, this policy can be implemented beginning in the CY 2024 performance period/2026 MIPS payment year. Regarding comments about specific cost measures, we note that we would analyze cost measures and implement this new cost measure exclusion policy on a case-by-case basis beginning with the CY 2024 performance period/2026 MIPS payment year.

Comment: One commenter recommended that if a cost measure meets the cost measure exclusion policy criteria, CMS replace the cost measure or remove it from MIPS for the following performance period. The commenter specifically referenced cost measures that the measure steward cannot maintain, for which they stated that updates would not be made to the specifications to account for changes in billing, coding practices, and other influences on the measure.

Response: We thank the commenter for their recommendation. The proposed cost measure exclusion policy only addresses cost measure exclusion and is not intended to be used for cost measure removal, for which there are separate defined criteria. As discussed further in section IV.A.4.e.(2)(d)of this final rule, we are finalizing the cost measure removal criteria as proposed and have codified this measure removal policy by amending § 414.1350 by adding the cost removal criteria in paragraph (e). CMS may remove a cost measure from MIPS based on one or more of the factors, which include that a measure steward is no longer able to maintain the cost measure. Under the cost measure removal policy, if a cost measure is excluded under the proposed cost measure exclusion policy and the measure steward can no longer maintain the measure, CMS may consider the cost measure for removal in future years.

After consideration of public comments, we are finalizing our proposal to adopt a new cost measure exclusion policy, with modification. Specifically, we are finalizing that, beginning with the 2026 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score leads to misleading or inaccurate results, then the affected cost measure will be excluded from the MIPS eligible clinician's or group's cost performance category score. We are also finalizing as proposed to specify that ''significant changes or errors'' are changes or errors external to the care provided. We are also finalizing as proposed to specify that CMS will determine whether ''Significant changes and errors'' lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. We are also finalizing as proposed to specify that significant changes or errors will include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. We are also finalizing as proposed that CMS will empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score will lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Lastly, we are finalizing our proposal to codify the new cost measure exclusion policy at § 414.1380(b)(2)(v)(B), with the modification above.

g. MIPS Payment Adjustments

(1) Background

Section 1848(q)(6)(A) of the Act requires that we specify a MIPS payment adjustment factor for each MIPS eligible clinician for a year. This MIPS payment adjustment factor is a percentage determined by comparing the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor.

For previously established policies regarding our determination and application of MIPS payment adjustment factors to each MIPS eligible clinician, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2022 PFS final rule (86 FR 65527 through 65537), CY 2023 PFS final rule (87 FR 70096 through 70102), and CY 2024 PFS final rule (88 FR 79373 through 79380).

(2) Establishing the Performance Threshold

(a) Statutory Authority and Background

As discussed above, to determine a MIPS payment adjustment factor for each MIPS eligible clinician for a year, we must compare the MIPS eligible clinician's final score for the given year to the performance threshold we established for that same year in accordance with section 1848(q)(6)(D) of the Act. Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Section 1848(q)(6)(D)(i) of the Act also provides that the Secretary may reassess the selection of the mean or median every 3 years.

Sections 1848(q)(6)(D)(ii) through (iv) of the Act provided special rules, applicable only for certain initial years of MIPS, for our computation and application of the performance threshold for our determination of MIPS payment adjustment factors. These special rules are no longer applicable for establishing the performance threshold for the CY 2025 performance period/2027 MIPS payment year. We refer readers to the CY 2024 PFS proposed rule (88 FR 52596) for further information on these previously applicable requirements as they explain our prior computations of the performance threshold.

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean as the methodology for

determining the performance threshold for the CY 2022 performance period/2024 MIPS payment year through CY 2024 performance period/2026 MIPS payment year. We also established regulation at § 414.1405(g) that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold would be the mean of the final scores for all MIPS eligible clinicians from a prior period. As discussed under section IV.A.4.g.(2)(b) of this final rule, we are finalizing our proposal to continue using the mean as the methodology for determining the performance threshold for the 2027, 2028, and 2029 MIPS payment years.

In the CY 2024 PFS final rule (88 FR 79373 through 79380), we established the performance threshold for the CY 2024 performance period/2026 MIPS payment year by calculating the mean of the final scores for all MIPS eligible clinicians using CY 2017 performance period/2019 MIPS payment year data. As further discussed under section IV.A.4.g.(2)(c) of this final rule, we are finalizing our proposal to continue using the mean of the final scores for all MIPS eligible clinicians from the CY 2017 performance period/2019 MIPS payment year to establish the performance threshold as 75 points for the CY 2025 performance period/2027 MIPS payment year.

For further information on our current performance threshold policies, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program final rule (82 FR 53787 through 53792), CY 2019 PFS final rule (83 FR 59879 through 59883), CY 2020 PFS final rule (84 FR 63031 through 63037), CY 2021 PFS final rule (85 FR 84919 through 84923), CY 2022 PFS final rule (86 FR 65527 through 65532), CY 2023 PFS final rule (87 FR 70096 through 70100), and CY 2024 PFS final rule (88 FR 79373 through 79380).

We codified the performance thresholds for each of the first 8 years of MIPS at § 414.1405(b)(4) through (9). These performance thresholds are shown in Table 85.

TABLE 85: Performance Thresholds for the CY 2017 Performance Period/2019 MIPS Payment Year through the CY 2024 Performance Period/ 2026 MIPS Payment Years

MIPS Performance Period	2017 MIPS Performance Period	2018 MIPS Performance Period	2019 MIPS Performance Period	2020 MIPS Performance Period	2021 MIPS Performance Period	2022 MIPS Performance Period	2023 MIPS Performance Period	2024 MIPS Performance Period
Year of MIPS	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**
Performance Threshold	3 points	15 points	30 points	45 points	60 points	75 points	75 Points	75 Points
Change from prior year	N/A	12 points	15 points	15 points	15 points	15 points	0 points	0 points

(b) Establishing the Performance Threshold Methodology for the 2027, 2028, and 2029 MIPS Payment Years

Section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every 3 years. In accordance with section 1848(q)(6)(D)(i) of the Act, we proposed in the CY 2025 PFS proposed rule to continue using the mean of the final scores for all MIPS eligible clinicians to compute the performance threshold for the 2027, 2028, and 2029 MIPS payment years (89 FR 62089 through 62091).

In the CY 2022 PFS final rule (86 FR 65527 through 65532), we selected the mean (rather than the median) as the methodology for determining the performance threshold for the 2024, 2025, and 2026 MIPS payment years. For the CY 2019 performance period/CY 2021 MIPS payment year through CY 2021 performance period/2023 MIPS payment year, section 1848(q)(6)(D)(iv) of the Act required that we methodically increase the performance threshold each year to ''ensure a gradual and incremental transition'' to the performance threshold we estimated would be applicable in the CY 2022 performance period/2024 MIPS payment year. Although sections 1848(q)(6)(D)(ii) through (iv) of the Act were no longer applicable for establishing the performance threshold for the CY 2024 performance period/ 2026 MIPS payment year, these previously applicable statutory requirements explained prior computations of the performance threshold that impacted our policy considerations for establishing the performance threshold for MIPS going forward. Based on our review of possible values for the CY 2022 performance period/2024 MIPS payment year, using the mean as our methodology for setting the performance threshold for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year would continue the ''gradual and incremental transition'' that was previously required under section 1848(q)(6)(D)(iv) of the Act, as well as to provide consistency to our stakeholders. Therefore, we finalized the proposal to use the mean as our methodology for setting the performance threshold for that 3-year period. We also codified this methodology in regulation at § 414.1405(g), providing that, for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold will be the mean of the final scores for all MIPS eligible clinicians from a prior period as specified.

At the time of the CY2025 PFS proposed rule, we had data available on MIPS eligible clinicians' final scores from the CY 2017 performance period/ 2019 MIPS payment year through CY 2022 performance period/2024 MIPS payment year, as shown in Table 86. These values represent all available computations of mean and median final scores for those performance periods/ MIPS payment years. As discussed in this section of the final rule, we may use

either the mean or median of the final scores from a prior period for computing the performance threshold for the next 3 years, beginning with the CY 2025 performance period/2027 MIPS payment year. As discussed in the CY 2025 PFS proposed rule, we did not have MIPS eligible clinicians' final scores available from performance periods after the CY 2022 performance period/2024 MIPS payment year, which may inform the performance thresholds for the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year (89 FR 62090). Therefore, we did not include the mean and median final scores for the CY 2023 performance period/2025 MIPS payment year for consideration as potential performance threshold values for the CY 2025 performance period/2027 MIPS payment year. As provided in section 1848(q)(6)(D)(i) of the Act, we must select whether we will use the mean or median of MIPS eligible clinicians' final scores from a prior period, which we may reassess after 3 years. We assessed these selection options based on the data we had available.

TABLE 86: Possible Values for the 2027 MIPS Payment Year Performance Threshold

MIPS Payment Years	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	2024 MIPS Payment Year
Mean	74.65	87.00	85.65	89.47	89.22	82.71
Median	89.71	99.63	92.32	96.82	97.22	85.17

As shown in Table 86, using the median final score gives a possible range of performance thresholds from 85.17 points to 99.63 points (rounded to 85 points and 100 points, respectively). Given our performance threshold of 75 points for the CY 2024 performance period/2026 MIPS payment year, these values would result in an increase of 10 points to 25 points for the CY 2025 performance period/2027 MIPS payment year, and potentially the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year. Selecting the median of final scores as our methodology would, at a minimum, result in a 13 percent increase in the performance threshold of 75 points, which we had established for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year. Further, as shown in Table 85, 75 points is the highest performance threshold we have established for any MIPS payment year to date.

As shown in Table 86, using the mean final score as the methodology would yield a possible range of performance thresholds from 74.65 points to 89.47 points (rounded to 75 points and 89 points, respectively). Given our performance threshold of 75 points in the CY 2024 performance period/2026 MIPS payment year, these values would result in an increase of zero to 14 points for the CY 2025 performance period/2027 MIPS payment year, and potentially the CY 2026 performance period/2028 MIPS payment year and CY 2027 performance period/2029 MIPS payment year. Selecting the mean of final scores as our methodology would, at a maximum, result in a 19 percent increase in the performance threshold of 75 points, which we had established for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year.

We aim to incentivize performance improvement while also ensuring that it is reflective of true clinician performance. Moreover, where possible, it is important to offer stability and consistency for MIPS eligible clinicians. After evaluating the possible values for mean and median shown in Table 86 and our prior policies for consistently selecting a performance threshold value of 75 points for the CY 2022 performance period/2024 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, we have determined that using the mean as our methodology for the 2027 through 2029 MIPS payment years would offer the most consistent and predictable approach for MIPS eligible clinicians. On this basis, we proposed in the CY 2025 PFS proposed rule to continue using the mean of the final scores for all MIPS eligible clinicians from a prior period as specified to compute the performance threshold for each of the 2027 through 2029 MIPS payment years (89 FR 62089 through 62091).

We also proposed to codify this proposal by amending our regulation at § 414.1405. We proposed to amend § 414.1405 by: (1) revising paragraph (g) to read only ''Performance Threshold Methodology''; (2) redesignating, with minor technical modification, the substantive provision at paragraph (g) as a new paragraph (g)(1) to reflect the performance threshold methodology we established and used to specify the performance threshold for the 2024, 2025 and 2026 MIPS payment years under § 414.1405(b)(9); and (3) adding paragraph (g)(2) to provide that, for each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b)(10).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed their support for establishing the performance threshold by continuing to use the mean as the methodology for calculating the performance threshold for the 2027, 2028, and 2029 MIPS payment years. A few commenters stated their appreciation for continued stability in the requirements determining payment adjustments under the MIPS program.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS remain flexible on whether to use the mean or median to compute the performance threshold in future years in case of unforeseen circumstances.

Response: We note that, in accordance with section 1848(q)(6)(D)(i) of the Act, we may reassess whether to use the mean or median to compute the performance threshold every three years. In the CY 2028 PFS proposed rule, we plan to reassess whether to select using the mean or median to

compute the performance threshold using the data available at that time to determine whether to use the mean or median for purposes of computing the performance threshold in future years, specifically the 2030 through 2032 MIPS payment years.

Comment: One commenter expressed concern with CMS using the mean of a prior period to calculate the performance threshold as CMS sunsets traditional MIPS and moves toward MVP reporting.

Response: We note that, in accordance with section 1848(q)(6)(D)(i) of the Act, we are required to choose between the mean or median of a prior period to calculate the performance threshold by which we compare MIPS final scores to determine the MIPS payment adjustment factors for each MIPS eligible clinician (see section 1848(q)(6)(A) of the Act). These statutory requirements apply regardless of whether a MIPS eligible clinician reports MIPS data under traditional MIPS or MVPs. As we continue to move toward MVP reporting, we intend to evaluate the final score data as it becomes available to determine a performance threshold that is most reflective of a MIPS eligible clinician's performance in addition to ensuring that we incentivize providing high quality and value of care without unfairly penalizing clinicians. Moreover, using the mean to calculate the performance threshold may provide consistency and stability as more MIPS eligible clinicians begin to report MVPs over traditional MIPS.

After consideration of public comments, we are finalizing our proposal to continue using the mean of the final scores for all MIPS eligible clinicians from a prior period as specified to compute the performance threshold for each of the 2027 through 2029 MIPS payment years, as proposed. We are also finalizing our proposal to amend our regulation at § 414.1405, as proposed. We amend § 414.1405 by: (1) revising paragraph (g) to read only ''Performance Threshold Methodology''; (2) redesignating, with minor technical modification, the substantive provision at paragraph (g) as a new paragraph (g)(1) to reflect the performance threshold methodology we established and used to specify the performance threshold for the 2024, 2025 and 2026 MIPS payment years under § 414.1405(b)(9); and (3) adding paragraph (g)(2) to provide that, for each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b)(10).

(c) Establishing the Performance Threshold for the CY 2025 Performance Period/2027 MIPS Payment Year

Using the mean of 75 points from the CY 2017 performance period/2019 MIPS payment year continues to be the most appropriate option for establishing the performance threshold for the CY 2025 performance period/2027 MIPS payment year for various reasons described in this section, including: providing consistency for MIPS eligible clinicians while allowing additional time for more recent data to become available, continuing to provide opportunities for MIPS eligible clinicians to gain experience with cost measure scoring (particularly the methodology we are finalizing in section IV.A.4.f.(1)(d)(ii)(B) of this final rule), and ensuring that we do not inadvertently disadvantage certain clinician types, such as small practices and solo practitioners, as we increase the performance threshold.

As shown in Table 86, we calculated the mean values for the CY 2017 performance period/2019 MIPS payment year through the CY 2022 performance period/2024 MIPS payment year, and determined that the mean of 75 points from the CY 2017 performance period/CY 2019 MIPS payment year continues to be the most appropriate option that would provide stability for MIPS eligible clinicians while still encouraging high quality of care. The final scores for the CY 2023 performance period/2025 MIPS payment year were not finalized in time for the proposed rule and, therefore, the mean final score for the CY 2023 performance period/2025 MIPS payment year was not included for consideration as a potential performance threshold value for the CY 2025 performance period/2027 MIPS payment year.

Though we did consider the mean of 87 points from the CY 2018 performance period/2020 MIPS payment year, a substantial increase of 12 points could unfairly impact clinicians as they continue to recover from the COVID–19 public health emergency (COVID–19 PHE), which ended on May 11, 2023. We also considered using the means of the final scores from the CY 2019 performance period/2021 MIPS payment year through the CY 2022 performance period/2024 MIPS payment year for establishing the CY 2025 performance period/2027 MIPS payment year performance threshold. However, we decided they would not be appropriate for measuring future clinician performance given the impact of the COVID–19 PHE on data for MIPS, as described below.

Given issues with underlying data in prior periods due to the COVID–19 PHE, it would be beneficial to wait for more recent data that better reflects clinicians' performance and continue to rely on data from the CY 2017 performance period/2019 MIPS payment year, which predated the COVID–19 PHE. Due to the timing of the COVID–19 PHE and our announcement on March 22, 2020, extending the deadline for MIPS data submission,[887] we are still evaluating the usability of data from the CY 2019 performance period/2021 MIPS payment year. While data collection occurred during the CY 2019 performance period prior to the start of the COVID–19 PHE, data submission for the CY 2019 performance period (occurring during the first quarter of CY 2020) was impacted. Specifically, in addition to extending the deadline for submitting MIPS data, we announced on April 6, 2020, that, due to the COVID–19 PHE, we would apply our extreme and uncontrollable circumstances reweighting policies described under § 414.1380(c)(2)(i) to MIPS eligible clinicians nationwide and extend the deadline to submit an application for reweighting the quality, cost, improvement activities or Promoting Interoperability performance categories for the CY 2019 performance period/2021 MIPS payment year (85 FR 19277 and 19278). These flexibilities for the submission of MIPS data occurring in the first quarter of CY 2020 were intended to alleviate the reporting burden on clinicians that were responding to the onset of the COVID–19 pandemic. The geographic differences of COVID–19 incidence rates along with different impacts resulting from Federal, State, and local laws and policy changes implemented in response to COVID–19 may have affected which MIPS eligible clinicians were able to submit data for the CY 2019 performance period. This may have led to final scores that were not wholly representative of performance for all MIPS eligible clinicians. Also, for the CY 2020 performance period/2022 MIPS payment year and the CY 2021 performance period/2023 MIPS payment year, we extensively applied our reweighting policies, described under § 414.1380(c)(2)(i), to MIPS eligible clinicians nationwide due to the COVID–19 PHE. Inherently, these

[887] *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

actions, particularly reweighting the performance categories, skewed the final scores from those years such that they are not an appropriate indicator for future performance of MIPS eligible clinicians. Specifically, we are concerned that the final scores during the COVID–19 PHE reflect the performance of only MIPS eligible clinicians that may have been less impacted by the pandemic, and do not accurately represent MIPS eligible clinician performance overall during this period.

As discussed further in the CY 2025 PFS proposed rule (89 FR 62083 through 62085) and section IV.A.4.f.(1)(d)(ii) of this final rule, MIPS eligible clinicians have expressed concern that the cost performance category scoring has a negative impact on their MIPS final score. The CY 2022 performance period/2024 MIPS payment year was the first MIPS payment year that the cost performance category score generally constituted 30 percent of MIPS eligible clinicians' final scores (section 1848(q)(5)(E)(i)(II) of the Act). We have observed lower category scores for the cost performance category as compared to the quality performance category. In light of these concerns, which are supported by our analysis of cost performance category scores as discussed in the CY 2025 PFS proposed rule (89 FR 62083 through 62087) and section IV.A.4.f.(1)(d)(ii) of this final rule, we stated that maintaining a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year would provide stability for MIPS eligible clinicians as they become acquainted with the cost performance category (particularly the scoring methodology we proposed and are finalizing in section IV.A.4.f.(1)(d)(ii)(B) of this final rule) without unfairly and negatively impacting their final scores and MIPS payment adjustments. We also stated that maintaining the performance threshold at 75 points for the 2027 MIPS payment year would provide us time to incorporate the impacts of this cost performance category scoring methodology as we establish future performance thresholds (89 FR 62091 and 62092).

As discussed in the CY 2025 PFS proposed rule (89 FR 62083 through 62087) and section IV.A.4.f.(1)(d)(ii) of this final rule, we stated that multiple factors have likely contributed to MIPS eligible clinicians' concerns, including increases in the weight for the cost performance category over time (see section 1848(q)(5)(E)(i)(II) of the Act), the number of cost measures, and the number of MIPS eligible clinicians that are being attributed new cost measures and receiving a score for the cost performance category. This increase in weight for the cost performance category over time has been particularly notable because, as discussed previously, due to the application of our reweighting policies described under § 414.1380(c)(2)(i) for the COVID–19 PHE, many MIPS eligible clinicians were not scored on the cost performance category for the CY 2019 performance period/2021 MIPS payment year through the CY 2021 performance period/2023 MIPS payment year (85 FR 19277 through 19278).[888] [889] In the CY 2025 PFS proposed rule, we stated our belief that our proposal to maintain a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year may help alleviate some of MIPS eligible clinicians' concerns related to the cost performance category and its impact on their MIPS final score (89 FR 62091 through 62092).

In the CY 2025 PFS proposed rule (89 FR 62092), we also stated our concern that any increase in the performance threshold may inadvertently and unfairly disadvantage certain clinician types, specifically small practices and solo practitioners. As we stated in the CY 2024 PFS final rule (88 FR 79377), we want to consider the impacts of the performance threshold and its related policies on small practices. We received feedback that many small practices and solo practitioners face challenges in their ability to participate in MIPS, including the costs to implement and maintain certified electronic health record (EHR) technology (CEHRT), staff and training costs, and limited staff capacity to manage the complexity of the program. We also heard that increases in the performance threshold add administrative and financial burden for small practices that discourage their participation in MIPS. Though we have several policies within MIPS that continue to support small and solo practices, including scoring and reweighting policies, we are interested in understanding how to best support small practices and enhance their ability to successfully participate in MIPS as MIPS continues to evolve. As such, we performed qualitative analysis through engagement with small practices, third party intermediaries, and other interested parties to gather information about the experience of small practices participating in the program. We also reached out to small practices and solo practitioners in CY 2024 to gather additional information about barriers for actively engaging with MIPS. On this basis, we stated that we anticipate establishing a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year will allow us time to gather additional data on the impacts of new policies on small and rural practices, and to develop strategies to reduce barriers for small practices and solo practitioners participating in MIPS (89 FR 62092).

We refer readers to the Regulatory Impact Analysis in the CY 2025 PFS proposed rule (89 FR 62152) and section VII.E.18.d.(4) of this final rule for an estimate of the percent of MIPS eligible clinicians that will receive a negative payment adjustment for the CY 2025 performance period/2027 MIPS payment year with the finalized policies in this final rule and the performance threshold we are finalizing at 75 points.

As discussed in the CY 2025 PFS proposed rule (89 FR 62092) and this section IV.A.4.g.(2)(c) of this final rule, maintaining a performance threshold of 75 points allows additional time for more data to become available, continues to provide opportunities for clinicians to become familiar with the cost measure scoring, and ensures that we do not inadvertently disadvantage certain clinician types, such as small practices and solo practitioners. Therefore, we proposed to establish a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year, and to codify this performance threshold by adding paragraphs at § 414.1405(b)(10) introductory text and (b)(10)(i) (89 FR 62091 and 62092).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS's proposal to use the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year (equal to 75 points) for the purposes of establishing the performance threshold for the CY 2025 MIPS performance period/2027 MIPS payment year.

Several commenters supported this proposal because they believed that this would continue to provide consistency and stability to MIPS while allowing some time to gather data that is unaffected by the COVID–19 PHE.

[888] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1198/2020%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf.*

[889] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1437/2021%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf.*

Commenters also agreed that this proposal provides consistency while clinicians continue gaining familiarity with cost measures and the changes to the cost measure scoring methodology. One commenter stated that changes to the performance threshold may discourage clinicians wishing to report MVPs.

Many commenters requested that we continue to maintain the performance threshold at 75 points in future years.

Response: We thank commenters for their support. We will continue to assess the data on MIPS final scores as they become available in future years to establish the performance threshold for each performance period/MIPS payment year in accordance with section 1848(q)(6)(D)(i) of the Act, and as we transition to MVPs.

Comment: A few commenters noted that it has become increasingly difficult for their specialty (for example, orthopedic physicians) to meet the 75-point performance threshold. More specifically, a few commenters expressed concerns that there were not enough quality measures within MIPS for certain specialties to successfully achieve the performance threshold of 75 points. Another few commenters stated their concerns that certain specialties only have topped out measures to report.

Response: We note that section 1848(q)(6)(D)(i) of the Act requires that we compute the performance threshold for a year such that it is the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Hence, we have limited flexibility in establishing the performance threshold since we are restricted to the data we have available from the prior period.

We also understand that some MIPS eligible clinicians may not have six measures to select in the quality performance category that are relevant to their practice or may have several measures in the quality performance category that are topped out measures. To address this, we established an eligible measure applicability policy within the quality performance category to reduce the denominator of required measures for the collection type used by a clinician if the clinician has fewer than six applicable measures to report in that collection type. This allows clinicians to be scored on the quality measures that are relevant to their scope of practice. For more information on the eligible measure applicability policy please see the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77290 through 77291, 82 FR 53730 through 53732). We also refer readers to section IV.A.4.f.(1)(b) of this final rule in which we are finalizing our proposal regarding scoring topped out measures to allow certain clinicians who practice in specialties impacted by limited measure choice to be scored according to defined topped out measure benchmarks that do not cap scores at 7 measure achievement points. The policy is intended to address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps and aims to facilitate fairer scoring of all specialties.

With respect to the commenters' concerns on the specialty measures available, we solicit commenter recommendations for new specialty measure sets and revisions to existing specialty measure sets on an annual basis. We encourage interested parties to provide recommendations during the specialty measure set solicitation process (for more information please see the QPP resource library at *http://www.qpp.cms.gov*). We also encourage clinicians that lack sufficient quality measures relevant to their scope of practice to work with groups or organizations that represent clinicians to provide recommendations during the specialty measure set solicitation process and to consider reporting a relevant MVP when one becomes available.

Comment: A few commenters supported CMS's proposal to establish the performance threshold at 75 points for the CY 2025 MIPS performance period/2027 MIPS payment year but expressed concerns that this policy may continue to inadvertently harm small and rural practices, creating further challenges for them to successfully participating in MIPS.

Response: We have several policies within MIPS that continue to support small and rural practices, including scoring and reweighting policies set forth in § 414.1380. For example, under § 414.1380(c)(2)(i)(C)(*9*), we automatically reweight the Promoting Interoperability performance category to zero percent of the MIPS final score for MIPS eligible clinicians that are in a small practice as defined in § 414.1305. Under this reweighting policy, MIPS eligible clinicians in small practices are not required to adopt or meaningfully use CEHRT to report the Promoting Interoperability performance category. As we consider the performance threshold and its related policies in future years, we will continue to consider the impact on small and rural practices, particularly as we transition to MVPs.

Comment: A few commenters advocated for legislative changes, including transitioning to an alternative performance payment system that would allow for a performance threshold of 60 points that would be in effect for at least 3 years. A few commenters stated this freeze would particularly benefit small practices that continue to face challenges in meeting the performance threshold. Additionally, a few commenters also said adapting an alternative performance system would eliminate the current tournament model.

Response: As discussed in detail in the CY 2025 PFS proposed rule (89 FR 62088 through 62092), our proposed performance threshold policy is based on current statutory requirements.

After consideration of public comments, we are finalizing our proposal to establish a performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year based on the mean of MIPS eligible clinicians' final scores from the CY 2017 performance period/2019 MIPS payment year, and to codify this performance threshold by adding paragraphs at § 414.1405(b)(10) introductory text and (b)(10)(i).

(3) Example of Adjustment Factors

Figure 4 provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor using the statutory formula and based on our finalized policies for the CY 2025 performance period/2027 MIPS payment year. In Figure 4, the performance threshold is set at 75 points, as we have finalized in section IV.A.4.g.(2)(c) of this final rule.

For purposes of determining the maximum and minimum range of potential MIPS payment adjustment factors, section 1848(q)(6)(B) of the Act defines the applicable percentage as 9 percent for the CY 2025 performance period/2027 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment.

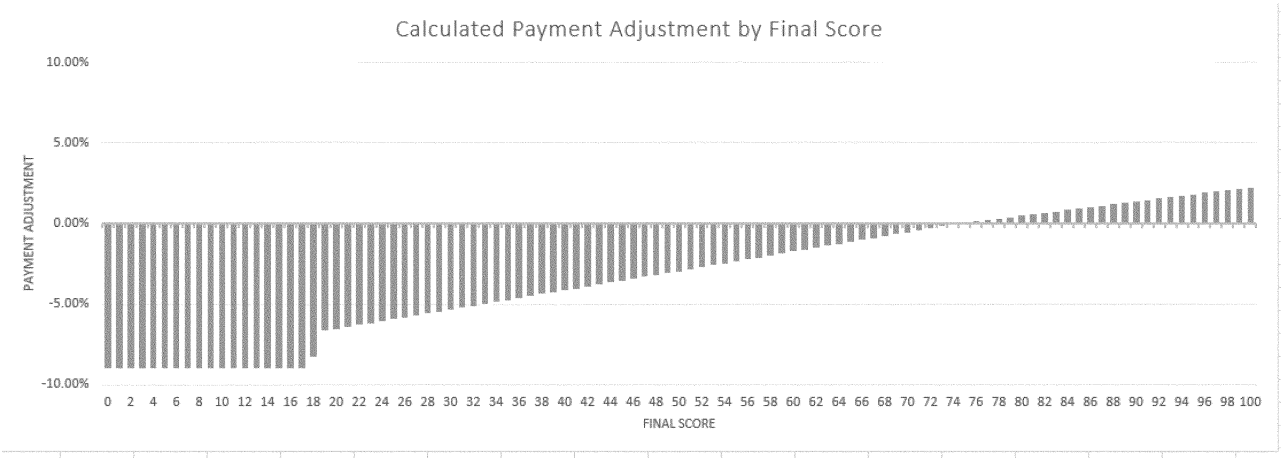
However, there are two modifications to this linear sliding scale. First, as specified in section 1848(q)(6)(A)(iv)(II) of the Act, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the finalized

performance threshold of 75 points for the CY 2025 performance period/2027 MIPS payment year). All MIPS eligible clinicians with a final score in this range will receive a negative MIPS payment adjustment factor equal to 9 percent (the applicable percentage). Second, the linear sliding scale for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0, as required by section 1848(q)(6)(F)(i) of the Act.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 will be less than or equal to 9 percent (the applicable percentage). If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 will be greater than 9 percent. Only those MIPS eligible clinicians with a final score equal to 75 points (the performance threshold proposed for the CY 2025 performance period/2027 MIPS payment year) will receive a neutral MIPS payment adjustment.

Beginning with the CY 2023 performance period/2025 MIPS payment year, the additional MIPS payment adjustment for exceptional performance described in section 1848(q)(6)(C) of the Act is no longer available. For this reason, Figure 4 does not illustrate an additional adjustment factor for MIPS eligible clinicians with final scores at or above the additional performance threshold described in section 1848(q)(6)(D)(ii) of the Act.

FIGURE 4: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold for the CY 2025 performance period/2027 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor will be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality (BN) but cannot be higher than 3.0. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 87 illustrates the changes in payment adjustment based on the final policies from the CY 2024 PFS final rule (88 FR 52599 through 56001) for the CY 2024 performance period/2026 MIPS payment year and the finalized policies for the CY 2025 performance period/2027 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

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TABLE 87: Illustration of Point System and Associated Adjustments Comparison between the CY 2024 Performance Period/2026 MIPS Payment Year and the CY 2025 Performance Period/2027 MIPS Payment Year

2024 Performance Period Final Score Points	MIPS Adjustment for 2024 Performance Period	2025 Performance Period Final Score Points	MIPS Adjustment for 2025 Performance Period
0.0-18.75	Negative 9%	0.0-18.75	Negative 9%
18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
75.00	0% adjustment	75.00	0% adjustment
75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	75.01-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from greater than 0% to 9% for scores from 75.01 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.

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h. Review and Correction of MIPS Final Score—Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called Promoting Interoperability) performance categories.

We made performance feedback available for the CY 2019 performance period/2021 MIPS payment year on August 5, 2020; for the CY 2020 performance period/2022 MIPS payment year on August 2 and September 27, 2021; for the CY 2021 performance period/2023 MIPS payment year on August 22, 2022; CY 2022 performance period/2024 MIPS payment year on August 10, 2023; and for the CY 2023 performance period/2025 MIPS payment year on August 12, 2024. We direct readers to *qpp.cms.gov* for more information.

i. Calculating the Final Score

For a description of the statutory basis and our previously finalized policies for calculating the final score for each MIPS eligible clinician, including performance category weights and reweighting the performance categories, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, CY 2022, and CY 2023 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, and 87 FR 70093 through 70096, respectively).

As described in more detail in the following sections, in the CY 2025 PFS proposed rule (89 FR 62094 through 62096), we proposed to supplement our current policies for reweighting one or more performance categories (that is, quality, improvement activities, and Promoting Interoperability) to permit reweighting in circumstances where we determine that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines.

In the CY 2025 PFS proposed rule (89 FR 62095 through 62096), we proposed that this reweighting policy only be available for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible clinician may delegate data submission to a third party

intermediary for these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on administrative claims data.

(1) Background

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards for the applicable measures and activities for each performance category applicable to such clinician for a performance period and, using the methodology, provide for a final score (using a scoring scale of 0 to 100) for each MIPS eligible clinician for the performance period.

Additionally, section 1848(q)(5)(E) of the Act specifies how we must weigh the scores for each performance category in our calculation of the MIPS eligible clinician's final score. We have codified these weights at § 414.1380(c)(1). Meanwhile, section 1848(q)(5)(F) of the Act provides that, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of 0). We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, they will receive a final score equal to the performance threshold (81 FR 77326 through 77328 and 82 FR 53778 and 53779).

We also finalized at § 414.1380(c)(2) several policies addressing on what basis we may reweight one or more performance categories, and how those weights will be redistributed to the remaining performance categories. For example, in the CY 2020 PFS final rule (84 FR 63023 through 63026), we finalized a reweighting policy at § 414.1380(c)(2)(i)(A)(*9*) and (c)(2)(i)(C)(*10*) for the four MIPS performance categories. Under this policy, we may reweight one or more of the performance categories for a MIPS eligible clinician if we determine, based on information known to us prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician for the applicable performance category(ies) are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the clinician and its agents. Under this policy, we are able to address circumstances where submitted data are inaccurate, unusable, or otherwise compromised.

However, we have found this policy, and our other reweighting policies at § 414.1380(c)(2), do not address circumstances where data are inaccessible or unable to be submitted due to circumstances outside of the control of the MIPS eligible clinician, particularly where the clinician has delegated submission of the data to a third party intermediary and that third party intermediary does not submit the data in accordance with applicable deadlines. In accordance with our regulations governing third party intermediaries at § 414.1400(a)(3)(iv) and (e)(1), we may take remedial action in the event a third party intermediary fails to meet the criteria necessary for their approval as a third party intermediary, fails to comply with other requirements applicable to third party intermediaries, has submitted a false certification, or discontinues their services and do not assist MIPS eligible clinicians in connecting with a different third party intermediary. However, our regulations do not address the impact of a third party intermediary's action or inaction resulting in failure to submit the MIPS eligible clinician's data as required, over which the MIPS eligible clinician has little to no control, on a MIPS eligible clinician's final score.

Currently, if we determine that data for a MIPS eligible clinician were not submitted during the MIPS data submission period for reasons outside the clinician's control, we assign the clinician a score of zero for the performance category or categories for which data were not submitted.[890] Because an excusable failure to submit data is not currently a basis for reweighting, the lack of data may reduce the MIPS eligible clinician's final score and therefore may reduce the clinician's MIPS payment adjustment. However, we believe that reweighting of the applicable performance categories may be appropriate in these rare cases as described in section IV.A.4.i. of this final rule.

Specifically, we believe that a MIPS eligible clinician should not be penalized in cases where the MIPS eligible clinician enters into an agreement with a third party intermediary to submit data on their behalf, and the data are not submitted due to reasons outside of the control of the MIPS eligible clinician. While we encourage the impacted MIPS eligible clinician to take steps to ensure data submission for subsequent years, by, for example, selecting an alternate third party intermediary, there may be cases where there is insufficient time for the MIPS eligible clinician to submit the data through an alternative mechanism in time for the data to be considered for the relevant performance period. For instance, the MIPS eligible clinician may become aware that their third party intermediary did not submit data on their behalf after the data submission period closes. In these cases, we believe it is appropriate to provide relief to the MIPS eligible clinician so that they are not unfairly penalized for their third party intermediary's inaction.

(2) Reweighting Performance Category(ies) Policy When a Third Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS Eligible Clinician's Control

In the CY 2025 PFS proposed rule (89 FR 62094 through 62096), we proposed to adopt a new reweighting policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*) to address this circumstance. Specifically, beginning with the CY 2024 performance period/2026 MIPS payment year, we proposed that we may reweight one or more of the quality, improvement activities, and Promoting Interoperability performance categories where we determine, based on documentation submitted to us through a reweighting request on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of their data to a third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and the third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We also proposed that, to determine whether to apply reweighting to the affected performance category(ies), we would consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible

[890] As set forth in § 414.1325(a), data is only required to be submitted for certain measures and activities as specified for certain performance categories. For example, MIPS eligible clinicians are not required to submit data for the cost performance category to receive a score for that category because cost measures are scored based on Medicare claims data. We refer readers to our data submission requirements at § 414.1325 and our proposals to modify these requirements in the CY 2025 PFS proposed rule (89 FR 62031 through 62036). As previously discussed in section IV.A.4.e.(1)(b)(i) of this final rule, we are finalizing our proposals to modify the data submission requirements at § 414.1325.

clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. We believe these factors are necessary to ensure we are only granting these requests in circumstances where MIPS eligible clinicians would otherwise be unfairly penalized due to the actions or inactions of a third party intermediary. MIPS eligible clinicians could request reweighting under this policy in circumstances where no data was submitted on their behalf by their third party intermediary through the help desk at *QPP@cms.hhs.gov*.

Under this policy, MIPS eligible clinicians would be able to request reweighting for each performance category for which their third party intermediary, to which the MIPS eligible clinician delegated submission of their data, did not submit data for reasons outside of the control of the MIPS eligible clinician. We note that we only proposed that this reweighting policy be available for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible clinician may delegate data submission to a third party intermediary only with respect to these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on Medicare claims data.

Under this proposed reweighting policy, the MIPS eligible clinician must submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. MIPS eligible clinicians would be able to submit reweighting requests on or before November 1st of the year preceding the associated MIPS payment year to allow time for CMS to re-calculate their final score and MIPS payment adjustment factor.

We would only approve reweighting requests with evidence of a written agreement between the MIPS eligible clinician and a third party intermediary. Such written agreement must provide that the MIPS eligible clinician delegated submission of their data to the third party intermediary, and that the third party intermediary agreed to submit data on their behalf in accordance with applicable deadlines, for the performance category or performance categories in question.

In the CY 2025 PFS proposed rule, we proposed that we would review requests and make determinations to reweight based on our assessment that data were not submitted outside the control of the MIPS eligible clinician. We proposed that we would determine whether to apply reweighting to the affected performance category(ies) under this policy based on our consideration of the following criteria: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines. These criteria would inform whether we would grant reweighting requests under our policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*). Circumstances resulting in a clinician's data being inaccessible or unable to be submitted that would merit reweighting could include, but are not limited to, a critical systems failure, the third party intermediary going out of business, the third party intermediary having collected data on a MIPS eligible clinician's behalf and refusing to hand it over for the MIPS eligible clinician to submit, or other circumstances CMS determines to be outside the control of the MIPS eligible clinician.

This reweighting policy is solely intended to mitigate the potentially adverse financial impact of no data being submitted during the MIPS data submission period for one or more performance categories on behalf of the MIPS eligible clinician due to the failure of a third party intermediary to fulfill its contractual responsibilities. Our determination to grant a reweighting request under this policy does not indicate, and should not be interpreted to suggest, that the third party intermediary could not be held liable for the failure to perform the task as delegated, that is, to submit data on the performance category(ies) on behalf of the MIPS eligible clinician. In these circumstances where we determine that a third party intermediary failed to fulfill its agreement with the MIPS eligible clinician to submit their data, we believe it is appropriate to give the MIPS eligible clinician the opportunity to request reweighting of the affected performance category(ies), provided that all elements of our policy are met.

In the CY 2025 PFS proposed rule, we proposed to apply reweighting only in cases when we receive documentation of a third party intermediary's failure to submit data on behalf of a MIPS eligible clinician demonstrating that all elements of our policy are met.

In the CY 2025 PFS proposed rule, we proposed that this policy would be effective beginning with CY 2024 performance period/2026 MIPS payment year. This policy change would become effective prospectively, prior to the beginning of the data submission period for the CY 2024 performance period/2026 MIPS payment year, which will occur January 2, 2025, through March 31, 2025. We proposed this effective date to provide relief to MIPS eligible clinicians, whose circumstances meet all requirements set forth in this reweighting policy, as soon as feasible.

In the CY 2025 PFS proposed rule, we also proposed to codify this new reweighting policy, including all proposed elements, at § 414.1380(c)(2)(i)(A)(*10*) for the quality and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*12*) for the Promoting Interoperability performance category.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed policy stating it provided appropriate relief for MIPS eligible clinicians impacted by a third party intermediary's failure to submit data on their behalf. One commenter further applauded CMS for proposing to make this policy effective for the CY 2024 performance period/2026 MIPS payment year so that clinicians can receive relief as soon as possible.

Response: We thank the commenters for their support.

Comment: A few commenters requested that CMS ensure reweighting is available across scenarios where complete data is not submitted due to reasons outside of a clinician's control. A few commenters asked that CMS consider additional circumstances for this policy, including instances when a third party intermediary submitted inaccurate or incomplete data (rather than no data), technical limitations by the electronic health record vendor to supply necessary data for aggregation, cybersecurity events experienced by third party intermediaries, failure of a clinician to provide complete data to a third party intermediary, and termination of a third party intermediary.

Response: We acknowledge commenters' recommendation to provide reweighting in additional scenarios. We note that we previously finalized reweighting policies for several scenarios outside of the control of the clinician, as set forth in § 414.1380(c)(2)(i). These circumstances include extreme and uncontrollable circumstances, insufficient internet access, and cases where submitted data are inaccurate, unusable, or otherwise compromised. In CY 2020 PFS final rule (84 FR 63025), we acknowledged certain scenarios that, depending on the specific circumstances, could be covered under the policy we finalized at § 414.1380(c)(2)(i)(A)(*9*) and (c)(2)(i)(C)(*10*) for reweighting when data that are inaccurate, unusable, or otherwise compromised for reasons outside the control both of a clinician and its agents. As discussed further in the CY 2020 PFS final rule, such scenarios may include the third party intermediary going out of business or experiencing a loss of data, including instances where data is impacted by a cyberattack (84 FR 63025).

As we proposed, we similarly would consider certain factors when making reweighting determinations under this new reweighting policy, including whether the MIPS eligible clinician knew, or had reason to know, of any data submission issues prior to the deadline for data submission and the MPS eligible clinician took reasonable efforts to correct the issue. For example, this policy would not apply to instances where a third party intermediary terminates a contract mid-year as we would anticipate that clinicians would take reasonable efforts to replace their party intermediary.

In proposing this new reweighting policy, we intended solely to mitigate the potential adverse financial impact on MIPS eligible clinicians' final scores and MIPS payment adjustments because no data was submitted due to the failure of a third party intermediary to fulfill its contractual responsibilities (89 FR 62096). We also proposed that such circumstances must be outside of the control of the MIPS eligible clinician to make reasonable efforts to remedy. Scenarios in which a MIPS eligible clinician does not provide complete data to a third party intermediary would not be covered by this new reweighting policy we proposed. We clarify that this new reweighting policy would only apply to situations in which data was not submitted on behalf of the MIPS eligible clinician due to circumstances outside of the control of the clinician. A MIPS eligible clinician's failure to submit complete data to the third party intermediary would be at least partially within the control of the MIPS eligible clinician.

We encourage MIPS eligible clinicians and their agents experiencing these types of circumstances to communicate with us as early as possible to provide details about the circumstances surrounding these events. Additionally, we may consider commenters' recommendations for additional scenarios for reweighting via future rulemaking.

Comment: One commenter expressed the belief that we should use existing processes, including the extreme and uncontrollable application and the targeted review process, for this policy. Commenters expressed the belief that creating a new process would be confusing to MIPS eligible clinicians.

Response: The CMS help desk is the proper forum for MIPS eligible clinicians to submit reweighting requests under this new policy. As we proposed, MIPS eligible clinicians would only be able to begin submitting reweighting requests under this new policy beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines (89 FR 62096). Further, we proposed they could submit such requests from the expiration of the data submission period through November 1st (89 FR 62096). This timeframe does not align with the timeframe for MIPS eligible clinicians to request reweighting under our other policies, such as our extreme and uncontrollable circumstances policy, which typically occur prior to the start of data submission period. Further, as we noted in the proposed rule, this policy addresses rare cases where a MIPS eligible clinician should not be penalized for a third party intermediary's failure to submit their data as promised in a written agreement (89 FR 62095). We do not expect the volume of these requests to be exceptional. Given these distinctions, the CMS help desk presents the best mechanism for MIPS eligible clinicians to submit their requests under this new reweighting policy as soon as feasible for the CY 2024 performance period/ 2026 MIPS payment year. We may reassess this process if the volume exceeds our expectations.

Similarly, MIPS eligible clinicians currently submit reweighting requests through the CMS help desk for our existing reweighting policy for when data are inaccurate, unusable, or otherwise compromised (84 FR 63023). This process for submitting certain reweighting requests is not wholly new or unfamiliar to MIPS eligible clinicians.

Further, the targeted review process established under section 1848(q)(13)(A) of the Act is limited to informal review of our calculation of the MIPS adjustment factor applicable to the MIPS eligible clinician. This includes requests for targeted review of errors in our application of policies, such as our reweighting policies, governing calculation of scores for measures and activities, performance category scores, and MIPS final scores (81 FR 77353). A MIPS eligible clinician should not be submitting a reweighting request for the first time during the targeted review process as such request is outside of the scope and purpose of targeted review.

Comment: One commenter requested that any requests for reweighting under this policy be kept confidential and that third party intermediaries not automatically be put on probation if a MIPS eligible clinician submits an application for reweighting.

Response: Similar to our existing policy for reweighting when data are inaccurate, unusable, or otherwise compromised (84 FR 63023), we intend for this policy to provide flexibility for MIPS eligible clinicians whose data are not submitted due to circumstances outside of their control. We did not develop this policy to hold harmless third party intermediaries or other agents for any role they play in data inaccuracies. We do not have authority to waive liability as it relates to fraud, waste, and abuse laws or to alter the certification requirements of health information technology. We also note that third party intermediaries that submit data that are inaccurate, unusable or otherwise compromised may be subject to remedial action or termination in accordance with § 414.1400(f).

Comment: A few commenters requested that CMS provide additional guidance on what constitutes reasonable efforts on the part of the clinician to correct the issue for their reweighting request to be approved. Similarly, a few comments asked that CMS be mindful of the potential for added administrative burden that may come with reweighting requests.

Response: In general, we expect the circumstances for which this policy applies to occur infrequently. In such cases, we expect that MIPS eligible clinicians, upon realizing that their third party intermediary did not submit data on their behalf, will reach out to their third party intermediary to try to identify the issue. If potential issues with data submission are discovered

before the close of the data submission period, we will consider whether the MIPS eligible made reasonable efforts to obtain data for submission or otherwise made efforts to ensure that data submission would be completed. If it is discovered that data submission was not completed after the close of the data submission period, we will consider if a clinician knew, or had reason to know, of any data submission issues prior to the deadline and whether the MPS eligible clinician took reasonable efforts to correct the issue.

Under our proposed policy, we would consider evidence of the MIPS eligible clinician attempting to select an alternate third party intermediary, any communication between the MIPS eligible clinician and their third party intermediary, and any documentation signifying that a clinician's data was not submitted due to reasons that could include, but are not limited to, a critical systems failure, the third party intermediary going out of business, the third party intermediary having collected data on a MIPS eligible clinician's behalf and refusing to transmit it to the MIPS eligible clinician to submit, or other circumstances CMS determines to be outside the control of the MIPS eligible clinician. As these actions, and any accompanying documentation, are ones we anticipate MIPS eligible clinicians would reasonably undertake and collect in circumstances where they unexpectedly discover that the third party intermediary may not submit their data on their behalf in accordance with applicable deadlines, we do not expect that our reweighting request requirements will be overly burdensome. We will review the documentation and make determinations for reweighting requests through the CMS help desk.

After consideration of public comments, we are finalizing as proposed adoption of the new reweighting policy for the quality, improvement activities, and Promoting Interoperability performance categories in circumstances in which third party intermediaries do not submit data on behalf of clinicians who have delegated the submission of this data to them beginning with the CY 2024 performance period/2026 MIPS payment year. We are also finalizing to codify this policy as proposed at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*).

j. Third Party Intermediaries General Requirements

(1) Requirements for CMS-approved Survey Vendors

(a) Background

As codified at § 414.1305, a CMS-approved survey vendor means a survey vendor that is approved by CMS for a particular performance period to administer the Consumer Assessment of Healthcare Providers & Systems (CAHPS) for MIPS survey and to transmit survey measures data to CMS.

We refer readers to § 414.1400(d), the CY 2017 Quality Payment Program final rule (81 FR 77386), the CY 2018 Quality Payment Program final rule (82 FR 53818 and 53819), the CY 2019 PFS final rule (83 FR 59907 and 59908), and the CY 2022 PFS final rule (86 FR 65538 and 65539) for previously finalized standards and criteria for CMS-approved survey vendors.

(b) Requirement To Submit Cost of Services

In the CY 2017 Quality Payment Program final rule (81 FR 77386 and 77387), we established that CMS-approved survey vendors may transmit data collected from the CAHPS for MIPS survey to CMS for use in MIPS. Section 414.1400(d)(2) requires that CMS-approved survey vendors submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. We implemented this requirement through the Vendor Participation Form, which is available at *https://qpp.cms.gov/resources/resource-library*.

The CY 2017 Quality Payment Program final rule contained requirements applicable to other types of third party intermediaries, which varied based on whether the third party intermediary was a Qualified Clinical Data Registry (QCDR) or qualified registry. For example, we established requirements for QCDRs and qualified registries to ''sign a document verifying the QCDR's name, contact information, cost for MIPS eligible clinicians or groups to use the QCDR or qualified registry'' (81 FR 77368 and 77369; 81 FR 77385 and 77386). If QCDRs and qualified registries do not provide this information, CMS may exclude them from MIPS in a subsequent year. This requirement helps eligible clinicians determine which vendors to use prior to registration and provides transparency on the cost of program participation. Currently, CMS-approved survey vendors are not required to provide cost information even though other third party intermediaries (QCDRs and qualified registries) are required to do so.

We proposed under the current application submission requirement at § 414.1400(d)(2) that beginning with the CY 2026 performance period/2028 MIPS payment year, a survey vendor must include on its application the range of costs of its third party intermediary services. Ranges of cost estimates would vary based on different levels of service (that is, number of survey respondents, languages provided, etc.). With respect to a third party intermediary that is solely a CMS-approved survey vendor, the publishable costs would be limited to the cost of services related to the CAHPS for MIPS survey (89 FR 62097). CMS has received inquiries from MIPS participants regarding survey vendor costs but has not been able to provide any specific information in response to those requests. The cost information from survey vendors is not easily available to the MIPS eligible clinicians who are considering contracting for services. Having such information in the publicly accessible QPP Resource Library (as part of the list of approved vendors) would make it easier for MIPS eligible clinicians to contract for services and educate themselves about the cost of using a third party intermediary survey vendor. In recent years, some participants who registered for the CAHPS for MIPS survey later withdrew their participation once they learned the costs of survey administration. Providing information on the cost of CMS-approved CAHPS for MIPS survey vendor services may support MIPS participants who are interested in the CAHPS for MIPS Survey but want to know what the costs of administering the survey will be, thus allowing them to make more informed decisions about whether to participate in the CAHPS for MIPS survey. This would also increase the consistency in requirements across different types of third party intermediaries.

With this proposal, the CAHPS for MIPS Survey Vendor Participation Form [891] and the CAHPS for MIPS Survey Minimum Business Requirements [892] in the QPP Resource Library would be updated to detail the required survey vendor cost estimate information. The CAHPS for MIPS Survey Vendor Participation Form submitted by vendors seeking CMS

[891] 2024 CAHPS for MIPS Survey Vendor Participation Form, March 25, 2024. *https://qpp.cms.gov/resources/document/6386fe4b-49b9-42c8-9a2b-a1149f7b142a.*

[892] 2024 CAHPS for MIPS Survey Vendor Minimum Business Requirements, March 11, 2024. *https://qpp.cms.gov/resources/document/02e6e596-51de-4336-a6a6-ab63fc639dbc.*

approval would be updated to include fields to report the cost information. The vendor-specific cost information would then be published in the list of CAHPS for MIPS Survey Approved Vendors which is also posted in the Resource Library.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement that survey vendors must include on their application the range of costs of their third party intermediary services. One commenter stated that the proposal will make requirements consistent across third party intermediary types. Another commenter agreed that the proposal will increase transparency regarding costs for Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Surveys and overall participation in MIPS, which would help participants be more successful when choosing a third party vendor.

Response: We thank the commenters for their support.

Comment: One commenter expressed their view that pricing models are proprietary business information and that they are concerned that the public disclosure of pricing information to competitors could have unintended negative effects on the market. While the commenter did not support the proposal, they recommended the following guidelines for its implementation: do not require strict standardization of pricing information as survey vendors have unique offerings that make comparing options challenging, allow survey vendors to clearly communicate the details of their offerings (for example, service tiers, or packages), and provide survey vendors flexibility to explain pricing models (for example, the factors that influence their pricing).

Response: The public disclosure of pricing information will be beneficial to MIPS participants and to survey vendors as it will minimize the risk of late withdrawals by survey registrants given that MIPS participants will understand the cost of services in advance. We understand that the cost of services can change over time and may differ based on a variety of factors including survey mode, language, sample size, etc. Cost estimates will be collected annually, to capture changes in cost over time, for a common set of factors including survey mode, language, and sample size, so the cost ranges (as provided by the survey vendor) will be displayed in the list of CAHPS for MIPS Survey Approved Vendors. The factors used for collecting cost information through the CAHPS for MIPS Survey Vendor Participation Form and how the cost information is displayed in the list of CAHPS for MIPS Survey Approved Vendors may be updated on a periodic basis due to changing survey requirements and survey vendor feedback.

Comment: One commenter requested clarification on CMS' review and approval process for cost information, including if the information submitted will be edited and whether vendors will have the opportunity to review the presentation of their cost information in the QPP Resource Library before it goes live. The commenter also requested clarification on whether there will be a process for vendors to correct any inaccurate cost information or make updates when pricing structures change.

Response: We will generally not make any edits to the information vendors submit, but we may ask the vendor to provide clarifying edits if information is lacking from the original submission. Survey vendors will have the opportunity to review the presentation of their cost information before it is released to the public in the QPP Resource Library. We will add a step to the current review process for the final list of CMS-approved vendors in which a vendor will be sent their ''row'' of information. The vendor will be asked to (a) confirm receipt and (b) provide any corrections by a specific date prior to the list going live. We already encourage survey vendors to provide updates to their information included in the final list of CAHPS for MIPS Survey Approved Vendors once it is published through the vendor technical assistance mailbox. Updates to cost information will be included in this existing process, and we will provide instructions for vendors regarding communicating updates and corrections to the information posted in the final approved vendor list.

After consideration of public comments, we are finalizing our proposal that beginning with the CY 2026 performance period/2028 MIPS payment year survey vendors are required to include on their application the range of costs of their third party intermediary services.

k. Overview of QP Determinations and the APM Incentive

(1) Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables the Department to advance accountability and encourage improvements in care. The Secretary also has adopted the closely related goal that all people with Original Medicare be in an accountable care relationship by 2030, so that their needs can be holistically assessed, and their care is coordinated within a broader total cost of care system. Our vision for increased participation among clinicians in Advanced APMs is driven by the belief that integrating individuals' clinical needs across a spectrum of clinicians and settings will improve patient care and population health.

As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation, including by specialists, in Advanced APMs.

In the CY 2017 Quality Payment Program final rule (81 FR 77450 through 77457), we finalized the payment amount method and patient count method for calculation of Threshold Scores used for QP determinations under the Medicare option and codified these methods at § 414.1435(a) and (b), respectively. The payment amount method is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''Attributed beneficiaries'' to ''Attribution-eligible beneficiaries,'' as defined at § 414.1305.

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. An attribution-eligible beneficiary is a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;
- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of:

++ One claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period.

++ Or, for an Advanced APM that does not base attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to

have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

In this section, we proposed to modify the definition of ''attribution-eligible beneficiary'' to include any beneficiary who has received a covered professional service (section 1833(z)(3)(A) of the Act; 42 CFR 414.1305; section 1848(k)(3)(A) of the Act) furnished by the eligible clinician (NPI) for whom we are making the QP determination. By no longer specifying E/M services as the default attribution basis, the QP determination methodology would better be able to account for Advanced APMs that do not use E/M services as the basis for beneficiary attribution or that use a combination of E/M and other services.

(2) Payment Amount and Patient Count Methods

The payment amount method for calculating Threshold Scores is based on payments for Medicare Part B covered professional services, including certain supplemental service payments, while the patient count method is based on numbers of patients. Both methods use the ratio of ''attributed beneficiaries'' to ''attribution-eligible beneficiaries,'' as defined at § 414.1305.[893]

Attributed beneficiaries are those who are attributed to the APM Entity (or individual eligible clinician) under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. Attribution-eligible beneficiaries generally are those who, during the QP Performance Period, meet six criteria (listed in this section) specified in the definition of that term at § 414.1305 and described in section IV.A.4.m.(3) of this final rule.

When making QP determinations, we begin by calculating Threshold Scores using the payment amount and patient count methodologies. These Threshold Scores are percentages based on the ratio of the payment amounts or patient counts for attributed beneficiaries to the payment amounts or patient counts for attribution-eligible beneficiaries during the QP performance period. If the Threshold Score (using either the payment amount or patient count method) calculated at the APM Entity or individual eligible clinician level, as applicable, meets or exceeds the relevant QP threshold described at § 414.1430(a), the relevant eligible clinician or clinicians (either the individual eligible clinician or all those on the APM Entity's Participation List) achieve QP status for such year.

FIGURE C-N1: QP Determination Calculation

$$\frac{\text{Attributed beneficiaries}}{\text{Attribution-eligible beneficiaries}}$$

Our regulation at § 414.1435(b)(3) provides that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) provides that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups. In the CY 2021 PFS final rule (85 FR 84951 through 84952), we amended § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. This means that beneficiaries who have been attributed to one APM Entity and are thus barred under the terms of an Advanced APM from attribution to another APM Entity are removed from the denominator of both the payment amount method and patient count method in QP Threshold Score calculations for the APM Entity to which they cannot be attributed. In other words, we do not penalize an APM Entity in the QP Threshold Score calculation by including a beneficiary in its denominator when the terms of an Advanced APM do not permit such beneficiary to be attributed to such APM Entity.

(a) Attributed Beneficiary

An attributed beneficiary is a beneficiary attributed to the APM Entity under the terms of the Advanced APM as indicated on the most recent available list of attributed beneficiaries at the time of a QP determination. There may be beneficiaries on the most recent available list who do not meet the criteria to be attribution-eligible beneficiaries because the QP performance period does not align with the Advanced APM's performance period or attribution period, or for other reasons. There may also be cases where a beneficiary's status changes, for example by enrolling in a Medicare Advantage Plan. We exclude these beneficiaries from our Threshold Score calculations because they do not meet criteria to be attribution-eligible beneficiaries. Although APMs may have reconciliation processes in place to address changes in beneficiary status at various intervals, those processes do not necessarily coincide with the timeframe of QP determinations. Therefore, when calculating Threshold Scores for QP determinations, we exclude from the list of attributed beneficiaries any beneficiaries who do not meet the criteria to be attribution-eligible beneficiaries at that point in time.

(b) Attribution-Eligible Beneficiary

Under our regulation at § 414.1305, we define an attribution-eligible beneficiary as a beneficiary who:

- Is not enrolled in Medicare Advantage or a Medicare cost plan;

[893] For technical information on the QP calculation methodology, see the ''QP Methodology Fact Sheet'' that we publish annually, which can be found as part of the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.com*.

- Does not have Medicare as a secondary payer;
- Is enrolled in both Medicare Parts A and B;
- Is at least 18 years of age;
- Is a United States resident; and
- Has a minimum of one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period or, for an Advanced APM that does not base beneficiary attribution on E/M services and for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for E/M services furnished by an eligible clinician who is in the APM Entity for any period during the QP Performance Period, the attribution basis determined by CMS based upon the methodology the Advanced APM uses for attribution, which may include a combination of E/M and/or other services.

Our stated intent when we finalized the definition of attribution-eligible beneficiary (81 FR 77451 through 77452) was to have a definition that would, for purposes of QP determinations, allow us to be consistent across Advanced APMs in how we consider the population of beneficiaries served by an APM Entity. The criteria we used to define attribution-eligible beneficiary were aligned with the attribution methodologies and rules for our contemporaneous Advanced APMs. The first five criteria are conditions that are required for a beneficiary to be attributed to any Advanced APM. The sixth criterion identifies beneficiaries who have received certain services from an eligible clinician who is associated with an APM Entity for any period during the QP Performance Period. We chose to refer to E/M services as the primary basis for purposes of attribution-eligibility because many of the Advanced APMs CMS offered at that time used E/M claims to attribute beneficiaries to their APM Entity groups. Over time, we have updated the list of services that are considered to be E/M services for purposes of identifying attribution-eligible beneficiaries and have published this list as part of the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov.*

We also included an exception in this sixth criterion to allow us to use an alternative approach for Advanced APMs that do not base beneficiary attribution on any E/M services, and thus for which attributed beneficiaries are not a subset of the attribution-eligible beneficiary population based on the requirement to have at least one claim for an E/M service. To date, we have implemented this alternative approach for four Advanced APMs:

- Bundled Payments for Care Improvement Advanced Model.
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track).
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement).
- Maryland Total Cost of Care Model (Care Redesign Program).

We have published links to the methodologies we use to identify attribution-eligible beneficiaries for these Advanced APMs in the ''2024 Learning Resources for QP Status and APM Incentive Payment'' materials on the Quality Payment Program Resource Library at *qpp.cms.gov*.

We adopted the general rule with flexibility to apply alternative methods for this criterion to ensure that, for the Advanced APMs for which beneficiary attribution is based on services other than E/M services, the attributed beneficiary population is truly a subset of such Advanced APMs' attribution-eligible beneficiary populations and, ultimately, so that our way of identifying beneficiaries for purposes of Threshold Score calculations for QP determinations would be appropriate for such Advanced APMs. That said, our thinking when we developed these approaches was shaped by the form and nature of the Advanced APMs that existed at that time. We believed that, by affording sufficient flexibility within the program, we could both foster innovation in Advanced APMs and simplify our execution of the program. However, with our more narrowly defined default approach to beneficiary attribution (relying on claims for E/M services), we have increasingly needed to exercise the flexibility to identify an alternative approach to attribution eligibility for Advanced APMs that fell into the exception, which meant that we identified several individually tailored ways of performing the beneficiary attribution methodology for specific Advanced APMs. We anticipate that Advanced APMs will continue to evolve and use novel approaches to value-based care that may emphasize a broad range of covered professional services, and in that event the application of our current regulations may result in increased variability among the ways we define attribution-eligible beneficiary when making QP determinations.

We proposed to modify the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include any beneficiary who has received a covered professional service furnished by the eligible clinician for whom we are making the QP determination, beginning with the 2025 QP Performance Period. By no longer specifying a claim for E/M services as the default attribution basis in the sixth criterion, and instead making the default attribution based on covered professional services, we had aimed to eliminate the need to create unique attribution bases that are tied to a specific Advanced APM's attribution methodology.

We proposed to consider all covered professional services for purposes of attribution, and not solely the limited range of E/M services currently used for attribution. This approach would include as attributed beneficiaries those who are receiving any services within the entire range of covered professional services through the Advanced APM. We believed that this proposal would result in a QP calculation that, by including beneficiaries receiving any covered professional service, more accurately reflects eligible clinicians' actual participation in Advanced APMs and would be consistent across all Advanced APMs, thereby improving transparency and predictability of the determinations as well as being more operationally efficient than the current policy. Further, we believed that the proposal better aligned the QP determination methodology with the universe of services to which the Quality Payment Program (including MIPS and APMs) applies, noting that the statutory provisions governing the Quality Payment Program generally pertain to covered professional services (for example, financial incentives for both MIPS eligible clinicians and QPs are applied to, and based on, payments for covered professional services) and that the statutory definition of qualifying APM participant (QP) refers to covered professional services.

In the 2025 Physician Fee Schedule proposed rule, we also acknowledged that, while this proposal would represent significant progress toward rationalizing attribution for the broader range of Advanced APMs, our continued analysis suggested that there may be more work to be done in this area. We have found that our proposed approach makes the above-described improvements to QP determinations, but we also see situations in which QP scores remain low in certain Advanced APMs, particularly where an Advanced APM is focused on a limited set of services, diseases, or conditions. As we describe further in this section, a few of our commenters also modeled this

effect. We recognize the need to provide, consistent with statutory requirements, equitable opportunities to achieve QP status for participants in Advanced APMs that have different focus areas, goals, scopes, and design features. Further, in the case of CMS Innovation Center models, we recognize that there will be ongoing evolution and innovation in the model tests that are Advanced APMs, including the development of new approaches to attribution that apply within the models.

We solicited comment on this proposal to revise the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305 to include a beneficiary who has at least one claim for a covered professional service furnished by an eligible clinician who is on the Participation List for the APM Entity (or by the individual eligible clinician, as applicable) at any determination date during the QP Performance Period. We also invited comment more generally on potential approaches we could consider to make QP determinations in the most equitable, rational, transparent, and meaningful way for eligible clinicians across the broad range of Advanced APMs, including Advanced APMs that are focused on a limited set of services. Based on the results of our ongoing analysis and feedback from commenters, we are not finalizing the proposed change to the definition of ''attribution-eligible beneficiary'' at § 414.1305.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal. Of these, several commenters also requested additional information and analysis on the impact of our proposal on QP determinations for eligible clinicians that participate in each Advanced APM.

Response: We thank the commenters for their support. Further, we appreciate commenters' desire for more information on our analysis regarding the proposal. We agree that information is critical, and one of the reasons we made the proposal was that we believed having a more consistent QP determination methodology to apply across Advanced APMs would offer greater transparency that in turn could foster understanding by eligible clinicians as to how we quantify their Advanced APM participation.

Qualitatively, our analysis showed that the proposed policy appeared to have a significant positive effect on eligible clinicians in the Innovation Center's kidney care models, specifically by allowing for more of the non-E/M covered professional services that clinicians furnish to contribute to attribution. The effects of the proposed policy within other Advanced APMs were more mixed and clustered closer to neutral. We note that our projections of future QP performance periods, which use available data from prior QP performance period, have historically yielded lower QP counts than the actual results for a performance period. We have observed that changes to an APM Entity's Participation List, services furnished, and attributed beneficiaries all have significant impacts on the number of QPs projected for future QP performance periods. But updates to an APM Entity's Participation List may be due to a variety of factors not limited to changes to the composition of a participating provider organization or changes in Advanced APM benchmarking methodology otherwise unknown to us. We further note that changes such as our proposed policy can lead to varied QP Threshold Scores for APM Entities within the same Advanced APM. In other words, the net change in the total number of QPs produced by the proposed policy may not be reflective of uniform directional shifts of the APM Entity scores within the same Advanced APM. For example, APM Entities vary not only in composition but also in size, so an estimated change in scores that puts just one large APM Entity above or below a QP or Partial QP threshold can appear to be a major change to the entire Advanced APM. Finally, because QP status is determined based on specific QP payment amount and QP patient count thresholds, only those changes in scores that result in an eligible clinician meeting or exceeding a QP threshold will contribute to the net estimated change in QP counts. While these are important endpoints, a focus on the outcome may mean we overstate important gains or losses in Threshold Scores.

Comment: One commenter specifically opposed our proposal as it relates to the Enhancing Oncology Model (EOM), citing the low number of cancer types included in this model as the reason eligible clinicians on an EOM Participation List will not achieve QP status. The same commenter also suggested that CMS create specialty-specific QP thresholds. QP determinations

Response: We noted in the proposed rule and earlier in this final rule that our proposal did not solve all of the problems we had identified with the current methodology, in particular when the Advanced APM is focused on a limited set of services. EOM is an Advanced APM for which this is true. We recognize that the design of some Advanced APMs, particularly those with a focus on specific services, diseases, or conditions, may limit the extent to which eligible clinicians are able to increase their participation in the Advanced APM when they have a broader practice outside the APM. We also understand that it may be difficult for certain specialists to increase participation in the available Advanced APMs. We agree with the commenter's concern that the EOM's focus on a subset of cancer types is a limiting factor with respect to the attribution of beneficiaries to participating eligible clinicians for purposes of QP determinations, and while our quantitative results were not identical to those that the commenter shared, we did see the same trend in the effects of the proposal that the commenter did. We are continuing to pursue an approach to QP determinations that can be applied consistently across Advanced APMs that would account for the limitation EOM participants face. We believe that all eligible clinicians that participate in an Advanced APM should have access to a fair QP calculation.

We also noted in the proposed rule and earlier in this final rule that we anticipate that Innovation Center models will continue to identify novel approaches to attribution as the Innovation Center implements its specialty care strategy.[894] While we intended for our proposal to better capture the universe of services these future Advanced APMs will focus on, we are continuing to analyze the effects of our current or proposed policy on future models. As we stated earlier in this final rule, we developed our current policy several years ago based on contemporaneous Advanced APMs, and we made our proposal in large part because we believe that that policy no longer serves the Advanced APMs that have come since. We continue to believe that our proposal is a better approach than the status quo, and we believe that it is likely to be part of a comprehensive approach to QP determinations that will better reflect the current and future state of Advanced APMs. In response to public comments, we believe that, even if, as we anticipate, our proposal will be part of the evolution of QP determination methodologies, we should come back with one or more proposals that reflect a complete

[894] *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

package of QP determination methodologies.

After consideration of public comments, we are not finalizing our proposal to revise the sixth criterion of the definition of ''attribution-eligible beneficiary'' at § 414.1305. We anticipate that we will propose a comprehensive approach to QP determination in future rulemaking, including a strategy to address the needs of condition-specific models, which may include this proposal as one element.

(3) QP Thresholds and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance period 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option in addition to an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance period 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b).

Section 304(a)(2) of Division G, Title I, Subtitle C, of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42, March 9, 2024) amended section 1833(z)(2) of the Act by extending for payment years 2025 and 2026 (performance periods 2023 and 2024) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2025 (performance period 2023) to payment year 2026 (performance period 2024). Additionally, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to require that, for payment year 2026, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. As such, the Medicare Option QP thresholds for payment year 2026 will remain at 50 percent for the payment amount method and 35 percent for the patient count method. Section 304(b) of the CAA, 2024, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2026 the Partial QP thresholds that were established beginning for payment year 2021 under the Medicare Option. Therefore, the Partial QP thresholds for payment year 2026 (performance period 2024) will remain at 40 percent for the payment amount method and 25 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for payment year 2026 (performance period 2025) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2026 (performance period 2024) will continue at 40 percent for the payment amount method and 25 percent for the patient count method. To become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2026 (performance period 2024), the minimum Medicare Option threshold an eligible clinician must meet to be eligible for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent for the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet to be eligible for the All-Payer Combination Option is 20 percent for the payment amount method or 10 percent for the patient count method.

To conform our regulation with the amendments made by the CAA, 2024, we proposed to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2026 (performance period 2024)

The revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds are as follows:

- Paragraph (a)(1)(v) to state that for 2026 the amount is 50 percent, and a new paragraph (a)(1)(vi) to state that for 2027and later, the amount is 75 percent.
- Paragraph (a)(2)(v) to state that for 2026 the amount is 40 percent, and a new paragraph (a)(2)(vi) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (a)(3)(v) to state that for 2026 the amount is 35 percent, and a new paragraph (a)(3)(vi) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (a)(4)(v) to state that for 2026 the amount is 25 percent, and a new paragraph (a)(4)(vi) to state that for 2027 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(A) to state that for 2021 through 2026 the amount is 50 percent, and paragraph (b)(1)(i)(B) to state that for 2027 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(A) to state that for 2021 through 2026 the amount is 40 percent and paragraph (b)(2)(i)(B) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (b)(3)(i)(A) to state that for 2021 through 2026 the amount is 35 percent, and paragraph (b)(3)(i)(B) to state that for 2027 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(A) to state that for 2021 through 2026 the amount is 25 percent, and paragraph (b)(4)(i)(B) to state that for 2027 and later, the amount is 35 percent.

As these changes are specified by statute, as described above, we are finalizing the extensions of these thresholds as proposed.

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TABLE 88: QP Threshold Score Updates

Medicare Option - Payment Amount Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Payment Amount Threshold	50		50		50		75	
Partial QP Payment Amount Threshold	40		40		40		50	
Medicare Option - Patient Count Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	35		35		35		50	
Partial QP Patient Count Threshold	25		25		25		35	
All-Payer Combination Option - Payment Amount Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method								
QP Performance Period / Payment Year	2022/2024 (Percent)		2023/2025 (Percent)		2024/2026 (Percent)		2025/2027 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

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(4) APM Incentive Payment

Prior to amendments made by section 304(a)(1) of the CAA, 2024, section 1833(z)(1) of the Act provided for APM Incentive Payments for eligible clinicians who are QPs with respect to a year in each of payment years 2019 through 2025. Specifically, for each of the specified payment years, in addition to the amount of payment that will otherwise be made for covered professional services furnished by an eligible clinician who is determined to be a QP for such year, an additional lump sum APM Incentive Payment will be made equal to 5 percent of the eligible clinician's estimated aggregate payment amounts for such covered professional services for the preceding year (which we defined as the ''base year'') in each of payment years 2019 through 2024, and 3.5 percent of such amounts in payment year 2025. Covered professional services are defined at § 414.1305, with reference to the statutory definition at section 1848(k)(3) of the Act, as services for which payment is made under, or based on, the PFS and which are furnished by an eligible clinician (physician; practitioner as defined in section 1842(b)(18)(C) of the Act; PT, OT, or speech-language pathologist; or qualified audiologist as defined under section 1861(ll)(4)(B) of the Act).

Section 304(a) of the CAA, 2024 amended section 1833(z)(1) of the Act to provide that eligible clinicians who are QPs with respect to payment year 2026 (performance period 2024) will receive an APM Incentive Payment equal to 1.88 percent of their estimated aggregate payment amounts for Medicare Part B covered professional services in the preceding year. In effect, this statutory change extends the APM Incentive Payment for one additional year, at 1.88 percent.

Accordingly, we proposed to incorporate the change made by the CAA, 2024, by amending the regulation text at § 414.1450 to add the payment year 2026 APM Incentive Payment amount of 1.88 percent of covered professional services payments. We proposed to amend paragraph (b)(1) to state that the amount of the APM Incentive Payment for payment years 2019 through 2024 is equal to 5 percent, for payment year 2025, 3.5 percent, and for payment year 2026, 1.88 percent of the estimated aggregate payments for

covered professional services furnished during the calendar year immediately preceding the payment year.

Beginning with the 2026 payment year, which relates to the 2024 QP Performance Period, section 1848(d)(1)(A) of the Act specifies that there shall be two separate PFS conversion factors, one for items and services furnished by an eligible clinician who is a QP for the year (the qualifying APM conversion factor), and the other for other items and services not furnished by a QP (the non-qualifying APM conversion factor). Each conversion factor will be equal to the conversion factor for the previous year multiplied by the applicable update for the year specified in section 1848(d)(20) of the Act. The update specified for the qualifying APM conversion factor for CY 2025 is 0.75 percent, while the update for the nonqualifying APM conversion factor is 0.25 percent.

As the establishment of a 1.88 percent APM Incentive Payment for payment year 2026 is established by statute, we are finalizing as proposed our incorporation of this change into § 414.1450(b)(1).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2025 PFS proposed rule (89 FR 61596), we solicited public comment on each of the aforementioned issues for the following sections of the rule that contained information collection requirements (ICRs). We did not receive such comments, and therefore, we are finalizing them in this rule as proposed.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2023/may/oes_nat.htm*). In this regard, Tables 89 and 90 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the May 2023 BLS data does not include median hourly wage rates for a number of the physician occupation types listed in Table 90; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the May 2021 and May 2022 data, provide similar notes for median wage rates for occupations that are above a given threshold ($100.00/hr or $208.000 per year for the May 2021 BLS data (*https://www.bls.gov/oes/2021/may/oes_nat.htm*), and $115.00/hr or $239,200 per year for the May 2022 BLS data (*https://www.bls.gov/oes/2022/may/oes_nat.htm*). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE 89: National Occupational Employment and Wage Estimates (Excluding Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	22.66	22.66	45.32
Business Operations Specialists	13-1000	42.33	42.33	84.66
Chief Executives	11-1011	124.47	124.47	248.94
Computer System Analysts	15-1211	53.27	53.27	106.54
Lawyers	23-1011	84.84	84.84	169.68
Licensed Practical and Licensed Vocational Nurses	29-2061	29.23	29.23	58.46
Medical and Health Services Managers	11-9111	64.64	64.64	129.28
Pharmacists	29-1051	64.81	64.81	129.62

For our purposes, BLS' May 2023 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we used an average conglomerate wage of $291.64/hr as demonstrated below in Table 90.

TABLE 90: National Occupational Employment and Wage Estimates (Physicians)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	163.21	163.21	326.42
Family Medicine Physicians	29-1215	115.77	115.77	231.54
General Internal Medicine Physicians	29-1216	118.01	118.01	236.02
Obstetricians and Gynecologists	29-1218	133.97	133.97	267.94
Orthopedic Surgeons, Except Pediatric	29-1242	181.85	181.85	363.7
Pediatric Surgeons	29-1243	216.02	216.02	432.04
Pediatricians, General	29-1221	98.97	98.97	197.94
Physicians, All Other	29-1229	119.54	119.54	239.08
Psychiatrists	29-1223	123.53	123.53	247.06
Surgeons	29-1240	167.74	167.74	335.48
Surgeons, All Other	29-1249	165.38	165.38	330.76
Total				3,207.98
Average Physician Wage (3,207.98/11)				291.64

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions (§ 414.504)

On November 17, 2023, section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024) was passed and delayed data reporting requirements for CDLTs that are not ADLTs, and it also delayed the phase-in of payment reductions under the Clinical Laboratory Fee Schedule (CLFS) from private payor rate implementation under section 1834A of the Act. After the publication of the proposed rule (CMS–1807–P) and the close of the comment period, however, the data reporting period and phase-in of payment reductions were further delayed. On September 26, 2024, section 221 of the Continuing Appropriations and Extensions Act, 2025 (Pub. L. 118–83) was passed and delayed CLFS data reporting requirements for CDLTs that are not ADLTs, as well as the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any burden estimates under this section of this final rule. Please refer to section VII.E.8. of this final rule for a discussion of the impacts associated with the changes described in section III.D. of this final rule.

2. ICRs Regarding the Updates to the Medicare Diabetes Prevention Program (§§ 410.79, 414.84, and 424.205)

In section § 410.79(b), we are finalizing our proposal to make conforming changes to our regulation Conditions of Coverage to align with the 2024 Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) Standards.[895] We are finalizing our proposal to amend § 410.79(b) to add a new term for MDPP, ''in-person with a distance learning component.'' The ''in-person with a distance learning component'' code will reduce administrative burden and allow MDPP suppliers to streamline data reporting to CDC because they will only have to maintain one code if they are providing in-person and distance learning delivery. To further align with 2024 CDC DPRP Standards, we also added the term ''combination with an online component'' and revised the current ''online'' definition. We also clarified in § 410.79(d)(1) that MDPP make-up sessions can only be furnished using distance learning and in-person delivery modes, in alignment with the Extended flexibilities as defined in the CY 2024 PFS final rule (88 FR 79528). We also finalized our proposal to amend § 410.79(e)(3)(iii)(C) in response to comments that beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations (88 FR 79249). We finalized our proposal to revise language to specify that a beneficiary can self-report their weight for an MDPP distance learning session by sending two (2) date-stamped photos: one with their weight on the digital scale and one of the beneficiary visible in their home. Additionally, at § 414.84(c), to make it possible for Medicare Administrative Contractors (MACs) to process claims for same day make-up sessions in MDPP, we finalized our proposal d that MDPP suppliers be required to append an existing claim modifier (Current Procedural Terminology (CPT) Modifier 79) to any claim for G9886 or G9887 to indicate a make-up session that was held on the same day as a regularly scheduled MDPP session. We finalized our proposal to remove the MDPP bridge payment in § 414.84(a), (d), and (e). This payment is no longer necessary in

[895] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

MDPP's CY 2024 fee for service payment structure and could introduce the potential for fraud, waste, or abuse. Finally, we finalized our proposal to make minor edits throughout §§ 410.79, 424.205, and 414.84 to update outdated references and align with previous rulemaking pertaining to MDPP terminology, payment structure, and requirements. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the provisions, including the collection of weights, per the CY 2024 PFS final rule.

3. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the preamble. Please refer to section VI.E.11. of this final rule for a discussion of the impacts associated with the changes to the Shared Savings Program as described in section III.G. of this final rule.

4. ICRs Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act (CMS–10858, OMB 0938–1474) (§§ 427.402, 428.302, and 428.303)

The following changes will be submitted to OMB for approval under control number 0938–INSERT (CMS–INSERT).

In sections III.I. of this final rule, we are finalizing the proposed policy that to receive consideration for an inflation rebate reduction for a specific rebatable drug when the manufacturer believes there is a severe supply chain disruption or likely shortage, a manufacturer must submit to CMS a rebate reduction request form along with supporting documentation. As stated in the proposed rule (89 FR 62104), we proposed this because manufacturers hold some of the information and documentation that is needed to determine whether the rebate amount for a Part B or Part D rebatable drug should be reduced due to either a severe supply chain disruption or a likely shortage as required by sections 1847A(i)(3)(G)(ii), 1860D–14B(b)(1)(C)(ii), and 1860D–14B(b)(1)(C)(iii) of the Act.

At §§ 427.402(c)(4) and 428.302(c)(4), we proposed the criteria that a Part B or Part D rebatable drug must meet for CMS to grant a severe supply chain disruption rebate reduction request. At §§ 427.402(c)(5) and 428.302(c)(5), we proposed that if a manufacturer believes a severe supply chain disruption continues into a fifth consecutive calendar quarter for a Part B rebatable biosimilar biological product, or a second applicable period for a generic Part D rebatable drug or biosimilar after the start of the natural disaster or other unique or unexpected event, the manufacturer may request an extension of the rebate reduction one time by submitting a rebate reduction extension request and supporting documentation. At § 428.303(c)(4), we proposed criteria that a generic Part D rebatable drug must meet for CMS to grant a rebate reduction request because the generic Part D rebatable drug is likely to be in shortage, including the requirements for a one-time extension of a rebate reduction. At § 428.303(c)(5), we proposed that if a manufacturer believes a generic Part D rebatable drug that was granted a reduction of the rebate amount and continues to be affected by the potential drug shortage continuing into 1 additional consecutive applicable period, the manufacturer may request an extension of the rebate reduction one time by submitting a rebate reduction extension request and supporting documentation.

We did not receive any public comments on the collection of information requirements for the rebate reduction requests provisions, and we are finalizing as proposed.

Additional instructions for submitting rebate reduction requests are provided in the collection of information that was approved on July 22, 2024, under OMB control number 0938–1474 and can be found on *reginfo.gov* (*https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202407-0938-012*). The approved collection of information includes the rebate reduction request forms that must be submitted to CMS for consideration for a rebate reduction.

As stated in the proposed rule (89 FR 62104), we believe that few manufacturers will submit a rebate reduction request form due to the statutory specifications regarding eligible drugs, as well as the policy criteria finalized in this rule. Using the wage rates in Table 89 of this final rule, we anticipate collecting a total of 10 rebate reduction request forms per year. We estimate a total annual burden of 3,100 hours (310 hr per form * 10 forms) at a cost of $37,378 [(160 hr × $84.66/hr for a Business Operations Specialist collect information and provide brief explanations detailing the specifics of the severe supply chain disruption or likely shortage, including determining changes in drug production and distribution and when supply is expected to meet demand, submit information on how the manufacturer plans to resolve or mitigate the severe supply chain disruption or likely shortage, compile supporting documentation providing evidence of the severe supply chain disruption and likely shortage, and submit such information as part of their request to CMS) + (80 hr × $129.62/hr for a Pharmacist to evaluate the impact and duration of a severe supply chain disruption or determine the likelihood of shortage and anticipated duration of the potential shortage T) + (50 hr × $169.68/hr for a Lawyer to review the submission and determine which information, if any, on the form or in the supporting documentation is considered proprietary and protected under Exemption 3 and/or Exemption 4 of the Freedom of Information Act) + (20 hr × $248.94/hr for a Chief Executive to review the Rebate Reduction Request Form and supporting documentation and certify the submission; certification must be done by the (1) CEO, (2) CFO, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3))].

Using the wage rates in Table 89 of this final rule, we also anticipate collecting a total of 10 rebate reduction extension request forms per year, and a total annual burden estimate of 3,100 hours (310 hr per form * 10 forms) at a cost of $37,378 [(160 hr × $84.66/hr for a Business Operations Specialist to collect information and provide brief explanations detailing the specifics of the continued severe supply chain disruption or likely shortage, including determining changes in drug production and distribution and when supply is expected to meet demand, submit information on how the manufacturer plans to resolve or mitigate the severe supply chain disruption or likely shortage, compile supporting documentation providing evidence of the severe supply chain disruption and likely shortage continuation, and submit such information as part of their request to CMS) + (80 hr × $129.62/hr for a Pharmacist to to evaluate the continued impact and duration of a severe supply chain disruption or determine the

continued likelihood of shortage and anticipated duration of the potential shortage) + (50 hr × $169.68/hr for a Lawyer to review the submission and determine which information, if any, on the form or in the supporting documentation is considered proprietary and protected under Exemption 3 and/or Exemption 4 of the Freedom of Information Act) + (20 hr × $248.94/hr for a Chief Executive to review the Rebate Reduction Request Form and supporting documentation and certify the submission; certification must be done by the (1) CEO, (2) CFO, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3)))].

CMS approximates that the burden estimates for the rebate reduction request form and the rebate reduction extension request form will be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

We did not receive any public comments on the collection of information requirements and burden estimates for the rebate reduction requests provisions, and we are finalizing as proposed.

5. ICRs Regarding Medicare Parts A and B Overpayment Provisions of the Affordable Care Act (§ 401.305(a)(2) and (b)(1), (2), and (3))

Section W of the December 2022 Overpayments Proposed Rule proposed amendments to § 401.305(a)(2) to change the standard for an ''identified overpayment'' for Medicare Parts A and B and include by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). The proposed amendments for Medicare Parts A and B are associated with OMB control number 0938–1323 (CMS–10405); however, we did not make any revisions to the currently approved requirements and burden under this control number. We were not able to predict if there will be any change in the number of overpayments identified or reported under the proposed amendments to the rule; however, we solicited comment on this assumption.

Section III.O. of this final rule discusses existing § 401.305(b)(1), which specifies when a person who has received an overpayment must report and return an overpayment. We proposed to amend § 401.305(b)(1) by referencing revised § 401.305(b)(2) and new § 401.305(b)(3). We proposed a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this paragraph may be applicable after the suspension described in new § 401.305(b)(3) is complete. New § 401.305(b)(3) identifies circumstances under which the deadline for reporting and returning overpayments will be suspended to allow time for providers to investigate and calculate overpayments. Again, the amendments for Medicare Parts A and B are associated with OMB control number 0938–1323 (CMS–10405); however, we did not make any revisions to the currently approved requirements and burden under this control number since we could not predict if there will be any change to the number of overpayments identified or reported based on this rulemaking's changes. We solicited comment on this assumption.

We did not receive public comments on the provisions and assumptions, and therefore, we are finalizing them as proposed.

6. The Quality Payment Program (42 CFR Part 414 and Section IV. of This Final Rule)

The following Quality Payment Program-specific ICRs reflect changes to our currently approved burden (that is, burden that is currently approved by OMB via an active collection of information request) to capture policy changes in this CY 2025 final rule.

In the CY 2025 PFS proposed rule (89 FR 62104 through 62152), we presented detailed burden updates that reflected the impact of proposed policy provisions as well as updated data and assumptions that were independent of policy proposals. We also solicited public comment on our approach to presenting burden such estimates, but we did not receive any comment.

In this final rule, we only present detailed burden estimates for Quality Payment Program ICRs that are new or revised and based on policies finalized in this rule. We also continue our discussions of policy provisions for which we did not propose burden updates. Non-rulemaking adjustments, due to updated data and assumptions, and the changes due to provisions of this rule, will be submitted to OMB for approval under the associated control numbers.

Outside of previous physician fee schedule payment policy rules which included adjustment-only burden, this follows our long-standing process for setting out PRA-related burden in the vast majority of our proposed and final rules. It is intended to focus our PRA score on the impact of the rulemaking document.

a. Background

(1) ICRs Associated With Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs)

In section V.B.6. of this final rule, we discuss a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The following sections describe the changes in the estimated burden for the information collections relevant to the policy provisions finalized in the CY 2025 PFS final rule for MIPS and Advanced APM ICRs. These changes, as well as non-rulemaking adjustments, will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The updated information collections for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey outlined in section IV.A.4.j.(1)(b) of this final rule will be submitted to OMB for review under control number 0938–1222 (CMS–10450), to be a requirement for CAHPS for MIPS survey vendors beginning with the CY 2026 performance period/2028 MIPS payment year. We have received approval for the collection of information associated with the virtual group election process under OMB control number 0938–1343 (CMS–10652).

(a) Summary of Annual Quality Payment Program Burden Estimates

Table 91 summarizes this rule's total burden estimates for the Quality Payment Program for the CY 2025 performance period/2027 MIPS payment year. For the Quality Payment Program, we provide estimates only for ICRs that have policy provisions finalized in this final rule that impact our burden estimates.

In the CY 2024 PFS final rule (87 FR 70169), the total estimated burden for the CY 2024 performance period/2026 MIPS payment year was 724,212 hours at a cost of $81,322,556 (see Table 91, row a). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs outlined in this section of this final rule compared to the CY 2024 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year is 635,303 hours at a cost of $75,919,246 (see Table 91, row b). These represent a decrease of 88,909 hours and $5,403,307. To understand the burden implications of the policies finalized in this rule, we provide an estimate of the total burden associated

with continuing the policies and ICRs currently approved by OMB and set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year. The estimated burden of 594,447 hours at a cost of $71,079,848 (see Table 91, row c) reflects the availability of more accurate data to account for all potential respondents and submissions across the ICRs with burden changes detailed in this section of the final rule and represents a decrease of 40,856 hours and $4,839,401 (see Table 91, row d).

Our total burden estimate for the CY 2025 performance period/2027 MIPS payment year, for ICRs that include changes due to provisions finalized in this final rule, is 586,877 hours and $70,166,672 (see Table 91, row e), which represents a decrease of 48,426 hours and $5,752,577 (see Table 91, row f) from the CY 2024 PFS final rule estimate with updated wage rates and ICRs. From these estimates, updated data and assumptions not related to policies in this final rule will reduce burden by 40,856 hours and $4,839,401 (see Table 91, row d). We estimate that the policies in this final rule will further reduce burden by 7,570 hours (−48,426 hours− −40,856 hours) and $913,176 (−$5,752,577− −$4,839,401) (see Table 91, row g) for the CY 2025 performance period/2027 MIPS payment year; this estimate is unchanged from the CY 2025 PFS proposed rule (89 FR 62105 and 62106). In Table 92, we identify the expected change in total hours and total responses for the included ICRs.

TABLE 91: Summary of Burden Estimates and Requirements from the CY 2025 PFS Final Rule

Burden Estimate Description	Time (Hours)	Cost
Currently Approved Burden in CY 2024 PFS Final Rule (a)	724,212	$81,322,556
CY 2024 PFS Final Rule w/ Updated Wage Rates and ICRs (b)	635,303	$75,919,249
CY 2024 PFS Final Rule w/ Updated Data and Assumptions (c)	594,447	$71,079,848
Change in Burden Due to Updated Data and Assumptions (d) = (c) – (b)	**-40,856**	**-$4,839,401**
CY 2025 PFS Final Rule Total Burden (e)	586,877	$70,166,672
Total Change in Burden (f) = (e) – (b)	-48,426	-$5,752,577
Change in Burden Associated with Policies (g) = (f) – (d)	**-7,570**	**-$913,176**

TABLE 92: Summary of Quality Payment Program Burden Estimates and Requirements CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses	CMS-1807-F Responses	Change in Responses	Currently Approved Total Time (Hours)	CMS-1807-F Total Time (Hours)	Change in Total Time (Hours)
§§ 414.1325 and 414.1335 Quality Performance Category: Medicare Part B Claims Collection Type (see Tables 97 and 98)	13,413	12,197	-1,216	190,465	173,197	-17,268
§§ 414.1325 and 414.1335 Quality Performance Category: QCDR/MIPS Clinical Quality Measure CQM Collection Type (see Tables 99 and 100)	16,632	17,008	+376	151,068	154,484	+3,416
§§ 414.1325 and 414.1335 Quality Performance Category: electronic Clinical Quality Measure eCQM Collection Type (see Tables 102 and 102)	28,714	27,179	-1,535	229,712	217,432	-12,280
§414.1365 MVP Registration (see Tables 103 and 104)	9,585	6,285	-3,300	2,396	1,571	-825
MVP Quality Submission (see Tables 105 and 106)	9,585	6,285	-3,300	61,662	40,193	-21,469
TOTAL	**77,929**	**68,954**	**-8,975**	**635,303**	**586,877**	**-48,426**

Table 93 provides the reasons for changes in the estimated burden for the CY 2025 performance period/2027 MIPS payment year for information collections in the Quality Payment Program section (IV.A) of this final rule. As with Tables 91 and 92, we updated Table 93 from the CY 2025 PFS proposed rule (89 FR 62108 through 62440) to only include ICRs for which policy provisions finalized in this rulemaking impact our burden estimates. We divided the reasons for our change in burden into those related to finalized policies in the CY 2025 PFS final rule and those related to adjustments in burden continued from the CY 2024 PFS final rule policies and as currently approved under CMS–10621 (OMB 0938–1314) that reflect updated data and revised methods.

TABLE 93: Reasons for Change in Burden Compared to The Currently Approved Information Collection Burden

ICR Title	Changes in Burden Due to CY 2025 Final Rule Policies	Adjustments in Burden Continued from CY 2024 PFS Final Rule Policies Due to Revised Methods or Updated Data
Quality Performance Category: Medicare Part B Claims Collection Type (see Table 98)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the claims collection type due to the addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
Quality Performance Category: QCDR/MIPS CQM Collection Type (see Table 100)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the QCDR and MIPS CQM collection type due to the addition of 6 new MVPs.	Increase in the number of respondents due to updated data.
Quality Performance Category: eCQM Collection Type (see Table 102)	Decrease in number of respondents due to the estimated increase in the number of respondents submitting for the MVP quality performance category via the eCQM collection type due to the addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
MVP Registration (see Table 104)	Increase in number of respondents due to the addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.
MVP Quality Submission (see Table 106)	Increase in number of respondents due to the addition of 6 new MVPs.	Decrease in the number of respondents due to updated data.

(2) Summary of Changes for the Quality Payment Program: MIPS

(a) MIPS ICRs With Changes Due to Policy Provisions

As identified in Tables 92 and 93, the following five MIPS ICRs under control number 0938–1314 (CMS–10621) show changes in burden due to the policies finalized in this final rule:

- Quality Performance Category Data Submission by Medicare Part B Claims Collection Type.
- Quality Performance Category Data Submission by Qualified Clinical Data Registry (QCDR) and MIPS Clinical Quality Measure (CQM) Collection Type.
- Quality Performance Category Data Submission by Electronic Clinical Quality Measure (eCQM) Collection Type.
- MIPS Value Pathways (MVP) Quality Performance Category Submission.
- MVP Registration.

In aggregate, we estimate policy provisions will result in a net decrease in burden of 7,570 hours and $913,176 for the CY 2025 performance period/2027 MIPS payment year (see Table 91). We detail changes to our currently approved estimates for these ICRs under control number 0938–1314 (CMS–10621) based on policy provisions as well as revised burden assumptions based on the updated data available at the time of preparation of this final rule; these discussions begin in section V.B.6.b. of this final rule.

As detailed in section V.B.6.b. of this final rule, updates to the information collections for the CAHPS for MIPS Survey will be submitted to OMB for review under control number 0938–1222 (CMS–10450). We did not propose updates to the burden estimates because of the forthcoming changes.

(b) MIPS ICRs With No Changes to Currently Approved Estimates

We did not propose adjustments to our burden estimates for the following ICRs in the CY 2025 PFS proposed rule. We are finalizing not to make any changes to these ICRs from our currently approved estimates under the control

numbers listed below. This includes the following ICRs:

- Beneficiary Responses to CAHPS for MIPS Survey Burden (0938–1222) (89 FR 62139).
- Group Registration for the CAHPS Survey (0938–1222) (89 FR 62139).
- Registration for Virtual Groups (0938–1343) (89 FR 62115).
- Nomination of Improvement Activities (0938–1314) (89 FR 62147).
- Open Authorization (OAuth) Credentialing and Token Request Process (0938–1314) (89 FR 62123).
- Opt-out of Performance Data Display on Compare Tools for Voluntary Participants (0938–1314) (89 FR 62151).
- Nomination of MVPs (0938–1314) (89 FR 62147).

Notably, we discuss related policy provisions for the following ICRs in this final rule, and why we believe they do not impact our current burden estimates, in sections V.B.6.c.(5).(a).(ii) and V.B.6.b.:

- Subgroup Registration (0938–1314) (89 FR 62136).
- CAHPS for MIPS Survey Vendor Requirements (0938–1222) (89 FR 62122).

(c) MIPS ICRs With Changes Due to Available Data

We proposed updates to the following ICRs for the CY 2025 performance period/2027 MIPS payment year due to the availability of updated data and assumptions that are not associated with policy provisions in this final rule. These burden updates, as presented in the CY 2025 PFS proposed rule, will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We did not receive public comment on our estimates for these ICRs provided in the CY 2025 PFS proposed rule.

- Call for Quality Measures (89 FR 62139 and 62140).
- Quality Payment Program Identity Management Application Process (89 FR 62127).

Notably, in sections V.B.6.d. and V.B.6.e. of this final rule, we discuss related policy provisions for the following ICRs and why we believe they do not impact our current burden estimates.

- Reweighting Applications for Promoting Interoperability and Other Performance Categories (89 FR 62140 through 62142).
- Data Submission for the Promoting Interoperability Performance Category (89 FR 62142 through 62145).
- Data Submission for the Improvement Activities Performance Category (89 FR 62145 through 62147).

In the CY 2025 PFS proposed rule, we proposed updates to the following ICRs for the CY 2025 performance period/2027 MIPS payment year due to the availability of updated data and assumptions that are not associated with policy provisions. We are further revising these estimates due to the availability of updated data and assumptions and will submit them to OMB under control number 0938–1314 (CMS–10621).

- QCDR Simplified Self-Nomination and other Requirements (89 FR 62115 and 62116).
- QCDR Full Self-Nomination and other Requirements (89 FR 62116 and 62117).
- Qualified Registry Simplified Self-Nomination and other Requirements (89 FR 62118 and 62119).
- Qualified Registry Full Self-Nomination and other Requirements (89 FR 62119 and 62120).
- Third Party Intermediary Plan Audits (89 FR 62120 through 62122).

(d) Data Considerations for MIPS Submissions

As noted in the CY 2025 PFS proposed rule (89 FR 62111), we incorporated submission data from CY 2022 performance period/2024 MIPS payment year to calculate the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories. The accuracy of our estimates of the total burden for data submission for those performance categories may be impacted by several primary factors. First, we are unable to predict with certainty who will be a Qualifying APM Participant (QP) for the CY 2025 performance period/2027 MIPS payment year. Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2025 performance period/2027 MIPS payment year compared to the CY 2022 performance period/2024 MIPS payment year. Therefore, the actual number of Advanced APM participants and how they elect to submit data may differ from our estimates. However, we believe our estimates are the most appropriate given the available data.

(3) Summary of Quality Payment Program Changes: Advanced APMs

In the CY2025 PFS proposed rule, we proposed updates to the following ICRs for the CY 2025 performance period/2027 MIPS payment year due to the availability of updated data and assumptions that are not associated with policy provisions. These burden updates, as presented in the CY 2025 PFS proposed rule, will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). This includes the following ICRs:

- Partial QP Elections (89 FR 62148).
- Other Payer Advanced APM Determinations: Payer-Initiated Process (89 FR 62149).
- Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process (89 FR 62149 and 62150).
- Submission of Data for QP Determinations under the All-Payer Combination Option (89 FR 62150 and 62151).

(4) Framework for Understanding the Burden of MIPS Data Submission

We refer readers to the CY 2024 PFS final rule (88 FR 79422 through 79424) for a framework on how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. We previously finalized in the CY 2021 PFS final rule (85 FR 84859 through 84866) that the APM Performance Pathway (APP) is available for clinicians who participate in a MIPS APM for both ACO participants and non-ACO participants to submit quality data. Due to data limitations and our inability to determine who will use the APP versus the traditional MIPS submission mechanism for the CY 2025 performance period/2027 MIPS payment year, we continue to assume Shared Savings Program ACO APM Entities will submit quality data through the APP as required. Additionally, we assume MIPS eligible clinicians in non-Shared Savings Program ACO APM Entities will participate through traditional MIPS or MVPs, submitting as an individual or group rather than as an APM Entity. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Accordingly, this burden is not included in Quality Payment Program burden estimates.

In section IV.A.4.c.(2) of this final rule, we are finalizing our proposal to create the APP Plus quality measure set that will allow for alignment of the APP with the Adult Universal Foundation measures. Shared Savings Program ACOs will be required to report the APP Plus quality measure set beginning with the CY 2025 performance period/2027 MIPS payment year. We did not propose to modify the existing APP quality measure set; instead, we are finalizing our proposal to create the APP Plus quality measure set that will be optional for MIPS eligible clinicians, groups, and APM Entities (not including Medicare Shared Savings Program ACOs) meeting the reporting requirements under the APP starting with the CY 2025 performance period/2027 MIPS payment year. However, for Medicare Shared Savings Program ACOs, they will be required to report the APP Plus quality measure set to meet the reporting requirements of the Medicare Shared Savings Program's quality performance standard. As finalized, each MIPS eligible clinician, group, or APM Entity that elects to report the APP may choose to report either the APP quality measure set or the APP Plus quality measure set. MIPS APM participants may also elect to report via traditional MIPS or MVPs.

We are finalizing, with modification, the proposed APP Plus quality measure set, which will include the five quality measures from the APP quality measure set that are also Adult Universal Foundation measures (Quality #001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control; Quality #134: Preventive Care and Screening: Screening for Depression and Follow-up Plan; Quality #236: Controlling High Blood Pressure; Quality #321: CAHPS for MIPS; and Quality #479: Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible MIPS Clinician Groups) as well as Quality #112: Breast Cancer Screening for a total of six measures for the CY 2025 performance period/2027 MIPS payment year. The number of quality measures within the APP Plus quality measure set will incrementally increase each performance period between CY 2026 and CY 2028, as described in section IV.A.4.c.(3) two new quality measures (including Quality #484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions) for the CY 2026 performance period/2028 MIPS payment year; one new quality measure for the CY 2027 performance period/2029 MIPS payment year; and two new quality measures for the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specifications become available for each respective measure, whichever is later.

We refer readers to section IV.A.4.c.(3)(f) of this final rule for additional details. As described in section IV.A.4.e.(1)(b)(i) of this final rule, we are finalizing our proposal to require the reporting of all measures in the APP Plus quality measure set (with the exception of the administrative claims-based quality measures automatically calculated by CMS) for the applicable performance period.

The APP quality measure set for performance year 2024 and subsequent years was finalized in the CY 2024 PFS final rule (88 FR 79112 through 79114) and consists of six measures: two administrative claims measures, the CAHPS for MIPS survey, and three measures that MIPS eligible clinicians, groups, and APM Entities reporting the APP must actively report to CMS via the Medicare CQM (available only to Shared Savings Program ACOs), eCQM, MIPS CQM, or Medicare Part B claims collection types (available only to individual MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs) that are considered small practices), as available per measure. MIPS eligible clinicians, groups, or APM Entities reporting the APP Plus quality measure set will be scored on data submitted via the available collection types described in section IV.A.4.c.(3)(f) of this final rule: six measures for the CY 2025 performance period/2027 MIPS payment year; eight measures for the CY 2026 performance period/2028 MIPS payment year; and nine measures for the CY 2027 performance period/2029 MIPS payment year. Two additional quality measures will be added to the APP Plus quality measure set for the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specifications become available for each respective measure, whichever is later.

The quality performance category burden for MIPS eligible clinicians who elect to report the APP Plus quality measure set varies compared to the APP quality measure set, traditional MIPs, and MVPs. We assume MIPS eligible clinicians incur no burden for reporting the two administrative claims quality measures (Quality #479 and Quality #484) required under the APP quality measure set, as similar to cost measures, we automatically calculate scores from administrative claims reporting. In the APP Plus quality measure set, Quality #479 will be automatically calculated beginning in the CY 2025 performance period/2027 MIPS payment year, and Quality #484 will be automatically calculated beginning in the CY 2026 performance period/2028 MIPS payment year. Additionally, burden estimates for the CAHPS for MIPS registration and beneficiary reporting are provided in the CAHPS for MIPS PRA package under OMB control number 0938–1222 (CMS–10450); we do not assume that MIPS eligible clinicians incur additional reporting burden for reporting this measure under the APP quality measure set, or the APP Plus quality measure set beginning with the CY 2025 MIPS performance period/2027 MIPS payment year. Therefore, we assume that MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set will incur burden for actively submitting their quality performance category data via the available collection types—eCQM and MIPS CQM. MIPS eligible clinicians, groups, and APM Entities reporting the APP, traditional MIPS, and MVPs may incur burden for actively submitting the quality performance category data via the available collection types—eCQM, MIPS CQM, and Medicare Part B Claims. We note these assumptions for actively submitting to assess clinician reporting burden may differ from MIPS scoring policy.

This active submission of quality performance data for the APP Plus quality measure set will include four of the six quality measures for the CY 2025 performance period/2027 MIPS payment year, five of the seven quality measures for the CY 2026 performance period/2028 MIPS payment year, and six of the nine measures for the CY 2027 performance period/2029 MIPS payment year. Once the additional two quality measures are added to the APP Plus quality measure set (for the CY 2028 performance period/2030 MIPS payment year or the performance period that is one year after the eCQM specifications become available for each respective measure, whichever is later), active submission of quality performance data will include eight of the 11 quality measures.

Continuing this burden comparison for MIPS eligible clinicians reporting the APP Plus quality measure set for the CY 2025 performance period/2027 MIPS payment year, clinicians will need to actively submit quality performance category data for two fewer quality measures than clinicians participating in traditional MIPS (six measures), one more quality measure than clinicians participating via the APP (three measures), and the same number of

quality measures as clinicians participating via MVPs (four measures). For the CY 2026 performance period/2028 MIPS payment year, clinicians reporting the APP Plus quality measure set will need to actively submit quality performance category data for one less quality measure than clinicians participating in traditional MIPS (six measures); they will need to report two more quality measures than clinicians participating via the APP (three measures), and one more quality measure than clinicians participating via MVPs (four measures). For the CY 2027 MIPS performance period/2029 MIPS payment per, clinicians reporting the APP Plus quality measure set will need to actively submit quality performance category data for the same number of quality measures as clinicians participating in traditional MIPS (six measures); they will need to report three more quality measures than clinicians participating via the APP (three measures), and two more quality measures than clinicians participating via MVPs (four measures). Once the additional two quality measures are added to the APP Plus measure set, for the CY 2028 performance period/2030 MIPS payment year, or the performance period that is one year after the eCQM specifications become available for each respective measure, whichever is later, clinicians reporting the APP Plus quality measure set will need to actively submit quality performance category data for two more quality measures than clinicians reporting via traditional MIPS (six measures), five more quality measures than clinicians participating via the APP (three measures), and four more measures than clinicians participating via MVPs (four measures). For this comparison of MIPS reporting requirements, we assume that clinicians reporting via traditional MIPS and MVPs will report eCQM, MIPS CQM, and Medicare Part B Claims collection types and will not elect to report the CAHPS for MIPS survey.

As finalized in section III.G.4.b.(2)(a) of this final rule, all Shared Savings Program ACOs will be required to report the APP Plus measure set for the CY 2025 performance period/2027 MIPS payment year. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. As the APP Plus quality measure set is new and optional for individual MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs), we are unable to estimate how many MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs) will submit quality measures via the APP Plus at this time via individual, group, or APM Entity (excluding a Shared Savings Program ACO) reporting. We continue to assume that MIPS eligible clinicians will report MIPS via traditional MIPS or MVPs. We will update these estimates as additional data are available. We refer readers to section VII.E.18.e.(2)(h) of this final rule for additional discussion.

b. ICRs Regarding Survey Vendor Requirements

The following changes (associated with CAHPS survey vendors to submit data for eligible clinicians) will be submitted to OMB for approval under control number 0938–1222 (CMS–10450). We will make the revised files available for public review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices which are expected to publish in the CY 2025 performance period/2027 MIPS payment year.

We refer readers to § 414.1400(d) for the requirements for CMS-approved survey vendors that may submit data on the CAHPS for MIPS Survey.

As discussed in section IV.A.4.j.(1)(b) of this final rule, we are finalizing our proposal that beginning with the CY 2026 performance period/2028 MIPS payment year, a survey vendor must include on its application the range of cost of its third party intermediary services (cost estimates would vary based on the level of services provided). With respect to a third party intermediary that is solely a CMS-approved survey vendor, the publishable costs will be limited to the cost of services related to the CAHPS for MIPS survey. We refer readers to section IV.A.4.j.(1)(b) of this final rule for additional detail on this policy.

In the CY 2025 PFS proposed rule (89 FR 62122 and 62123), we anticipated that the fields for cost information will request cost information that is readily available to survey vendors. Therefore, we did not propose any adjustments in burden because we assumed the additional cost requirement will not add significant burden to the currently approved 10 hour per application burden estimate. We also assumed this change will not affect survey vendor participation. We did not receive any public comment on our proposed burden assumptions and are finalizing as proposed.

This finalized policy will require CMS updates to the CAHPS for MIPS survey vendor application and the CAHPS for MIPS Survey Minimum Business Requirements as a requirement for CAHPS for MIPS survey vendors beginning in the CY 2026 performance year/2028 MIPS payment year. As mentioned, the updated files will be made available for public review through the stand-alone non-rule PRA process.

c. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Changes and Adjustments to Quality Performance Category Respondents

To estimate QPs that are excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot for the 2022 QP Performance period and the QP thresholds applied to the regulatory impact analysis, as detailed in section VII.E.18.a.(1) of this final rule. As presented in the CY 2025 PFS proposed rule (89 FR 62123 through 62126), we used updated submissions data from the CY 2022 performance period/2024 MIPS payment year to estimate the number of respondents that will submit data for the CY 2025 performance period/2027 MIPS payment year. These estimates are for MIPS eligible clinicians for reporting at the individual, group, virtual group, or subgroup level (as applicable for MVP reporting).

We assumed 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional quality reporting for ACO APM entities, consistent with assumptions used in the CY 2021, CY 2022, CY 2023, and CY 2024 PFS final rules (85 FR 84972, 86 FR 65567, 87 FR 70145, and 88 FR 79434, respectively), we included all quality data voluntarily submitted by MIPS APM participants at the individual or TIN-level in our respondent estimates. As stated in section V.B.6.a.(4) of this final rule, we assumed non-Shared Savings Program ACO APM Entities will participate through traditional MIPS or MVPs and submit as an individual or group rather than as an entity. Our burden estimates for the quality performance category did not include the burden for the quality data that Shared Savings Program APM Entities submit to fulfill the requirements of their APMs. The associated burden is excluded from this Collection of Information section of this final rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C.

1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA. The regulatory impact analysis discusses impacts to the Shared Savings Program from provisions finalized in this final rule.

For the CY 2025 performance period/2027 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types. We estimated the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, and eCQMs. We did not estimate burden for administrative claims quality measures; similar to cost measures, we automatically calculate scores for individuals, groups, virtual groups, or APM Entities that meet requirements to be scored on individual measures due to their administrative claims reporting. Additionally, we captured the burden for clinicians who choose to submit via these collection types for the quality performance category of MVPs. Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected and submitted data via multiple collection types during the CY 2022 performance period/2024 MIPS payment year.

There are no changes to the estimated quality performance category submission burden per response due to the policies finalized in section IV.A.4. of this final rule. We discuss in this section these policies and our reasons for not changing the currently approved per response burden for the ICRs related to submitting quality performance category data.

In section IV.A.4.d.(2)(b) of this final rule, we are finalizing our proposal to update § 414.1325(a)(1)(i) to state that a data submission for the quality performance category must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures. Additionally, we are finalizing our proposal to codify our existing policies governing our treatment of multiple data submissions received for the quality performance category at § 414.1325(f)(1) in section IV.A.4.d.(3)(b) of this final rule. We refer readers to these sections for details. The finalized policies intend to eliminate certain issues with the scoring of an unintended data submission affecting MIPS payment adjustments. We do not expect that these policies will affect the number of quality submissions or the time to complete a submission, and there are no changes to our currently approved estimated burden for this ICR.

In section IV.A.4.e.(1)(c)(i) of this final rule, we are finalizing, as proposed, the proposal to maintain the data completeness criteria threshold of at least 75 percent for the CY 2027 and CY 2028 performance periods/2029 and 2030 MIPS payment years. As the data completeness criteria threshold policy extends the data completeness criteria previously established in rulemaking for the CY 2024, CY 2025, and CY 2026 performance periods/2026, 2027, 2028 MIPS payment years (87 FR 70049 through 70052; and 88 FR 79334 through 79337), this policy will not increase burden for the applicable interested parties. We refer readers to section IV.A.4.e.(1)(c)(i) of this final rule for additional information on this policy.

Several factors drove our proposed updates to the number of responses for the Medicare Part B claims data, QCDR and MIPS CQMs, and eCQMs in the CY 2025 PFS proposed rule (89 FR 62123 through 62134). First, we incorporated updated submission data available for the CY 2022 performance period/2024 MIPS payment year as outlined in section V.B.6.c.(1) of this final rule. These changes reflect updated submission counts to traditional MIPS per collection type, which create a new baseline to which we apply our estimates our MVP participation estimates. Second, our updated estimates for MVP participation impact the number of estimated clinicians submitting quality data using each collection type. We adjusted our estimates for the number of participants in previously finalized MVPs to account for both the availability of updated data and updated assumptions for MVP participation (from 14 percent to 6 percent). Changes due to updated data and assumptions are identified as non-policy adjustments. We also updated our estimates to account for our expected increase in MVP participation of 4 percentage points due to the addition of six new MVPs; we associate this incremental effect, all else equal, with policy provisions. With this approach, any increase to our expected MVP participation rate reduces the number of estimated submissions for each quality performance category collection type via traditional MIPS, all else equal. Similarly, any decrease to our estimated MVP participation rate will increase the number of estimated submissions for each quality performance category collection type via traditional MIPS, all else equal.

Medicare Part B claims, MIPS CQM/QCDR, eCQM Collection Type: Individuals. Table 94 of this final rule identifies our methods to estimate the number of MIPS eligible clinicians that will submit data as individual clinicians via each collection type in the CY 2025 performance period/2027 MIPS payment year. We continue our estimates for the total number of clinicians from the CY 2025 PFS proposed rule (89 FR 62125) and have added additional rows to this table to distinguish the impact of policies vs adjustments. We identify estimated individual-clinician submissions per collection type from CY 2022 performance period/2024 MIPS payment year data (row a). We first estimated that 10 percent of clinicians who reported MIPS as individuals in CY 2022 performance period/2024 MIPS payment year may move to MVP reporting for the CY 2025 performance period/2027 MIPS payment year (row b). This 10 percent encompasses our estimate that 6 percent of clinicians will report the MVPs previously finalized in the CY 2024 rulemaking (row c), and that 4 percent of clinicians will submit MVPs due to the six new MVPs finalized in this rule (row d). The basis for these estimates is discussed in section V.B.6.c.(5).(a) of this final rule. The following paragraphs provide our estimates for the number of clinicians submitting traditional MIPS as individuals, per Medicare Part B claims, CQM/QCDR, and eCQM collection types. In this section, we estimate the number of individual and group respondents per collection type. We estimate the impact of the six newly finalized MVPs. We also aggregate the impact of both the updated submission data and our updated assumption that only 6 percent of MIPS submissions from CY 2022 performance period/2024 MIPS payment year will move to MVP submissions due to the MVPs finalized in the CY 2024 PFS final rule (88 FR 79981 through 80047), rather than 14 percent as established in the CY 2024 PFS final rule (88 FR 79443) and applied in our currently approved estimates.

Medicare Part B Claims Collection Type: Individual Clinicians. We estimate that approximately 12,197 clinicians will submit data as individuals using the Medicare Part B claims collection type for the CY 2025 performance period/2027 MIPS

payment year. This estimate of 12,197 clinicians equates to 12,197 respondents, as we assume each clinician per collection type completes one submission. From our currently approved estimate of 13,413 respondents, we estimate that updated submission data and assumptions will result in 674 fewer clinicians reporting traditional MIPS for this collection type. Additionally, we estimate that the six new MVPs finalized in section IV.A.4.a(1) of this final rule will result in 542 fewer clinicians reporting traditional MIPS. Together, we estimate a total decrease of 1,216 individual clinicians reporting this collection type (674 clinicians + 542 clinicians or 13,413 current estimate − 12,197 revised estimate) (see Table 94).

MIPS CQM and QCDR Collection Type: Individual Clinicians: We estimate that approximately 10,850 clinicians will submit data as individuals using the MIPS CQM and QCDR collection types for the CY 2025 performance period/2027 MIPS payment year. This estimate of 10,850 clinicians equates to 10,850 respondents, as we assume each clinician per collection type completes one submission. Our currently approved estimate of 16,632 combined individual, group, and virtual group respondents (reflected in Table 100) for this collection type via traditional MIPS included 10,682 individual submissions. For individual clinician submitters, we estimate that the updated submission data and assumptions will result in an increase of 651 clinicians reporting traditional MIPS as individuals. Additionally, we estimate that the six new MVPs finalized in section IV.A.4.a(1) of this final rule will result in 483 fewer clinicians reporting traditional MIPS as individuals. Together, we estimate a total increase of 168 individual clinicians reporting this collection type (651 clinicians − 483 clinicians or 10,850 revised estimate − 10,682 current estimate) (see Table 94).

eCQM Collection Type: Individual Clinicians: We estimate that approximately 21,240 clinicians will submit data as individuals using the eCQM collection type for the CY 2025 performance period/2027 MIPS payment year. This estimate of 21,240 clinicians equates to 21,240 respondents, as we assume each clinician per collection type completes one submission. Our currently approved estimate of 28,714 combined individual, group, and virtual group respondents (reflected in Table 102) includes 22,897 individual submissions. We estimate that the updated submission data and assumptions will result in 713 fewer clinicians reporting traditional MIPS as individuals. Additionally, we estimate that the six new MVPs finalized in section IV.A.4.a(1) of this final rule will result in 944 fewer clinicians reporting traditional MIPS as individuals. Together, we estimate a total decrease of 1,657 individual clinicians reporting this collection type (713 clinicians + 944 clinicians or 21,240 revised estimate − 22,897 current estimate) (see Table 94).

TABLE 94: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/MIPS CQM	eCQM
2025 MIPS Performance Period (Excludes QPs) Prior to Adjustments (a)	13,552	12,056	23,600
Total Adjustment for MVPs (10%) (b) = (a) × - 0.10 or (c) + (d)	*-1,355*	*-1,206*	*-2,360*
Adjustment for CY 2024 Approved MVPs (6%) (c)= (a) x -0.06	-813	-723	-1,416
Adjustment for MVPs Finalized in the CY 2025 Final Rule (4%) (d) = (b) - (c)	-542	-483	-944
2025 MIPS Performance Period (Excludes QPs and Adjusted for MVPs) (e) = (a) - (b)	12,197	10,850	21,240
Currently Approved 2024 MIPS Performance Period (Excludes QPs) (f)	13,413	10,682	22,897
Difference in Number of Individuals (g) = (e) − (f)	-1,216 clinicians	+168 clinicians	-1,657 clinicians
Change Due to Policies Finalized in the CY 2025 Final Rule (h) = (d)	-542	-483	-944
Change Due to Updated Data Adjustments (i) = (g) – (h)	-674	+651	-713

Medicare Part B claims, MIPS CQM/QCDR, eCQM Collection Type: Groups. Table 95 of this final rule provides our estimates for the number of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2025 performance periods/2027 MIPS payment year. We identify estimated group and virtual group level submissions from CY 2022 performance period/2024 MIPS payment year submissions (row (a)). We assume clinicians who submitted quality data as groups or virtual groups in the CY 2022 performance period/2024 MIPS payment year will continue to submit data for the quality performance category using the same participation and collection types for the CY 2025 performance period/2027 MIPS payment years. We applied the same methodology described in the CY 2022 PFS final rule (86 FR 65577) on our

assumptions related to the use of an alternate collection type for groups that submitted data via the CMS Web Interface collection type for the CY 2022 performance period/2024 MIPS payment year. The following paragraphs provide our estimates for the number of group and virtual group submissions for traditional MIPS, per Medicare Part B claims, MIPS CQM/QCDR, and eCQM collection types. We continue our estimates for the total number of groups from the CY 2025 PFS proposed rule (89 FR 62125 and 62126) and have added additional rows to this table to distinguish the impact of policies vs adjustments, as described under Medicare Part B claims, MIPS CQM/QCDR, eCQM Collection Type: Individuals in section V.B.6.c.(1) of this final rule.

Medicare Part B Claims Collection Type: Groups and Virtual Groups: Not applicable (see Table 95).

QCDR and MIPS CQM Collection Types: Groups and Virtual Groups: We estimate that approximately 6,158 groups and virtual groups will submit data for the MIPS CQM and QCDR collection types for the CY 2025 performance period/2027 MIPS payment year. This estimate of 6,158 groups and virtual groups equates to 6,158 respondents, as we assume each group or virtual group per collection type completes one submission. Our currently approved estimate of 16,632 combined individual, group, and virtual group respondents (reflected in Table 100) includes 5,950 groups and virtual groups. We estimate that the updated submission data and assumptions on reporting will result in 481 more groups and virtual groups reporting traditional MIPS. Additionally, we estimate that the six new MVPs finalized in this rule will result in 273 fewer groups and virtual groups reporting traditional MIPS. Together, we estimate a total increase of 208 groups and virtual groups reporting this collection type (481 groups − 273 groups or 6,158 revised estimate − 5,950 current estimate) (see Table 95).

eCQM Collection Type: Groups and Virtual Groups: We estimate that approximately 5,939 groups and virtual groups will submit data for the eCQM collection type for the CY 2025 performance period/2027 MIPS payment year. This estimate of 5,939 groups and virtual groups equates to 5,939 respondents, as we assume each group or virtual group per collection type completes one submission. Our currently approved estimate of 28,714 combined individual, group, and virtual group respondents (reflected in Table 102) includes 5,817 groups and virtual groups. We estimate that the updated submission data and assumptions will result in 386 more groups and virtual groups reporting traditional MIPS. Additionally, we estimate that the six new MVPs finalized in this rule will result in 264 fewer groups and virtual groups reporting traditional MIPS. Together, we estimate a total increase of 122 groups and virtual groups reporting this collection type (386 groups − 264 groups or 5,939 revised estimate − 5,817 current estimate) (see Table 95).

TABLE 95: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type

Burden and Respondent Description	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM
2025 MIPS Performance Period (Excludes QPs) Prior to Adjustments (a)	n/a	6,842	6,599
Total Adjustment for MVPs (10%) (b) = (a) × -0.10 or (c) + (d)	*n/a*	*-684*	*-660*
Adjustment for CY 2024 Approved MVPs (6%) (c)= (a) × -0.06	n/a	-411	-396
Adjustment for MVPs Finalized in the CY 2025 Final Rule (4%) (d) = (b) – (c)	n/a	-273	-264
2025 MIPS Performance Period (Excludes QPs and Adjusted for MVPs) (e) = (a) – (b)	**n/a**	**6,158**	**5,939**
Currently Approved 2024 MIPS Performance Period (Excludes QPs) (f)	n/a	5,950	5,817
Difference in Number of Groups and Virtual Groups (g) = (e) − (f)	n/a	+208	+122
Change Due to Policies Finalized in the CY 2025 Final Rule (h) = (d)	n/a	-273	-264
Change Due to Updated Data Adjustments (i) = (g) – (h)	**n/a**	**+481**	**+386**

The burden associated with the submission of quality performance category data has some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type.

We also believe that the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third party. As such,

we separately estimate the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we assume that, on average, each clinician, group, third party or subgroup will submit six quality measures to align with the number of required quality measures for which traditional MIPS data must be submitted. See § 414.1315 for definitions for each of these participation and submission types.

As finalized in the CY 2022 PFS final rule (86 FR 65394 through 65397), group tax identification numbers (TINs) could also choose to participate as subgroups for MVP reporting beginning with the CY 2023 performance period/2025 MIPS payment year. We refer readers to the CY 2022 PFS final rule for details on MVP quality reporting requirements (86 FR 65411 through 65412).

We proposed a MIPS quality measure inventory of 196 MIPS quality measures for the CY 2025 performance period/2027 MIPS payment year (89 FR 62042). As shown in Table 96, we are finalizing, with modification, the MIPS quality measure inventory to include 195 MIPS quality measures for the CY 2025 performance period/2027 MIPS payment year.

As discussed in section IV.A.4.e.(1)(d)(iii) of this final rule, we are finalizing, with modification, our proposal to add seven new MIPS quality measures (instead of nine MIPS quality measures as proposed). Also, we are finalizing, with modification, our proposal to remove 10 MIPS quality measures (instead of 11 MIPS quality measures as proposed). This is a net decrease of one MIPS quality measure from the current MIPS quality measure inventory of 197 measures (198 current + 9 new measures − 10 removed measures). Lastly, we are finalizing, as proposed, our proposal to make substantive changes to 66 MIPS quality measures.

We do not anticipate that the provision to remove 10 MIPS quality measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for a minimum of six MIPS quality measures in traditional MIPS reporting or submit quality data for four MIPS quality measures in an MVP. The new MIPS quality measures finalized for inclusion in MIPS for the CY 2025 performance period/2027 MIPS payment year and future years are found in Table Group A of Appendix 1 of this final rule; the MIPS quality measures finalized, with modification, for removal are found in Table Group C of Appendix 1 of this final rule; and the MIPS quality measures with substantive changes are found in Table Group D of Appendix 1 of this final rule.

TABLE 96: Summary of Quality Measure Inventory Finalized for the CY 2025 Performance Period/2027 MIPS Payment Year

Collection Type	# Measures Proposed as New*	# Measures Finalized for Removal*	# Measures Finalized with a Substantive Change*	# Measures Finalized for CY 2025*
Medicare Part B Claims	0	-2	10	25
MIPS CQMs Specifications	+6	-11	60	169
eCQM Specifications	+1	-1	16	47
Survey – CSV	0	0	0	1
Administrative Claims	0	0	1	4
Total*	**+7****	**-10****	**66**	**195*****

*A measure may be specified under multiple collection types but is only counted once in the total.
**Note that one new measure and one measure removal included above were finalized in the CY 2024 PFS final rule with a 1-year delay to the CY 2025 performance period/2027 MIPS payment year.
***Three of the 195 quality measures are only available in MVPs.

(2) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2025 PFS proposed rule (89 FR 62128 through 62130), we proposed updates to the estimated burden for the Quality Data Submission by Individuals and Groups Using Medicare Part B Claims-Based Collection Type. As noted in Table 93 of this final rule, the changes in burden reflect adjustments for updated data and assumptions, and as well as the finalized of six new MVPs as outlined in section IV.A.4.a.(1) of this final rule. We refer readers to sections V.B.6.c.(1) and V.B.6.c.(5).(a) of this final rule for the factors affecting the proposed changes and adjustments for each quality measure collection type. We are finalizing our overall burden estimates as proposed; however, we have provided additional detail on the impact of policy provisions and updated data and adjustments on our burden changes.

We estimated that 12,197 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. From our currently approved estimate of 13,413 clinicians, we estimate that updated data will result in a decrease of 674 respondents, and that the six new MVPs finalized in this rule will result in an additional decrease of 542 respondents (see Table 94). Taken together, we estimate a total decrease of 1,216 respondents (674 clinicians + 542 clinicians or 13,413 current estimate − 12,197 revised estimate). For this collection type, we assume one response (or submission) per respondent per year.

Consistent with our currently approved per response time figures and using the wage rates in Tables 89 and 90 of this final rule, we continue to estimate the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $15.98 (0.15 hr × $106.54/hr) to 7.2 hours at a cost of

$767.09 (7.2 hr × $106.54/hr) for a computer systems analyst.

We believe that the aggregate start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of: 3 hours for a medical and health services manager at $129.28/hr, 1 hour for a computer systems analyst at $106.54/hr, 1 hour for a Licensed Practical Nurse (LPN) at $58.46/hr, 1 hour for a billing and posting clerk at $45.32/hr, and 1 hour for a physician at $291.64/hr. Consequently, we are finalizing our approach to continue our currently approved estimate of time per response.

Considering both data submission and start-up requirements, the estimated time (per clinician using the Medicare Part B claims collection type) ranges from a minimum of 7.15 hours (0.15 hr data submission + 7 hr start up) to a maximum of 14.2 hours (7.2 hr data submission + 7 hr start up) (see Table 97). In aggregate, the estimated total annual time for the CY 2025 performance period/2027 MIPS payment year ranges from 87,209 hours (7.15 hr/response × 12,197 responses) to 173,197 hours (14.2 hr/response × 12,197 responses). The associated total annual cost ranges from a minimum of $11,047,799 (12,197 responses × $905.78/response) to a maximum of $20,209,087 (12,197 responses × $1,656.89/response). These estimates combine changes to the number of responses due to policies finalized in this rule and updated data to our currently approved figures.

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TABLE 97: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
# of Clinicians (a) (equal to number of submissions)	12,197	12,197	12,197
Hours Per Computer Systems Analyst to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) × (h)	**87,209**	**98,186**	**173,197**
Cost to Submit Quality Data (Computer Systems Analyst's Labor Rate of $106.54/hr at varying times) (j)	$15.98	$111.87	$767.09
Cost to Review Measure Specifications (Medical and Health Services Manager's Labor Rate of $129.28/hr for 3 hr) (k)	$387.84	$387.84	$387.84
Cost to Review Measure Specifications (Computer Systems Analyst's Labor Rate of $106.54/hr for 1 hr) (l)	$106.54	$106.54	$106.54
Cost to Review Measure Specifications (LPN's Labor Rate of $58.46/hr for 1 hr) (m)	$58.46	$58.46	$58.46
Cost to Review Measure Specifications (Billing Clerk's Labor Rate of $45.32/hr) (n)	$45.32	$45.32	$45.32
Cost to Review Measure Specifications (Physician's Labor Rate of $291.64/hr) (o)	$291.64	$291.64	$291.64
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$905.78	$1,001.67	$1,656.89
Total Annual Cost (q) = (a) × (p)	**$11,047,799**	**$12,217,369**	**$20,209,087**

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In Table 98, we calculate the net change in estimated burden for quality data submissions from clinicians using the Medicare Part B Claims-based collection type using the burden currently approved under control number 0938–1314 (CMS–10621) and described in the CY 2024 PFS final rule

(88 FR 79438 and 79439). The decrease of 1,216 responses will result in a total maximum change of −17,268 hours at a cost of −$2,014,779 for the CY 2025 performance period/2027 MIPS payment year. For purposes of calculating total burden, only the maximum burden is used. The total time and cost estimate includes the burden associated with this rule's finalized policies provisions and availability of more up-to-date data and assumptions. In Table 128 (section VII.E.18.e.(1) of this final rule), we identify the estimated change in burden due to policies finalized in this rule.

TABLE 98: Change in Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	190,465
Total Annual Hours for Respondents in CY 2025 PFS Final Rule (b) (see Table 97, row (i))	173,197
Difference in Annual Hours (c) = (b) − (a)	**-17,268**
Total Currently Approved Annual Cost (d)	$22,223,866
Total Annual Cost for Respondents in CY 2025 PFS Final Rule (e) (see Table 97, row (q))	$20,209,087
Difference in Annual Cost (f) = (e) − (f)	**-$2,014,779**
Total Currently Approved Annual Responses (g)	13,413
Total Annual Responses in CY 2025 PFS Final Rule (h) (see Table 97, row (a))	12,197
Difference in Total Annual Responses (i) = (h) – (g)	**-1,216**

We did not receive any comments on our proposed requirements and burden estimates for the estimated burden on the requirements for the Medicare Part B Claims Collection Type. We are finalizing our burden estimates as proposed.

(3) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2025 PFS proposed rule (89 FR 62130 through 62132), we proposed to update burden for the Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types. As noted in Table 93 of this final rule, the change in burden reflects adjustments for updated data and assumptions, as well as finalizing our proposal for additional MVPs outlined in section IV.A.4.a(1) of this final rule. We refer readers to sections V.B.6.c.(1) and V.B.6.c.(5).(a) of this final rule for the factors affecting the proposed changes and adjustments for each quality measure collection type. We are finalizing our overall burden estimates as proposed; however, we have provided additional detail on the impact of policy provisions and updated data and adjustments on our burden changes.

As noted in Tables 94 and 95, we estimate that 17,008 clinicians (10,850 individuals and 6,158 groups and virtual groups) will submit quality data as individuals or groups using MIPS CQM or QCDR collection types for the CY 2025 performance period/2027 MIPS payment year. We estimate that updated data will result in an increase in 1,132 respondents (651 individuals and 481 groups), and that the six new MVPs finalized in this final rule will result in a decrease of 756 respondents (−483 individuals and −273 groups). In aggregate, this is an increase of 376 respondents from the currently approved estimate of 16,632 under control number 0938–1314 (CMS–10621) and provided in the CY 2024 PFS final rule (88 FR 79439 through 79441). Given the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group. For this collection type, we assume one response (or submission) per respondent per year.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third party intermediary to submit the data to us on the clinician's or group's behalf. We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both collection types together. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe the burden for an individual clinician or group to review measure specifications and submit quality data is a total of 9 hours at a cost of $1,088.98 per response. This consists of 3 hours at $106.54/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $129.28/hr for a medical and health services manager, 1 hour at $106.54/hr for a computer systems analyst, 1 hour at $58.46/hr for a LPN, 1 hour at $45.32/

hr for a billing clerk, and 1 hour at $291.64/hr for a physician to review measure specifications.

Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hr) at $106.54/hr for a computer systems analyst at a cost of $8.84 (0.083 hr × $106.54/hr).

Overall, we estimate 9.083 hr/response at a cost of $1,088.98/response (see Table 99). In aggregate, we estimate a burden of 154,484 hours (9.083 hr/response × 17,008 responses) at a cost of $18,521,372 for the CY 2025 performance period/2027 MIPS payment year (17,008 responses × $1,088.98/response). These estimates combine burden changes due to policies finalized in this rule and updated data.

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TABLE 99: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of Clinicians Submitting as Individuals (a)	10,850
# of Groups Submitting via QCDR or MIPS CQM on Behalf of Individual Clinicians (b)	6,158
Total # of Respondents (c) = (a) + (b) (Equal to Total Number of Responses)	**17,008**
# of Hours Per Respondent to Report Quality Data (d)	3
# of Hours per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours for Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours for LPN to Review Measure Specifications (g)	1
# of Hours for Billing Clerk to Review Measure Specifications (h)	1
# of Hours for Physician to Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c)×(k)	**154,484**
Cost Per Respondent to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (m) = $106.54/hr × (d)	$319.62
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (n) = $129.28/hr × (e)	$258.56
Cost per Computer System's Analyst Review of Measure Specifications (at Computer Systems Analyst's Labor Rate of $106.54/hr) (o) = $106.54/hr × (f)	$106.54
Cost per LPN to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (p) = $58.46/hr × (g)	$58.46
Cost per Billing Clerk to Review Measure Specifications at Clerk's Labor Rate of $45.32/hr) (q) = $45.32/hr × (h)	$45.32
Cost for Physician to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (r) = $291.64/hr × (i)	$291.64
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (at Computer Systems Analyst's Labor Rate of $106.54/hr) (s) = $106.54/hr × (j)	$8.84
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$1,088.98
Total Annual Cost (u) = (c) × (t)	**$18,521,372**

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In Table 100, we calculated the net change in estimated burden for quality performance category submissions using the MIPS CQM and QCDR collection type by using the currently approved burden described in the CY 2024 PFS final rule (88 FR 79439 through 79441) and approved under control number 0938–1314 (CMS–10621). In aggregate, using the unchanged currently approved time per response estimate, the overall increase of 376 respondents from 16,632 to 17,008 for the CY 2025 performance period/2027 MIPS payment year results in an increase of 3,416 hours at a cost of +$409,457. The total time and cost estimate includes the burden associated with this rule's finalized policies provisions and availability of more up-to-date data and assumptions. In Table 128 and section VII.E.18.e.(1) of this final rule, we identify the changes in burden to this ICR due to policy provisions.

TABLE 100: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	151,068
Total Annual Hours for Respondents in CY 2025 PFS Final Rule (b) (see Table 99, row (l))	154,484
Difference in Annual Hours (c) = (b) − (a)	**+3,416**
Total Currently Approved Annual Cost (d)	$18,111,915
Total Annual Cost for Respondents in CY 2025 PFS Final Rule (e) (see Table 99, row (u))	$18,521,372
Difference in Annual Cost (f) = (e) − (d)	**+$409,457**
Total Currently Approved Annual Responses (g)	16,632
Total Annual Responses in CY 2025 PFS Final Rule (h) (see Table 99, row (c))	17,008
Difference in Total Annual Responses (i) = (h) − (g)	**+376**

We did not receive any comments on our proposed requirements and burden estimates for the estimated burden on the requirements for MIPS CQM and QCDR collection types. We are finalizing our burden estimates as proposed.

(4) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). These changes reflect the impact of the six MVPs finalized in section IV.A.4.a(1) of this final rule and the availability of more up-to-date data and assumptions.

In the CY 2025 PFS proposed rule (89 FR 62132 and 62133), we proposed to update the number of currently approved respondents for the eCQM Collection Type. As noted in Table 93 of this final rule, this change in burden reflects adjustments for updated data and assumptions, as well as the finalizing our proposal for additional MVPs as outlined in section IV.A.4.a(1) of this final rule. We refer readers to sections V.B.6.c.(1) and V.B.6.c.(5).(a) of this final rule for the factors affecting the proposed changes and adjustments for each quality measure collection type. We are finalizing our overall burden estimates as proposed; however, we have provided additional detail on the impact of policy provisions and updated data and adjustments on our burden changes.

We estimated that 27,179 clinicians (21,240 individual clinicians and 5,939 groups) will submit quality data using the eCQM collection type for the CY 2025 performance period/2027 MIPS payment year. As identified in Tables 94 and 95, we estimate that updated data will result in a decrease of 327 respondents (−713 individuals and +386 groups), and that the new MVPs will result in a decrease of 1,208 respondents (−944 individuals and −264 groups). Taken together, this is a decrease of 1,535 respondents from the currently approved estimate of 28,714 under control number 0938–1314 and described in the CY 2024 PFS final rule (88 FR 78818). We assume clinicians incur the same burden whether participating in MIPS as an individual or group. For this collection type, we assume one response (or submission) per respondent per year.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third party intermediary to derive data from their certified electronic health record technology (CEHRT) and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a QCDR or qualified registry to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry. We note that the CY 2024 PFS final rule eliminated the category of health IT vendors for the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment year (88 FR 79390 and 79391).

We estimated that it will take no more than 2 hours at $106.54/hr for a computer systems analyst or their equivalent to submit the data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimated it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimated 2 hours at $129.28/hr for a medical and health services manager, 1 hour at $291.64/hr for a physician, 1 hour at $106.54/hr for a computer systems analyst, 1 hour at $58.46/hr for an LPN, and 1 hour at $45.32/hr for a billing clerk. Overall, we estimated a cost of $973.60/response (see Table 101). For the CY 2025 performance period/2027 MIPS payment year, in aggregate, we estimate a burden of 217,432 hours (8 hr × 27,179 responses) at a cost of $26,461,474 (27,179 responses × $973.60/response). These estimates combine burden changes due to policies finalized in this rule and updated data.

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TABLE 101: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of Clinicians Submitting as Individuals (a)	21,240
# of Groups Submitting via EHR on Behalf of Individual Clinicians (b)	5,939
Total # of Respondents (c)=(a)+(b) (Equal to Number of Responses)	**27,179**
# of Hours Per Respondent to Submit MIPS Quality Data File (d)	2
# of Hours Per Medical and Health Services Manager to Review Measure Specifications (e)	2
# of Hours Per Computer Systems Analyst to Review Measure Specifications (f)	1
# of Hours Per LPN to Review Measure Specifications (g)	1
# of Hours Per Billing Clerk to Review Measure Specifications (h)	1
# of Hours Per Physician to Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) × (j)	**217,432**
Cost Per Respondent to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (l) = $106.54/hr × (d)	$213.08
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (m) = $129.28/hr × (e)	$258.56
Cost to Review Measure Specifications (at Computer System's Analyst's Labor Rate of $106.54/hr) (n) = $106.54/hr × (f)	$106.54
Cost to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (o) = $58.46/hr × (g)	$58.46
Cost to Review Measure Specifications (at Clerk's Labor Rate of $45.32/hr) (p) = $45.32/hr) × (h)	$45.32
Cost to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (q) = $291.64/hr × (i)	$291.64
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$973.60
Total Annual Cost (s) = (c) × (r)	**$26,461,474**

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In Table 102, we illustrate the net change in burden for submissions in the quality performance category using the eCQM collection type from the currently approved burden in the CY 2024 PFS final rule (88 FR 79441 and 79442). In aggregate, using our currently approved time per response burden estimate, the decrease of 1,535 respondents from 28,714 to 27,179 for the CY 2025 performance period/2027 MIPS payment year results in a decrease of 12,280 hours (1,535 responses × 8 hr/response) at a cost of −$1,494,476 (−1,535 responses × $973.60/response). The total time and cost estimate includes the burden associated with this rule's finalized policies provisions and availability of more up-to-date data and assumptions. In Table 128 and section VII.E.18.e.(1) of this final rule, we identify the changes in burden to this ICR due to policy provisions.

TABLE 102: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	229,712
Total Annual Hours for Respondents in CY 2025 PFS Final Rule (b) (see Table 101, row (k))	217,432
Difference in Annual Hours (c) = (b) − (a)	**-12,280**
Total Currently Approved Annual Cost (d)	$27,955,950
Total Annual Cost for Respondents in CY 2025 PFS Final Rule (e) (see Table 101, row (s))	$26,461,474
Difference in Annual Cost (f) = (e) − (d)	**-$1,494,476**
Total Currently Annual Approved Responses (g)	28,714
Total Annual Responses in CY 2025 PFS Final Rule (h) (see Table 101, row (c))	27,179
Difference in Annual Responses (i) = (h) − (g)	**-1,535**

We did not receive any comments on our burden estimates for the eCQM collection type. We are finalizing our burden estimates as proposed.

(5) ICRs Regarding Burden for MVP Reporting

The following changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We are finalizing our overall burden estimates as proposed; however, we have provided additional detail on the impact of policy provisions and updated data and adjustments on our burden changes.

(a) Burden for MVP Reporting Requirements

In the CY 2022 PFS final rule, we finalized an option for clinicians choosing to report MVPs to participate through subgroups beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We refer readers to the CY 2022, CY 2023, and CY 2024 PFS final rules for our previously finalized burden assumptions and requirements for submission data for the MVP performance category, and for the estimated number of clinicians participating as subgroups in the CY 2024 performance period/2026 MIPS payment year (86 FR 65590 through 65592, 87 FR 70155, and 88 FR 79443).

Advanced Primary Care Management (APCM) payment finalized in section II.G.2.b. of this final rule incorporates several specific, existing care management and communication technology-based services into a bundle and includes performance measurement requirements that, for MIPS eligible clinicians, could be met by reporting the Value in Primary Care MVP beginning in the CY 2025 performance period/2027 MIPS payment year. Billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) will not have to report the MVP in order to furnish and bill for APCM services. Billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) will not have to report the MVP in order to furnish and bill for APCM services. We estimate MVP reporting as a percentage of previous traditional MIPS quality submissions, as outlined in section V.B.6.c.(5).(a) of this final rule. In line with this approach, we are unable to determine how many additional clinicians or practices will report the Value in Primary Care MVP above our current MVP submission estimates due to the finalized APCM requirements. Similarly, we cannot assess what participation levels clinicians or practices who may use these APCM codes have reported MIPS in the past (for example, eligibility requirements and special statuses, participation at the individual, group, virtual group, or APM Entity level, or reporting via traditional MIPS, the APP, or MVPs), or if they will be MIPS eligible clinicians in future years. We refer readers to section II.G.2.b. of this final rule for details on this policy, and section VII.E.18.e.(2)(f) for additional discussion on burden impacts to the Quality Payment Program.

In the CY 2024 PFS final rule (88 FR 79442), we calculated the average quality measure submission rate for each newly finalized MVP for the CY 2024 performance period/2026 MIPS payment year. For this analysis, we assessed measures submissions in the CY 2021 performance period/2023 MIPS payment year for clinicians with relevant clinical specialties for each proposed MVP. The total of these average quality measure submissions for each MVP was equivalent to about 2 percent of total quality measure submissions in the CY 2021 performance period/2023 MIPS payment year. We added this incremental increase of 2 percentage points to the previously approved estimate in the CY 2023 PFS final rule that 12 percent of clinicians who participated in MIPS for the CY 2021 performance period/2023 MIPS payment year will submit data for the quality performance category through MVP reporting in the CY 2023 performance period/2025 MIPS payment year (88 FR 79443).

In the CY 2025 PFS proposed rule (89 FR 62134 and 62135), we conducted the analysis identified in the preceding paragraph for the 16 MVPs approved for the CY 2024 performance period/2026 MIPS payment year (88 FR 79978 through 80047) using updated submission data available for the CY 2022 performance period/2024 MIPs payment year. The total of these average quality measure submissions for each approved MVP was equivalent to 6 percent of the total quality measure submissions in the CY 2022 performance period/2024 MIPS payment year. This is a decrease from the 14 percent estimate provided in the CY 2024 PFS final rule (88 FR 79443).

As detailed in section IV.A.4.a(3) of this final rule, we are finalizing modifications to 16 MVPs approved for the CY 2024 performance period/2026 MIPS payment year reporting with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). We are also finalizing our proposals to consolidate the previously finalized Optimal Care for Patients with Episodic Neurological Conditions MVP and Supportive Care

for Neurodegenerative Conditions MVP into a consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions, and to add six new MVPs to the MVP inventory.

For each new MVP finalized in this rule, we similarly calculated the average quality measure submission rate across the measures available in each MVP for the CY 2022 performance period/2024 MIPS payment year (89 FR 62134 and 62135). The total of these average quality measure submissions for each MVP was equivalent to about 4 percent of total quality measure submissions. We assumed the consolidation of the measures in the Optimal Care for Patients with Episodic Neurological Conditions MVP and Supportive Care for Neurodegenerative Conditions MVP into the Quality Care for Patients with Neurological Conditions MVP will not affect the number of MVP submissions. We assumed clinicians who may have submitted the Optimal Care for Patients with Episodic Neurological Conditions MVP or the Supportive Care for Neurodegenerative Conditions MVP will instead submit the Quality Care for Patients with Neurological Conditions MVP. Therefore, we estimated the changes to the MVP inventory in this final rule will result in an additional 4 percent of MIPS clinicians moving from traditional MIPS to MVP reporting.

We estimated that a total of 10 percent of the clinicians will participate in MVP reporting in the CY 2025 performance period/2027 MIPS payment year. This estimate takes together the aforementioned analyses where we assessed the MVP participation rate for the 16 established MVPs at 6 percent using updated quality measure submission data from the CY 2022 performance period/2024 MIPS payment year, and where we assessed that 4 percent of MIPS clinicians may move to the 6 proposed MVPs due to quality measure submission trends for the CY 2022 performance period/2024 MIPS payment year. This is a decrease of 4 percentage points from the currently approved estimate of 14 percent in the CY 2024 PFS final rule (88 FR 79443) and currently approved under control number 0938–1314 (CMS–10621).

Continuing our approach from the CY 2022, CY 2023, and CY 2024 PFS final rules (86 FR 65589 and 65590, 87 FR 70155 and 701566, and 88 FR 79443 and 79444, respectively), we assume that the number of MVP registrations will equal our estimated MVP quality submissions.

(i) Burden for MVP Registration: Individuals, Groups, and Subgroups

In the CY 2022 PFS final rule (86 FR 65417), we finalized at § 414.1365(b)(2)(i) that MVP Participants are required to select one population health measure at the time of MVP registration. Since the MVP population health measures are administrative claims-based, they do not require data submission from clinicians and do not contribute to reporting burden. In section IV.A.4.b.(1) of this final rule, we are finalizing our proposal to update the registration process and scoring policies for population health measures. These changes include revising § 414.1365(d)(3)(i)(A) to state that we would use the highest score of all available population health measures beginning in the CY 2025 performance period/2027 MIPS payment year. We refer readers to section IV.A.4.b.(1) of this rulemaking for details on this policy and scoring implications. This policy will remove the requirement for MVP Participants to select a population health measure during MVP registration, which is currently completed via a drop-down selection. We assume the associated reduction in burden per application will be minimal. Therefore, we did not adjust the burden per MVP registration from the currently approved registration time of 15 minutes (0.25 hr) under CMS–10621 (OMB 0938–1314) (88 FR 79443 and 79444).

In the CY 2025 PFS proposed rule (89 FR 62134 through 62136), we estimated that approximately 10 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. For the CY 2025 performance period/2027 MIPS payment year, we assumed that the total number of individual clinicians, groups, and subgroups that will complete the MVP registration process is 6,285 (4,921 individuals (Table 94, sum of row b), 1,344 groups (Table 95, sum of row b), and 20 subgroups (as currently approved under control number 0938–1314)). We estimate that the six new MVPs finalized in this rule will result in an increase of 2,506 MVP registrants (1,969 individuals (Table 94, sum of row (d) and 537 groups (Table 95, sum of row (d)). We estimate that updated data and assumptions will result in a decrease of 5,806 respondents. Taken together, this is a decrease of 3,300 respondents from the currently approved estimate of 9,585 under control number 0938–1314 and described in the CY 2024 PFS final rule (88 FR 79443 and 79444). In Table 103, we estimate that it will take 1,571 hours (6,285 responses × 0.25 hr/response) at a cost of $167,432 (6,285 registrations × $26.64/registration) for individual clinicians, groups, and subgroups to register for MVP reporting in the CY 2025 performance period/2027 MIPS payment year. For this collection type, we assume one response (or submission) per respondent per year. There are no changes to the estimated submission burden per response due to the policies finalized in section IV.A.4. of this final rule.

TABLE 103: Estimated Burden for MVP Registration (Individuals, Groups, and Subgroups)

Burden and Respondent Descriptions	Burden Estimate
Estimated # of Individual Clinicians, Groups, Subgroups and APM Entities Registering (a) (Equal to Number of Responses)	6,285
Estimated Time Per Registration (hr) (b)	0.25
Estimated Total Annual Time for MVP Registration (c) = (a) × (b)	**1,571**
Computer Systems Analyst's Labor Rate (d)	$106.54/hr
Estimated Cost Per Registration (e) = (d) × (b)	$26.64
Estimated Total Annual Cost for MVP Registration (f) = (a) × (e)	**$167,432**

In Table 104, we illustrate the net change in estimated burden for MVP registration using the currently approved burden. The change in responses will result in a decrease of 825 hours (−3,300 responses × 0.25 hr/

response) at a cost of −$87,912 (−3,300 responses × $26.64/response). The total time and cost estimate includes the burden associated with this rule's finalized policies provisions and availability of more up-to-date data and assumptions. In Table 128 and section VII.E.18.e.(1) of this final rule, we identify the changes in burden to this ICR due to policy provisions.

TABLE 104: Change in Estimated Burden for MVP Registration (Individuals, Groups, Subgroups, and APM Entities)

Burden and Respondent Descriptions	Burden Estimate
Total Currently Approved Annual Hours (a)	2,396
Total Annual Hours for Respondents in CY 2025 PFS Final Rule (b) (See Table 103, row (c))	1,571
Difference in Annual Hours (c) = (b) – (a)	**-825**
Total Currently Approved Annual Cost (d)	$255,344
Total Annual Cost for Respondents in CY 2025 PFS Final Rule (e) (See Table 103, row (e))	$167,432
Difference in Annual Cost (f) = (e) − (d)	**-$87,912**
Total Currently Approved Annual Responses (g)	9,585
Total Annual Responses in CY 2025 PFS Final Rule (h) (See Table 103, row (a))	6,285
Difference in Annual Responses (i) = (h) – (g)	**-3,300**

We did not receive any comments on our proposed requirements and burden estimates for the estimated burden on the requirements for MVP registration. We are finalizing our burden estimates as proposed.

(ii) Burden for Subgroup Registration

We did not propose any revised burden for subgroup registration for the CY 2025 performance period/2027 MIPS payment year. As identified in section V.B.6.a.(2)(b) of this final rule, we note that the subgroup policies do not impact the currently approved burden for subgroup registration. As discussed later in this section, we discuss the policies and our reasons for not changing the currently approved burden for subgroup registration. The burden relevant to the subgroup registration requirement is currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes pertaining to subgroup registration under that control number.

As outlined in section IV.A.4.b.(1) of this final rule, we are finalizing our proposal to remove the selection of a population health measure at the time of registration. As detailed in section V.B.6.c.(5).(a) of this final rule, we believe this modification will not significantly impact the currently approved burden for MVP registration. We continued this assumption to subgroup registration. We did not propose any adjustments to our previously finalized estimate in the CY 2022 PFS final rule (86 FR 65590) that 20 subgroups will participate in MVP reporting per year.

We previously finalized a mandatory subgroup reporting requirement for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). In CY 2025 PFS proposed rule, we sought feedback back via Request for Information (RFI on what guidance/parameters are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided. Absent available submission data on MVP reporting with the available CY 2022 performance period/2024 MIPS payment year data, we were unable to estimate the effect of this established policy on reporting for the CY 2026 performance period/2028 MIPS payment year at this time. Data for MVP and subgroup submissions will be available in the CY 2023 performance period/2025 MIPS payment year data that will be available for the CY 2026 rulemaking cycle. We refer readers to section VII.E.18.e.(2)(g) of this final rule for additional discussion on burden impacts of this established policy to the Quality Payment Program.

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2022 PFS final rule (86 FR 65411 through 65415), we finalized the reporting requirements for the MVP quality performance category at § 414.1365(c)(1)(i).

In sections IV.A.4.d.(2)(b) and IV.A.4.d.(3)(b) of this final rule, we are finalizing our proposals to adopt minimum criteria for a qualifying data submission for a MIPS performance period for the quality performance category and to codify our existing policies governing our treatment of multiple submissions received for the quality performance category. In accordance with our discussion of this policy relevant to traditional MIPS quality reporting in section V.B.6.c.(1) of this final rule, these policies will not introduce new requirements to submit data for the quality performance category of MVPs. Therefore, we will continue our currently approved per response time estimates for submitting the MVP quality performance category data per collection type.

In the CY 2025 PFS proposed rule (89 FR 62136 through 62139), we estimated that 10 percent of the clinicians who submitted MIPS quality performance data in the CY 2022 performance period/2024 MIPS payment year will submit data for the quality performance category through an MVP in the CY 2025 performance period/2027 MIPS payment year. We also estimated there will be 20 subgroup reporters in the CY 2025 performance period/2027 MIPS payment year, split across the eCQM and CQM collection types. In the following paragraphs, we detail the estimated changes from our currently approved estimates. For each collection type, we assume one response (or submission) per respondent per year. We are finalizing our overall burden

estimates as proposed; however, we have provided additional detail on the impact of policy provisions and updated data and adjustments on our burden changes.

We estimated 3,030 respondents for the eCQM collection type (see Table 105, line c). From our currently approved estimate of 4,684 respondents, we estimate that the six new MVPs finalized in this rule will result in approximately 1,208 respondents moving from traditional MIPS to MVPs (944 for individuals + 264 for groups; see Tables 94 and 95, row (d)). We also estimate that updated data and assumptions discussed in sections V.B.6.c.(1) and V.B.6.c.(5).(a). of this final rule will result in a decrease of 2,862 respondents. Taken together, we estimate a net decrease of 1,654 respondents.

We estimated 1,900 respondents for the MIPS CQM and QCDR collection types (see Table 105, line c). From our currently approved estimate of 2,717 respondents, we estimate that the six new MVPs finalized in this rule will result in approximately 756 respondents moving from traditional MIPS to MVPs (483 for individuals + 273 for groups; see Tables 94 and 95, row (d)). We also estimate that updated data and assumptions discussed in sections V.B.6.c.(1) and V.B.6.c.(5).(a). of this final rule will result in a decrease of 1,573 respondents. Taken together, we estimate a net decrease of 817 respondents.

We estimated 1,355 respondents for the Medicare Part B collection type (see Table 105, line c). From our currently approved estimate of 2,184 respondents, we estimate that the six new MVPs finalized in this rule will result in approximately 542 individual respondents moving from traditional MIPS to MVPs (see Table 94, row (d)). We also estimate that updated data and assumptions discussed in sections V.B.6.c.(1) and V.B.6.c.(5).(a). of this final rule will result in a decrease of 1,371 respondents. Taken together, we estimate a net decrease of 829 respondents.

For the CY 2025 performance period/2027 MIPS payment year, using our currently approved per response time estimates for the clinicians and subgroups submitting data for the MVP quality performance category, we estimated a burden of 16,059 hours [5.3 hr × 3,030 (3,020 +10) responses] at a cost of $1,954,138 (3,030 responses × $644.93/response) for the eCQM collection type, 11,343 hours [5.97 hr × 1,900 (1,890 +10 responses)] at a cost of $1,360,989 (1,900 responses × $716.31/response) for the MIPS CQM and QCDR collection type, and 12,791 hours (9.44 hr × 1,355 responses) at a cost of $1,492,180 (1,355 responses × $1,101.24/response) for the Medicare Part B claims collection type.

TABLE 105: Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	MIPS CQM and QCDR Collection Type	Medicare Part B Claims Collection Type
# of Submissions from Pre-existing collection types (a)	3,020	1,890	1,355
# of Subgroup Reporters (b)	10	10	0
Total MVP Participants (c) = (a) + (b) (Equal to Number of Responses)	**3,030**	**1,900**	**1,355**
Hours Per Computer Systems Analyst to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) × (j)	**16,059**	**11,343**	**12,791**
Cost to Submit Quality Data (at Computer Systems Analyst's Labor Rate of $106.54/hr) (l) = $106.54/hr × (d) varying times	$141.70	$213.08	$511.39
Cost to Review Measure Specifications (at Medical and Health Services Manager's Labor Rate of $129.28/hr) (m) = $129.28/hr × (e) varying times	$171.94	$171.94	$258.56

Burden and Respondent Descriptions	eCQM Collection Type	MIPS CQM and QCDR Collection Type	Medicare Part B Claims Collection Type
Cost to Review Measure Specifications (at Computer Systems Analyst's Labor Rate of $106.54/hr) (n) = $106.54/hr × (f)	$70.32	$70.32	$70.32
Cost to Review Measure Specifications (at LPN's Labor Rate of $58.46/hr) (o) = $58.46/hr × (g)	$38.58	$38.58	$38.58
Cost to Review Measure Specifications (at Billing Clerk's Labor Rate of $45.32/hr) (p) = $45.32/hr × (h)	$29.91	$29.91	$29.91
Cost to Review Measure Specifications (at Physician's Labor Rate of $291.64/hr) (q) = $291.64/hr × (i)	$192.48	$192.48	$192.48
Total Annual Cost Per Submission (r) = (l) + (m) + (n) + (o) + (p) + (q)	$644.93	$716.31	$1,101.24
Total Cost (s) = (c) × (r)	**$1,954,138**	**$1,360,989**	**$1,492,180**

Table 106 illustrates the changes in estimated burden for clinicians who will submit the MVP quality performance category utilizing the eCQM, MIPS CQM and QCDR, and Medicare Part B claims collection types in the CY 2025 performance period/2027 MIPS payment year. We used the currently approved burden under control number 0938–1314 (CMS–10621), as described in the CY 2024 PFS final rule (88 FR 79444 through 79446) as the baseline to determine the net change in burden. In aggregate, when combined with our currently approved per response time estimate, the decrease in 3,300 respondents who will submit data for the MVP quality performance category will result in a change of -8,766 hours and -$1,066,714 for the eCQM collection type, -4,877 hours and -$585,225 for the CQM and QCDR collection type, and -7,826 hours and -$912,928 for the Medicare Part B claims collection type. The total time and cost estimate increase combines the burden associated with this rule's policy change along with the changes associated with having more up-to-date data and assumptions. In Table 128 (section VII.E.18.e.(1) of this final rule), we identify the changes in burden to this ICR due to policy provisions.

TABLE 106: Change in Estimated Burden for MVP Quality Performance Category Submission

Burden and Respondent Descriptions	eCQM Collection Type	MIPS CQM and QCDR Collection Type	Medicare Part B Claims Collection Type
Total Currently Approved Annual Hours (a)	24,825	16,220	20,617
Total Annual Hours for Respondents in CY 2025 PFS Final Rule (b) (See Table 105, row (k))	16,059	11,343	12,791
Difference in Annual Hours (c) = (b) − (a)	**-8,766**	**-4,877**	**-7,826**
Total Currently Approved Annual Cost (d)	$3,020,852	$1,946,214	$2,405,108
Total Annual Cost for Respondents in CY 2025 PFS Final Rule (e) (See Table 105, row (s))	$1,954,138	$1,360,989	$1,492,180
Difference in Annual Cost (f) = (e) − (d)	**-$1,066,714**	**-$585,225**	**-$912,928**
Total Currently Approved Annual Responses (g)	4,684	2,717	2,184
Total Annual Responses in CY 2025 PFS Final Rule (h) (See Table 105, row (c))	3,030	1,900	1,355
Difference in Annual Responses (i) = (h) – (g)	**-1,654**	**-817**	**-829**

d. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

We refer readers to CY 2025 PFS proposed rule (89 FR 62140) for requirements for details and assumptions on the methods by which MIPS eligible clinicians, groups, subgroups, and APM Entities can submit Promoting Interoperability performance category data.

(2) Reweighting Applications for MIPS Performance Categories

In the CY 2025 PFS proposed rule (89 FR 62140 through 62142), we proposed to update our currently approved burden estimates due to updated reweighting application data for the CY 2024 performance period/2024 MIPS payment year. We proposed to revise the number of responses due to this update data. These adjustments will be submitted to OMB for approval under control number 0938–1314 (CMS–10621) via the standard non-rule PRA process. We are not setting out such burden in this collection of information section since the change is unrelated to policies finalized in this final rule. In the following paragraphs, we outline these policies and our rationale for not changing the currently approved burden for reweighting applications due to these policies.

As detailed in section IV.A.4.i.(2) of this final rule, we are finalizing our proposal to adopt a new reweighting performance category(ies) policy at § 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*) for occurrences where we determine that a third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. We believe these occurrences will be rare based on our experience with related requests for reweighting, and the extent and source of documentation provided to us for each event may vary considerably. Therefore, we did not propose any changes to our currently approved burden estimates. We refer readers to section VII.E.18.e.(2)(e) of this final rule for additional discussion on these burden assumptions.

We did not receive any comments on our assumptions for reweighting applications for MIPS Performance Categories. We are finalizing our changes as proposed.

(3) Submitting Promoting Interoperability Data

We did not propose to update our currently approved burden for submitting Promoting Interoperability data as a result of policies finalized in section IV.A.(4) of this final rule. In the following paragraphs, we outline these policies and our rationale for not changing the currently approved burden for submitting Promoting Interoperability data due to these policies. Independent of policies finalized in this final rule, we proposed to update our currently approved burden estimates due to the availability of updated submission data for the CY 2022 performance period/2024 MIPS payment year, which reflect updated estimates for the number of respondents. These adjustments, detailed in the CY 2025 proposed rule (89 FR 62142 through 62145), will be submitted to OMB for approval under control number 0938–1314 (CMS–10621) via the standard non-rule PRA process. We are not setting out such burden in this collection of information section since the change is unrelated to the provisions that are being finalized in this rule.

We refer readers to § 414.1375 for our previously established policies regarding reporting for the Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and § 414.1380(b)(4) for Promoting Interoperability performance category scoring. We refer readers to § 414.1380(c)(2)(i)(C) for our previously finalized policies regarding scoring of data submission in the Promoting Interoperability performance category after an approved reweighting for the performance category.

In section IV.A.4.d.(2)(d) of this final rule, we are finalizing our proposal to adopt minimum criteria for a qualifying data submission for the Promoting Interoperability performance category at § 414.1325(a)(1)(iii). This policy will clarify what counts as a data submission for MIPS eligible clinicians and it would potentially avoid partial data submissions from overriding an approved reweighting or a previously scored submission for the Promoting Interoperability performance category. As described in section IV.A.4.d.(2)(d), we did not revise existing scoring or reweighting policies described under § 414.1380; therefore, we did not adjust our currently approved per response time estimate.

In section IV.A.4.d.(3)(c) of this final rule, we are finalizing our proposal to modify our policy governing our treatment of multiple data submissions received for the Promoting Interoperability performance category. Specifically, we are finalizing our proposal that, in cases where we receive multiple submissions for the Promoting Interoperability performance category, we will calculate a score for each data submission received and assign the highest of the scores. In our analysis of the information collection and reporting burden, we did not adjust our estimated number of respondents submitting Promoting Interoperability data. These policies intend to reduce certain issues with the scoring of unintended data submissions affecting MIPS payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. Our currently approved per response estimate incorporates our historical approach to estimate the required measures and attestations and other required data elements identified in sections IV.A.4.d.(2)(d) and IV.A.4.d.(3)(c) of this final rule.

In the CY 2022 PFS final rule (86 FR 65413 and 65414), we finalized the Promoting Interoperability performance category's reporting requirements for a subgroup participating in MVP reporting at § 414.1365(c)(4)(i)(A). In section IV.A.4.b.(4) of this final rule, we are finalizing our proposal to modify § 414.1365(c)(4)(i)(A) to allow a subgroup to submit the affiliated group's data for the MVP Promoting Interoperability performance category for the CY 2025 performance period/2027 MIPS payment year and beyond. As this policy will not create new reporting requirements, there are no burden implications.

The Department of Health and Human Services (HHS) final rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the Disincentives final rule) was released on June 24, 2024 (89 FR 54662). Section IV.A.4.e.(4)(d) of this final rule summarizes several policies in the Disincentives final rule under which a MIPS eligible clinician that the Office of Inspector General determines has committed information blocking will not be a meaningful EHR user, and therefore will be unable to earn a score (instead earning a score of zero) for the Promoting Interoperability performance category. The Disincentives final rule described in section IV.A.4.e.(4)(d) of this final rule will not create any additional reporting, recordkeeping, or third party disclosure requirements (89 FR 54715) or burden. Consequently, we did not propose any burden updates for the Quality Payment Program.

In the CY 2025 PFS proposed rule (89 FR 8757 and 8758), we noted the CMS Interoperability and Prior Authorization

final rule (89 FR 8758). In the CMS Interoperability and Prior Authorization final rule, we finalized the addition of the ''Electronic Prior Authorization'' measure, under the Health Information Exchange (HIE) objective for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8909 through 8927). The burden estimate for MIPS clinicians to report the ''Electronic Prior Authorization measure'' was provided in the CMS Interoperability and Prior Authorization final rule (89 FR 8953 through 8956). In the CMS Interoperability and Prior Authorization final rule, we identified that this measure will be included in a PRA package related to the CMS Interoperability and Prior Authorization final rule (89 FR 8946). Consequently, we did not propose any burden updates in the CY 2025 PFS proposed rule.

We did not receive any comments on our proposed assumptions for the submission of Promoting Interoperability data. We are finalizing our provisions as proposed.

e. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We did not propose to update our currently approved burden for improvement activities submissions as a result of policy provisions finalized in section IV.A.4.e.(3) of this final rule. In the following paragraphs, we outline these policies and our rationale for not changing our currently approved burden due to these policies. Separate from policy provisions finalized in this rule, we proposed to update our currently approved burden estimates due to the availability of updated submission data for the CY 2022 performance period/2024 MIPS payment year, which reflect updated estimates for the number of respondents. These adjustments, detailed in the CY 2025 PFS proposed rule (89 FR 62145 through 62147), will be submitted to OMB for approval under control number 0938–1314 (CMS–10621) via the standard non-rule PRA process. We are not setting out such burden in this collection of information section since the change is unrelated to the provisions that are being finalized in this rule.

As detailed in section IV.A.4.e.(3)(b)(iv) of this final rule, we are finalizing as proposed two scoring and reporting policy changes for the improvement activities performance category beginning in the CY 2025 performance period/2027 MIPS payment year. First, we are finalizing our proposal to eliminate the weighting of improvement activities established in the CY 2017 Quality Payment Program final rule (81 FR 28210) and codified at § 414.1380(b)(3) (81 FR 77177 and 77178). Second, we are finalizing our proposal to further simplify improvement activity reporting requirements by reducing the number of activities to which clinicians are required to attest in order to achieve a score for the improvement activities performance category. We are finalizing our proposal that MIPS eligible clinicians who participate in traditional MIPS will be required to report two activities and MVP Participants will be required to report one activity to achieve 40 points, or full credit. In addition, we are finalizing our proposal that MIPS eligible clinicians who are categorized as small practice, rural, in a provider-shortage area, or non-patient facing will be required to report one activity (for either traditional MIPS or MVPs). We refer readers to section IV.A.4.e.(3)(b)(iv) of this final rule for details on these policies.

In the CY 2019 PFS final rule (83 FR 60016), we established our currently approved estimate that it takes five minutes for a computer analyst to log in and manually attest that improvement activities were completed. We believe the removal of weighting for improvement activities will decrease burden for MIPS eligible clinicians who previously reported medium-weighted activities. As MIPS eligible clinicians who previously only reported high-weighted activities will have the same attestation burden under this proposal, we did not propose a change to our currently estimated per response burden. We refer readers to section VII.E.18.e.(2)(c) of this final rule where we outline our burden impact analysis for this policy.

In section IV.A.4.e.(3)(b)(iii) of this final rule, we are finalizing our proposed changes to the improvement activities inventory for the CY 2025 performance period/2027 MIPS payment year and future years: adding two new improvement activities; modifying one existing improvement activity; and removing four previously adopted improvement activities. We are also finalizing, with modification, our proposed changes to the improvement activities inventory for the CY 2026 performance period/2028 MIPS payment year: removing four improvement activities; and modifying one improvement activity. In the CY 2023 PFS final rule (87 FR 70211) and the 2024 PFS final rule (88 FR 79519), we anticipated that most clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). We believe these changes will not significantly affect burden because the majority of activities are not revised. We refer readers to section VII.E.18.e.(2)(b) of this final rule where we outline our burden impact analysis.

In section IV.A.4.d.(2)(c) of this final rule, we are finalizing our proposal to adopt minimum criteria for a qualifying data submission for a performance period for the improvement activities performance category. We are finalizing our proposal to specify that a data submission for the improvement activities performance category must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory. Additionally, we are finalizing our proposal to codify existing policies governing multiple data submissions received for the improvement activities performance category at § 414.1325(f)(1) in section IV.A.4.d.(3)(b). We assume these policies will not affect the number of improvement activities submissions, as the intent is to eliminate certain issues with the scoring of an unintended data submission affecting payment adjustments for individual MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. Therefore, we did not propose any updates to our currently approved estimated burden due to these policies.

We did not receive any comments on our proposed requirements and assumptions for the submission of improvement activities. We are finalizing our burden estimates due to updated data as proposed.

f. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the following finalized policies in section IV.A.4.e.(2) of this final rule will not result in the need to add or revise or delete any claims data fields: (1) add six new episode-based measures; (2) modify two existing episode-based measures; (3) update the operational list of care episode and patient condition groups and codes to

reflect new and modified measures; (4) and adopt criteria to specify objective bases for the removal of any cost measures from the MIPS cost performance category. Consequently, we did not propose any changes under the aforementioned control number.

C. Summary of Annual Burden Estimates

Table 107 sets out the burden for this rulemaking's finalized provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the provisions.

TABLE 107: Annual Requirements and Burden Estimates

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1325, 414.1335, 414.1365 Quality Payment Program	0938-1314 (CMS-10621)	41,195 Clinicians 10,765 Group TINs 20 Subgroups 6 Virtual Groups Total: 51,986	68,954	Varies	586,877	Varies	70,166,672
§§ 427.402(c)(4) and (5), 428.302(c)(4) and (5), and 428.303(c)(4) and (5) (Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act)	0938-1474 (CMS-10858)	20	20	31	620	Varies	74,756
TOTAL		**57,267**	**(35,337)**	**Varies**	**(77,746)**	**Varies**	**(8,926,078)**

VI. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we finalized payment and policy changes under the Medicare PFS and changes to implement amendments made under the section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024). Our policies in this rulemaking specifically address: changes to the PFS; and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; updates and refinements to Medicare Shared Savings Program (Shared Savings Program) requirements; updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biologicals products paid under Medicare Part B, changes to the Clinical Laboratory Fee Schedule requirements, other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers, the Medicare coverage of opioid use disorder services furnished by opioid treatment programs and coverage and payment for certain preventive services; updates to electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan (section 2003 of the SUPPORT Act); and changes to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Clinical Laboratory Fee Schedule (CLFS)—Revisions Consistent With Recent Statutory Changes

As discussed in section III.D. of this final rule, we proposed conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (Pub. L. 118–22) (FCAOEA, 2024). For clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), section 502(b) of the FCAOEA, 2024 delayed the next data reporting period by one year. Instead of taking place from January 1, 2024, through March 31, 2024, the FCAOEA, 2024 stated that data reporting would take place from January 1, 2025, through March 31, 2025, based on the original data collection period of January 1, 2019, through June 30, 2019. Additionally, section 502(a) of the FCAOEA, 2024 amended the statutory provisions for the phase-in of payment reductions resulting from private payor rate implementation to specify that the applicable percent for CY 2024 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2024 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2023. Section 502(a) of the FCAOEA, 2024 further amended the statutory phase-in provisions to provide that for CYs 2025 through 2027, the payment amount for a CDLT may not be reduced by more than 15 percent as compared to the payment amount for that test established in the preceding year. After the publication of the CY 2025 PFS proposed rule and the close of the comment period, however, the data reporting period and phase in reductions were further delayed. On September 26, 2024, section 221 of the Continuing Appropriations and Extensions Act, 2025 (Pub. L. 118–83) was passed and delayed data reporting requirements for CDLTs that are not ADLTs, as well as the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. Specifically, as amended by section

221(b), section 1834A(1)(B) of the Act now provides that, in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that: (i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2025; (ii) reporting is required during the period beginning January 1, 2026, and ending March 31, 2026; and (iii) reporting is required every 3 years after the period described in subparagraph (ii). Essentially, data reporting will now be required during the period of January 1, 2026, through March 31, 2026, instead of January 1, 2025, through March 31, 2025. The 3-year data reporting cycle for CDLTs that are not ADLTs will resume after that data reporting period.

Section 221 of the Continuing Appropriations and Extensions Act, 2025 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2026, through March 31, 2026) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019.

Section 221(a) of the Continuing Appropriations and Extensions Act, 2025 further amends provisions in section 1834A(b)(3) of the Act pertaining to the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2028. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2025 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2025 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2024. Finally, section 221(a) further amends section 1834A(b)(3)(B)(iii) of the Act to specify that the applicable percent of 15 percent will apply for CYs 2026 through 2028.

b. Medicare Prescription Drug Inflation Rebate Program

Section III.I. of this rule finalizes regulations to implement provisions of the Inflation Reduction Act (IRA) that establish the Medicare Prescription Drug Inflation Rebate Program. Section 11101 of the IRA adds new section 1847A(i) to the Act, which establishes a requirement for manufacturers to pay Medicare Part B rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation, beginning on January 1, 2023. Section 11102 of the IRA adds new section 1860D–14B to the Act, which established a requirement for manufacturers to pay Medicare Part D rebates for certain Part D drugs and biological products with prices that increase faster than the rate of inflation, beginning on October 1, 2022.

c. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

In section III.L. of this rulemaking, we finalized two changes to the electronic prescribing for controlled substances (EPCS) requirement specified in § 423.160(a)(5) (referred to as the CMS EPCS Program). In section III.L. of this final rule, we finalized revisions to § 423.160(a)(5) to specify that prescriptions written for a beneficiary in a long-term care (LTC) facility will not be included in determining CMS EPCS Program compliance until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility will commence on or after January 1, 2028.

d. Quality Payment Program

This final rule is also necessary to make changes to the Quality Payment Program to move the program forward to focus more on measurement efforts, refine how clinicians would be able to participate in a more meaningful way through the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), and highlight the value of participating in Advanced Alternative Payment Models (APMs). Authorized by MACRA, the Quality Payment Program is an incentive program that includes two participation tracks, MIPS and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. Currently, reporting for traditional MIPS is seen as siloed across the performance categories. These policy proposals are intended to promote better quality reporting to improve patient health outcomes by coordinating reporting for MIPS across performance categories and make changes to scoring that would provide a better picture of clinicians' performance.

2. Discretionary Provisions

a. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this final rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we are finalizing a clarification on how we will identify certain drugs that are excluded from the definition of refundable drug for those which payment has been made under Part B for fewer than 18 months; how we identify drugs from a single-dose container; and the requirement to use the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts during the preparation process before supplying the drug to the patient. We also discuss an application received for increased applicable percentage.

In section III.A.2 of this final rule, we finalized how payment limits will be calculated when manufacturers report negative or zero ASP data to CMS. Generally, we finalized that negative and zero ASP data be considered ''not available'' under section 1847A(c)(5)(B) of the Act and that positive ASP data be considered available. In circumstances in which negative or zero ASP data is reported for some, but not all National Drug Codes (NDCs) associated with a billing and payment code for a drug, we are finalizing to calculate the payment limit using only NDCs with positive ASP data. In certain circumstances, we are finalizing to carryover the most recent positive ASP data for the drug to calculate a payment limit when the manufacturer's ASP is negative or zero. For biosimilars with negative or zero ASP data for all NDCs, we are finalizing to use positive ASP data from the most recent available positive manufacturer's ASP data from a previous quarter.

In section III.A.3. of this final rule, we finalized a clarification to how Medicare Administrative Contractors (MACs) pay for radiopharmaceuticals that are furnished in the physician's office. We are finalizing to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or

prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

In section III.A.4. of this final rule, we finalized policies to reduce barriers faced by beneficiaries receiving immunosuppressive drugs under the Medicare Part B immunosuppressive drug benefit. That is, we finalized at § 410.30 to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs that have approved immunosuppressive indications or FDA-approved drugs that have been determined by a MAC to be reasonable and necessary for a specific purpose in immunosuppressive treatment included in the immunosuppressive drug benefit. In addition, we are finalizing changes regarding supplying fees and refills for immunosuppressive drugs. These proposals include allowing payment of a supply fee for a prescription of a supply of up to 90 days and allowing prescriptions for immunosuppressive drugs to be refillable.

In section III.A.5. of this final rule, we are finalizing to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. We are also clarifying in § 410.63(b) that therapies that enable the body to produce clotting factor and do not directly integrate into the coagulation cascade are not themselves clotting factors for which the furnishing fee applies. Additionally, we are finalizing to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS. That is, we are finalizing to clarify through revisions to § 410.63 that clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products.

b. RHCs and FQHCs

In section III.B.2. of this final rule, we are finalizing several changes to the furnishing of care coordination services in RHCs and FQHCs. We are finalizing with a modification that starting in 2025, RHCs and FQHCs will report the individual CPT and HCPCS codes that describe care coordination services instead of the single HCPCS code G0511. We are also allowing for a delayed compliance of 6 months until July 1, 2025, to enable RHCs and FQHCs to be able to update their billing systems. We are also finalizing to permit billing of the add-on codes associated with these services. In addition, beginning in CY 2025, we are finalizing to adopt the coding and policies regarding Advanced Primary Care Management (APCM) services, as discussed in section II.G of this final rule.

For all of the care coordination services, we are finalizing to allow separate payment at the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services. Payment rates will be updated annually. We also solicited comment on how we can improve the transparency and predictability regarding which HCPCS codes are considered care coordination services to automate processes downstream for RHCs and FQHCs and plan to evaluate the comments received for potential future rulemaking.

In section III.B.3. of this final rule, we are finalizing the policy to continue to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2025, for RHCs and FQHCs. We are also finalizing, on a temporary basis, to allow payment for medical care non-behavioral health visits furnished via telecommunication technology in a manner that is similar to the payment mechanisms mandated by statute through December 31, 2024, RHCs and FQHCs will continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2025. In addition, we are finalizing our policy to continue to delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026.

In section III.B.4. of this final rule, we are finalizing a payment rate for IOP services in RHCs and FQHCs when there are 4 or more services per day in the RHC and FQHC setting.

In section III.B.5. of this rulemaking, we are finalizing our proposal to allow RHCs and FQHCs to bill for Part B preventive vaccines and the administration at the time of service. Therefore, payments for RHC and FQHC vaccine claims will be made according to Part B preventive vaccine payment rates in other settings, to be annually reconciled with the facilities' actual vaccine costs on their cost reports. Due to the operational systems changes needed to facilitate payment through claims, we explain that RHCs and FQHCs can begin billing for preventive vaccines and their administration at the time of service effective for dates of service on or after July 1, 2025.

In section III.B.6. of this final rule, we are finalizing our proposal to remove productivity standards for RHCs effective for cost reporting periods beginning on or after January 1, 2025.

In section III.B.7. of this final rule, we are finalizing to rebase the FQHC PPS market basket from a 2017 base year to a 2022 base year. We are finalizing the use of the 2022-based FQHC market basket update effective for annual payment updates to the FQHC PPS base rate effective beginning with CY 2025.

In section III.B.8. of this final rule, we clarified that when RHCs and FQHCs furnish dental services that align with the inextricably linked policies and operational requirements in the physician setting, we will consider those services to be a qualifying visit and the RHC will be paid at the RHC AIR and the FQHC will be paid under the FQHC PPS.

c. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In section III.F.2 of this final rule, we finalized telecommunication flexibilities related to periodic assessments and initiation of treatment with methadone. We finalized to allow periodic assessments to be furnished via audio-only communications when two-way audio-video communications technology is not available to the beneficiary on a permanent basis, to the extent that this flexibility is authorized by SAMHSA and DEA at the time the service is furnished, and all other applicable requirements are met. We believe that making this current flexibility permanent is appropriate, as it will allow a beneficiary to decide with their provider the best modality for receiving care, and evidence has shown that audio-only visits produce many of the same benefits as video-based visits.[896] Additionally, permanently extending the flexibility to allow periodic assessments to be furnished via audio-only communications will further contribute towards health equity, especially among Medicare beneficiaries who are from underserved

[896] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9446840.*

populations.[897] We also are finalizing to allow OTPs to use audio-visual telecommunications for initiation of treatment with methadone for any new patient who will be treated by the OTP with methadone if the OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. We will allow the OTP intake add-on code (HCPCS code G2076) to be paid for two-way audio-video communications technology when it is billed for the initiation of treatment with methadone to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished, and all other applicable requirements are met. We believe this flexibility is needed to align with new policy amendments finalized by SAMHSA for initiation of treatment with methadone at § 8.12(f)(2)(v)(A), and it will help reduce barriers for many individuals beginning treatment with methadone who often experience at least one barrier to accessing treatment (for example, reliable transportation, work schedule conflicts, distance to treatment, etc.).[898]

In section III.F.3 of this final rule, we are finalizing several payment updates to the Medicare OTP benefit in response to recent regulatory reforms finalized by SAMHSA at 42 CFR part 8 that aim to recognize more patient-centered and evidence-based paradigms of care for OUD treatment (for example, harm reduction interventions, recovery support services, etc.). Specifically, we are finalizing our proposal to update the payment for intake activities (HCPCS code G2076) to include payment for social determinants of health risk assessments (HCPCS code G0136) in order to adequately reflect additional effort for OTPs to identify a patient's unmet health-related social needs (HRSNs), or the need and interest for harm reduction interventions and recovery support services that are critical to the treatment of an OUD. These will be consistent with new revisions to standards for initial assessment service activities required by SAMHSA under § 8.12(f)(4)(i). In addition, CMS is also finalizing an update in payment for periodic assessments (HCPCS code G2077) to include payment for social determinants of health risk assessments (HCPCS code G0136) after being persuaded by comments in response to the proposed rule. This update would reflect additional reassessments of unmet HRSNs, and harm reduction intervention and recovery support service needs that OTPs may need to conduct throughout the duration of MOUD treatment. We believe these refinements are necessary to help OTPs address key issues during initial and periodic assessments that may increase the risk of a patient leaving OUD treatment prematurely or that pose as barriers to treatment engagement. For example, patients with an OUD are more likely to have lower educational attainment, be food insecure, encounter financial hardship, and housing instability, and they often report financial and logistical barriers (for example, lack of access to transportation) as reasons for not receiving treatment.[899] In the proposed rule, CMS included a request for information to understand how OTPs currently coordinate care and make referrals to community-based organizations (CBOs) that address unmet HRSNs, provide harm reduction services, and/or offer recovery support services. Providers (including SUD treatment facilities) who coordinate care with CBOs, including peer support organizations, housing agencies, and educational and employment agencies, to address unmet HRSNs (for example, housing, transportation, etc.) identified during assessments can positively influence health outcomes and better support a patient's engagement in SUD treatment.[900] In response to the proposed rule, commenters highlighted these coordinated care and referral activities are routinely provided at OTPs and integral to MOUD treatment and recovery. Accordingly, CMS finalized to create new add-on codes to describe coordinated care and referral services (G0534), patient navigational services (G0535), and peer recovery support services (G0536) that can be billed in addition to the bundled payments under the OTP benefit. Payment for these services would reflect additional efforts required by OTPs to link patients with adequate community resources to address unmet health-related social needs, including harm reduction interventions and recovery support services a patient needs and wishes to pursue, along with services to assist Medicare beneficiaries with an OUD in navigating multiple settings of care and achieving patient-driven treatment and recovery goals.

Furthermore, in section III.F.4 of this final rule, we finalized to establish payment for new opioid agonist and antagonist medications that were recently approved by the FDA. We will create a new add-on code (HCPCS code G0532) to the bundled payment to reflect take-home supplies for nalmefene hydrochloride (nalmefene) nasal spray, which is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids. The add-on code will include payment for a carton of two 2.7 mg nasal sprays of nalmefene and overdose education furnished in conjunction with distributing nalmefene. We also are finalizing payment for a new extended-release injectable buprenorphine product (Brixadi®), indicated to treat moderate to severe OUD and that comes in a weekly (8 mg, 16 mg, 24 mg, 32 mg) and monthly formulation (64 mg, 96 mg, and 128 mg). We will create a new weekly bundled payment code (including both a non-drug and drug component) for weekly injectable buprenorphine to reflect the weekly formulation of Brixadi® described by HCPCS code G0533. In addition, we will update payment for the drug component of the existing bundled payment under the Medicare OTP benefit for monthly injectable buprenorphine (HCPCS G2069) in order to reflect payment for the monthly formulation of Brixadi®. We believe these proposals are consistent with our statutory authority under sections 1861(jjj)(1)(A) and 1834(w) of the Act, which allow the Secretary to establish Medicare bundled payment for opioid agonist and antagonist treatment medications that are approved by the FDA. These proposals will expand access to new opioid agonist and antagonist medications that are important to help prevent additional opioid overdose deaths, reduce illicit opioid use, and retain more individuals with an OUD in treatment.[901]

Lastly, in section III.F.5 of this final rule, we clarified a billing requirement that an OUD diagnosis code is required on claims submitted under the Medicare OTP benefit for OUD treatment services. This clarification is needed to ensure payments made to OTPs are in

[897] *https://pubmed.ncbi.nlm.nih.gov/33471458/; https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/; https://pubmed.ncbi.nlm.nih.gov/34534186/.*

[898] *https://ascpjournal.biomedcentral.com/articles/10.1186/s13722-022-00316-3.*

[899] *https://www.sciencedirect.com/science/article/pii/S1544319123000560?via%3Dihub. https://www.sciencedirect.com/science/article/pii/S0749379722001040?via%3Dihub.*

[900] *https://www.commonwealthfund.org/sites/default/files/202209/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf; https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf.*

[901] *https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf; https://pubmed.ncbi.nlm.nih.gov/24247147/.*

alignment with statutory requirements under sections 1861(s)(2)(HH), 1861(jjj)(1), and 1834(w) of the Act, which all specify that services paid to OTPs under Medicare Part B must be for the treatment of opioid use disorder.

d. Medicare Shared Savings Program

In section III.G. of this final rule, we are finalizing modifications to the Shared Savings Program to further advance Medicare's value-based care strategy of growth, alignment, and equity, and to allow for timely improvements to program policies and operations.

The changes to the Shared Savings Program include the following:

Changes to the quality performance standard and other quality reporting requirements, including to (1) require Shared Savings Program ACOs to report the APP Plus quality measure set that will incrementally grow to comprise of 11 measures, consisting of the 6 measures in the existing APP quality measure set and 5 new measures from the Adult Universal Foundation measure set that will be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028 or the performance year that is one year after eCQM specifications become available for Quality ID: 487 Screening for Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later, (2) focus the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set to all payer/all patient eCQMs and Medicare CQMs by performance year 2027 and include MIPS CQMs for performance years 2025 and 2026, before they are removed in performance year 2027, to provide ACOs with more time before the sunsetting of this collection type given that ACOs may have already contracted with vendors for this collection type, (3) require Shared Savings Program ACOs that report the APP Plus quality measure set to report on all measures in the APP Plus quality measure set, as applicable, (4) establish a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs, (5) score Medicare CQMs using flat benchmarks in their first 2 performance periods in MIPS, and (6) extend the eCQM reporting incentive in order to promote the adoption of eCQMs and also extend the reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026 to support ACOs in meeting the Shared Savings Program quality performance standard.

Changes to establish a new ''prepaid shared savings'' option for eligible ACOs with a history of earning shared savings, to assist these ACOs with cash flow and encourage investments that will aid beneficiaries such as investments in direct beneficiary services, staffing, and healthcare infrastructure, and refinements to recently-established advance investment policies.

Modifications to the Shared Savings Program's financial methodology including to (1) ensure the benchmarking methodology includes sufficient incentive for ACOs serving underserved communities to enter and remain in the program through the application of a health equity benchmark adjustment, (2) specify a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a), (3) establish a methodology for excluding payment amounts for HCPCS and CPT codes exhibiting significant, anomalous, and highly suspect (SAHS) billing activity during CY 2024 or subsequent calendar years that warrant adjustment, and (4) make technical changes in provisions of the Shared Savings Program regulations on financial calculations, to align and clarify the language used to describe weights applied to the growth in ACO and regional risk scores for each Medicare enrollment type, as part of the calculation for capping ACO and regional risk score growth, respectively.

Changes to other programmatic areas, including: to sunset a requirement under which CMS would be required to terminate an ACO's participation agreement, under certain circumstances, if it failed to maintain at least 5,000 assigned beneficiaries during an agreement period in connection with the Shared Savings Program compliance requirements; updates to provisions of the Shared Savings Program regulations on application procedures to reflect the latest approach Antitrust Agencies use to evaluate ACOs and enforce the antitrust laws; updates to the beneficiary assignment methodology including to (1) revise the definition of primary care services to align with payment policy changes and include, among other services for the purposes of beneficiary assignment, Safety Planning Interventions, Post-Discharge Telephonic Follow-up Contacts Intervention, Virtual Check-in Service, Advanced Primary Care Management Services, Cardiovascular Risk Assessment and Risk Management Services, Interprofessional Consultation Service, Direct Care Caregiver Training Services, and Individual Behavior Management/Modification Caregiver Training Services, and (2) broaden the existing exception to the program's voluntary alignment policy to allow for beneficiaries to be claims-based assigned to entities participating in certain disease- or condition-specific CMS Innovation Center ACO models; notwithstanding their voluntary alignment to a Shared Savings Program ACO; and modifications to the beneficiary information notification requirements.

e. Medicare Part B Payment for Preventive Services

Section III.H.1 of this final rule outlines the implementation of policies that impact the payment amount for administration of preventive vaccines paid under the Part B vaccine benefit, as well COVID–19 monoclonal antibodies and the in-home additional payment for Part B vaccine administration. These provisions are necessary to provide stable payment for preventive vaccine administration and related policies, and to allow predictability for providers and suppliers to rely on for building and sustaining robust vaccination programs.

Section III.H.2 of this final rule addresses two items related to payment for hepatitis B vaccine administration under Part B. In section III.M. of this rule, we are finalizing an expansion of hepatitis B vaccine coverage by revising existing regulations. In this section of the rule, we clarify that a physician's order is no longer required for the administration of a hepatitis B vaccine in Part B, which will facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We are also finalizing a policy to set payment for hepatitis B vaccines and their administration at 100 percent of reasonable cost in RHCs and FQHCs, separate from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, to streamline payment for all Part B vaccines in those settings.

In section III.H.3. of this final rule, we are finalizing a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS), per section 1833(a)(1)(W)(ii) of the Act. We will determine payment limits for DCAPS drugs based on the ASP payment methodology set forth under section 1847A of the Act if possible, and we provide alternative payment mechanisms for calculating payment limits for DCAPS drugs if ASP data is not available. We are also finalizing payment limits for supplying and administration fees for DCAPS drugs

that are similar to those fees for drugs paid under the ASP payment methodology set forth under section 1847A of the Act. Finally, we will determine payment limits for DCAPS drugs in RHCs and FQHCs, and any supply and administration fee, using this same fee schedule, and we will pay for DCAPS drugs and their administration on a claim-by-claim basis.

f. Modifications to Coverage of Colorectal Cancer Screening

In section III.K. of this rulemaking, we are finalizing regulatory changes, as proposed, that update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure in regulations at § 410.37, (2) adding coverage for the computed tomography colonography (CTC) procedure in regulations at § 410.37, and (3) expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) returns a positive result. The U.S. Centers for Disease Control and Prevention (CDC) describes CRC as ''a disease in which cells in the colon or rectum grow out of control. Sometimes abnormal growths, called polyps, form in the colon or rectum. Over time, some polyps may turn into cancer. Screening tests can find polyps so they can be removed before turning into cancer. Screening also helps find colorectal cancer at an early stage, when treatment works best.'' [902] The National Cancer Institute reports that CRC is the fourth most common type of cancer and estimates that the United States experienced 153,020 new cases and 52,550 new deaths from CRC in 2023. In addition, the rate of new cases and new deaths from CRC is higher in men than women and significantly greater for those of African American and Non-Hispanic American Indian/Alaska Native descent compared to all races.[903] See the impact analysis later in this section at VII.E.14.

g. Expand Hepatitis B Vaccine Coverage

In section III.M. of this rulemaking, we are finalizing our proposal to expand Hepatitis B vaccine coverage by revising our regulatory definition for intermediate risk groups by adding a new paragraph to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown (§ 410.63(a)(2)). Hepatitis B is a vaccine-preventable liver disease caused by the hepatitis B virus.[904] The vaccine consists of a series of typically 2–3 doses delivered at various intervals.[905] Hepatitis B virus is transmitted when body fluid (blood, semen, or other) from a person infected with the virus enters the body of someone who is uninfected.[906] This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; transmission from the gestational parent to baby during pregnancy or at birth; direct contact with blood or open sores; or sharing contaminated items such as toothbrushes, razors or medical equipment (such as a glucose monitor) of a person who has hepatitis B.[907] Hepatitis B can be an acute, short-term illness and it can develop into a long-term, chronic infection. Chronic hepatitis B can lead to serious health problems, including cirrhosis, liver cancer, and death. Treatments for hepatitis B are available but no cure exists. There are currently an estimated 2.4 million individuals in the U.S. living with hepatitis B virus and an estimated 20,000 new infections every year.[908] We believe our proposal will help protect Medicare beneficiaries from acquiring hepatitis B infection, contribute to eliminating viral hepatitis as a public health threat in the United States and is in the best interest of the Medicare program and its beneficiaries. We are finalizing our proposals to expand access to the hepatitis B vaccine. Please see section III.M. of this final rule for additional discussion on the policy and regulatory changes and see section VII.E.16, below to read the impact analysis related to this provision.

h. Medicare Parts A and B Overpayment Provisions of the Affordable Care Act ((§§ 401.305(a)(2), 401.305(b)(1), (2), and (3))

Section W of the December 2022 Overpayments Proposed Rule proposed amendments to § 401.305(a)(2) to change the standard for an ''identified overpayment'' for Medicare Parts A and B and adopt by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). We do not have a basis for estimating the impact associated with this amendment. We solicited comment on the analysis and conclusions provided in the RIA.

Section III.O. of this final rule discusses existing § 401.305(b)(1), which specifies when a person who has received an overpayment must report and return an overpayment. We proposed to amend this regulation to reference revised § 401.305(b)(2) and new § 401.305(b)(3). We proposed a technical modification to the introductory language in § 401.305(b)(2) to acknowledge that this paragraph might be applicable after the suspension described in new § 401.305(b)(3) is complete. New § 401.305(b)(3) identifies circumstances under which the deadline for reporting and returning overpayments will be suspended to allow time for providers to investigate and calculate overpayments. We do not have a basis for estimating the impact associated with this amendment. We solicited comment on the analysis and conclusions provided in the RIA.

We did not receive public comments on the provisions, and therefore, we are finalizing as proposed.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993), Executive Order 13563, Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132, Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

[902] CDC website: *https://www.cdc.gov/colorectal-cancer/about/?CDC_AAref_Val=https://www.cdc.gov/cancer/colorectal/basic_info/what-is-colorectal-cancer.htm.*

[903] NCI website: *https://seer.cancer.gov/statfacts/html/colorect.html.*

[904] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[905] CDC. Clinical overview of Hepatitis B. Atlanta, GA: U.S. HHS, CDC; 2024. Retrieved from *https://www.cdc.gov/hepatitis-b/hcp/clinical-overview/?CDC_AAref_Val=https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.*

[906] CDC, 2023. Hepatitis B surveillance 2021. Retrieved from *https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-b.htm.*

[907] CDC. 2024. Hepatitis B basics. Retrieved from *https://www.cdc.gov/hepatitis-b/about/?CDC_AAref_Val=https://www.cdc.gov/hepatitis/hbv/bfaq.htm.*

[908] Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and testing for hepatitis B virus infection: CDC recommendations—United States, 2023. *MMWR Recomm Rep.* 2023;72(1):1–25. Retrieved from *https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm.*

environmental, public health and safety effects, distributive impacts, and equity).

A regulatory impact analysis (RIA) must be prepared regulatory action that are significant under section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on State, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2024 with payment rates for CY 2025 using CY 2023 Medicare utilization. The payment impacts described in this rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS). The PFS update adjustment factor for CY 2025, as specified in section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the estimated CY 2025 PFS conversion factor (CF), we took the CY 2024 conversion factor without the payment increase of 1.25 percent provided by the CAA, 2023 that applied to services furnished from January 1, 2024 through March 8, 2024, and the 2.93 percent payment increase provided by the CAA, 2024 that replaced the previous 1.25 percent increase and applies to services furnished from March 9, 2024 through December 31, 2024 and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs. We estimate the CY 2025 PFS CF to be 32.3465 which reflects a 0.02 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the removal of the temporary 2.93 percent payment

increase for services furnished from March 9, 2024 through December 31, 2024, as provided in the CAA, 2024. We estimate the CY 2025 anesthesia CF to be 20.3178, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 108: Calculation of the CY 2025 PFS Conversion Factor

CY 2024 Conversion Factor		33.2875
Conversion Factor without the CAA, 2024 (2.93 Percent Increase for CY 2024)		32.3400
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.02 percent (1.0002)	
CY 2025 Conversion Factor		**32.3465**

TABLE 109: Calculation of the CY 2025 Anesthesia Conversion Factor

CY 2024 National Average Anesthesia Conversion Factor		20.7739
Conversion Factor without the CAA, 2024 (2.93 Percent Increase for CY 2024)		20.1826
CY 2025 Statutory Update Factor	0.00 percent (1.0000)	
CY 2025 RVU Budget Neutrality Adjustment	0.02 percent (1.0002)	
CY 2025 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.65 percent (1.0065)	
CY 2025 Conversion Factor		**20.3178**

Table 110 shows the impact on PFS payment for physicians' services based on the policies included in this rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 110 (CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 110.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the PE RVUs.
- Column E (Impact of MP RVU Changes): This column shows the estimated CY 2025 impact on total allowed charges of the changes in the MP RVUs.
- Column F (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 110: CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$218	0%	-1%	0%	-1%
Anesthesiology	$1,591	1%	1%	0%	2%
Audiologist	$74	0%	0%	0%	0%
Cardiac Surgery	$166	0%	0%	0%	-1%
Cardiology	$6,117	0%	0%	0%	0%
Chiropractic	$656	0%	1%	0%	1%
Clinical Psychologist	$737	3%	1%	0%	3%
Clinical Social Worker	$854	3%	1%	0%	4%
Colon And Rectal Surgery	$151	0%	0%	0%	0%
Critical Care	$333	0%	0%	0%	0%
Dermatology	$3,885	0%	0%	0%	0%
Diagnostic Testing Facility	$942	0%	-2%	0%	-2%
Emergency Medicine	$2,440	0%	0%	0%	0%
Endocrinology	$517	0%	0%	0%	0%
Family Practice	$5,515	0%	0%	0%	0%
Gastroenterology	$1,453	0%	0%	0%	0%
General Practice	$379	0%	0%	0%	0%
General Surgery	$1,602	0%	0%	0%	0%
Geriatrics	$222	0%	0%	0%	1%
Hand Surgery	$265	-1%	-1%	0%	-1%
Hematology/Oncology	$1,579	0%	-1%	0%	-1%
Independent Laboratory	$561	0%	0%	0%	0%
Infectious Disease	$555	0%	0%	0%	0%
Internal Medicine	$9,491	0%	0%	0%	0%
Interventional Pain Mgmt	$839	0%	0%	0%	0%
Interventional Radiology	$445	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$152	0%	0%	0%	0%
Nephrology	$1,706	0%	0%	0%	0%
Neurology	$1,333	0%	0%	0%	0%
Neurosurgery	$706	0%	0%	0%	0%
Nuclear Medicine	$50	0%	0%	0%	0%
Nurse Anes / Anes Asst	$1,056	0%	1%	0%	1%
Nurse Practitioner	$7,029	0%	0%	0%	0%
Obstetrics/Gynecology	$565	0%	0%	0%	-1%
Ophthalmology	$4,667	-1%	-1%	0%	-2%
Optometry	$1,361	0%	0%	0%	-1%
Oral/Maxillofacial Surgery	$64	0%	0%	0%	0%
Orthopedic Surgery	$3,426	-1%	0%	0%	-1%
Other	$58	0%	-1%	0%	-1%
Otolaryngology	$1,155	0%	0%	0%	0%
Pathology	$1,187	0%	0%	0%	0%
Pediatrics	$55	0%	0%	0%	0%
Physical Medicine	$1,127	0%	0%	0%	0%
Physical/Occupational Therapy	$5,905	0%	0%	0%	0%
Physician Assistant	$3,699	0%	0%	0%	0%
Plastic Surgery	$303	0%	0%	0%	-1%
Podiatry	$1,928	0%	0%	0%	0%

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(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Portable X-Ray Supplier	$79	0%	1%	0%	1%
Psychiatry	$867	1%	0%	0%	1%
Pulmonary Disease	$1,269	0%	0%	0%	0%
Radiation Oncology and Radiation Therapy Centers	$1,538	0%	0%	0%	0%
Radiology	$4,557	0%	0%	0%	0%
Rheumatology	$520	0%	-1%	0%	0%
Thoracic Surgery	$297	0%	0%	0%	-1%
Urology	$1,617	0%	0%	0%	0%
Vascular Surgery	$998	0%	-2%	0%	-2%
Total	$90,861	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We provided an additional impact table for this rulemaking cycle that includes a facility/non-facility breakout of payment changes. The following is an explanation of the information represented in Table 111.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or nonfacility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2023 utilization and CY 2024 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Combined Impact): This column shows the estimated CY 2025 combined impact on total allowed charges.

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TABLE 111: CY 2025 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
Allergy/Immunology	*TOTAL*	$218	-1%
	Non-Facility	$211	-1%
	Facility	$7	0%
Anesthesiology	*TOTAL*	$1,591	2%
	Non-Facility	$315	0%
	Facility	$1,276	2%
Audiologist	*TOTAL*	$74	0%
	Non-Facility	$72	0%
	Facility	$3	0%
Cardiac Surgery	*TOTAL*	$166	-1%
	Non-Facility	$30	-2%
	Facility	$136	0%
Cardiology	*TOTAL*	$6,117	0%
	Non-Facility	$3,826	-1%
	Facility	$2,290	0%
Chiropractic	*TOTAL*	$656	1%
	Non-Facility	$654	1%
	Facility	$2	1%
Clinical Psychologist	*TOTAL*	$737	3%
	Non-Facility	$595	3%
	Facility	$142	3%
Clinical Social Worker	*TOTAL*	$854	4%
	Non-Facility	$722	4%
	Facility	$132	4%
Colon And Rectal Surgery	*TOTAL*	$151	0%
	Non-Facility	$55	0%
	Facility	$96	0%
Critical Care	*TOTAL*	$333	0%
	Non-Facility	$53	0%
	Facility	$281	0%
Dermatology	*TOTAL*	$3,885	0%
	Non-Facility	$3,740	0%
	Facility	$144	0%
Diagnostic Testing Facility	*TOTAL*	$942	-2%
	Non-Facility	$940	-2%
	Facility	$1	0%
Emergency Medicine	*TOTAL*	$2,440	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$205	0%
	Facility	$2,235	0%
Endocrinology	*TOTAL*	$517	0%
	Non-Facility	$415	1%
	Facility	$102	0%
Family Practice	*TOTAL*	$5,515	0%
	Non-Facility	$4,424	0%
	Facility	$1,090	0%
Gastroenterology	*TOTAL*	$1,453	0%
	Non-Facility	$532	0%
	Facility	$921	0%
General Practice	*TOTAL*	$379	0%
	Non-Facility	$304	0%
	Facility	$75	0%
General Surgery	*TOTAL*	$1,602	0%
	Non-Facility	$464	-1%
	Facility	$1,138	0%
Geriatrics	*TOTAL*	$222	1%
	Non-Facility	$149	1%
	Facility	$74	0%
Hand Surgery	*TOTAL*	$265	-1%
	Non-Facility	$141	0%
	Facility	$124	-3%
Hematology/Oncology	*TOTAL*	$1,579	-1%
	Non-Facility	$1,024	-1%
	Facility	$555	0%
Independent Laboratory	*TOTAL*	$561	0%
	Non-Facility	$547	0%
	Facility	$14	0%
Infectious Disease	*TOTAL*	$555	0%
	Non-Facility	$86	-1%
	Facility	$469	0%
Internal Medicine	*TOTAL*	$9,491	0%
	Non-Facility	$4,714	0%
	Facility	$4,777	0%
Interventional Pain Mgmt	*TOTAL*	$839	0%
	Non-Facility	$660	0%
	Facility	$179	0%
Interventional Radiology	*TOTAL*	$445	-2%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$273	-3%
	Facility	$172	1%
Multispecialty Clinic/Other Phys	*TOTAL*	$152	0%
	Non-Facility	$76	0%
	Facility	$76	0%
Nephrology	*TOTAL*	$1,706	0%
	Non-Facility	$1,020	1%
	Facility	$686	0%
Neurology	*TOTAL*	$1,333	0%
	Non-Facility	$852	0%
	Facility	$481	0%
Neurosurgery	*TOTAL*	$706	0%
	Non-Facility	$121	0%
	Facility	$585	-1%
Nuclear Medicine	*TOTAL*	$50	0%
	Non-Facility	$24	-1%
	Facility	$26	1%
Nurse Anes / Anes Asst	*TOTAL*	$1,056	1%
	Non-Facility	$21	1%
	Facility	$1,035	1%
Nurse Practitioner	*TOTAL*	$7,029	0%
	Non-Facility	$4,611	0%
	Facility	$2,418	0%
Obstetrics/Gynecology	*TOTAL*	$565	-1%
	Non-Facility	$386	-1%
	Facility	$179	0%
Ophthalmology	*TOTAL*	$4,667	-2%
	Non-Facility	$3,294	-2%
	Facility	$1,372	-1%
Optometry	*TOTAL*	$1,361	-1%
	Non-Facility	$1,297	-1%
	Facility	$64	0%
Oral/Maxillofacial Surgery	*TOTAL*	$64	0%
	Non-Facility	$52	0%
	Facility	$12	0%
Orthopedic Surgery	*TOTAL*	$3,426	-1%
	Non-Facility	$1,498	0%
	Facility	$1,928	-2%
Other	*TOTAL*	$58	-1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$47	-1%
	Facility	$12	1%
Otolaryngology	*TOTAL*	$1,155	0%
	Non-Facility	$918	0%
	Facility	$237	0%
Pathology	*TOTAL*	$1,187	0%
	Non-Facility	$629	0%
	Facility	$558	0%
Pediatrics	*TOTAL*	$55	0%
	Non-Facility	$35	0%
	Facility	$20	1%
Physical Medicine	*TOTAL*	$1,127	0%
	Non-Facility	$550	0%
	Facility	$576	0%
Physical/Occupational Therapy	*TOTAL*	$5,905	0%
	Non-Facility	$5,905	0%
	Facility	$	4%
Physician Assistant	*TOTAL*	$3,699	0%
	Non-Facility	$2,531	0%
	Facility	$1,169	0%
Plastic Surgery	*TOTAL*	$303	-1%
	Non-Facility	$135	-1%
	Facility	$168	-1%
Podiatry	*TOTAL*	$1,928	0%
	Non-Facility	$1,714	0%
	Facility	$214	0%
Portable X-Ray Supplier	*TOTAL*	$79	1%
	Non-Facility	$76	1%
	Facility	$3	1%
Psychiatry	*TOTAL*	$867	1%
	Non-Facility	$508	1%
	Facility	$359	0%
Pulmonary Disease	*TOTAL*	$1,269	0%
	Non-Facility	$550	0%
	Facility	$719	0%
Radiation Oncology and Radiation Therapy Centers	*TOTAL*	$1,538	0%
	Non-Facility	$1,048	-1%
	Facility	$490	2%
Radiology	*TOTAL*	$4,557	0%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
	Non-Facility	$2,004	-1%
	Facility	$2,553	1%
Rheumatology	*TOTAL*	$520	0%
	Non-Facility	$467	-1%
	Facility	$53	0%
Thoracic Surgery	*TOTAL*	$297	-1%
	Non-Facility	$59	-2%
	Facility	$238	0%
Urology	*TOTAL*	$1,617	0%
	Non-Facility	$1,136	0%
	Facility	$480	0%
Vascular Surgery	*TOTAL*	$998	-2%
	Non-Facility	$715	-3%
	Facility	$283	0%
TOTAL	***TOTAL***	***$90,861***	***0%***
	Non-Facility	$57,431	0%
	Facility	$33,429	0%

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2. CY 2025 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers and clinical psychologists, anesthesiology and nurse anesthetists, psychiatry, geriatrics, chiropractic, and endocrinology, reflect increases relative to other specialties. These increases can largely be attributed to the Year 4 update to clinical labor pricing and/or the proposed adjustments to transfer of post-operative care for global surgical procedures. These increases are also due to increases in values for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, the second year of our 4 year transition of work increases for timed behavioral health services, and increased payments resulting from supply and equipment pricing updates.

The estimated impacts for several specialties, including vascular surgery, diagnostic testing facilities, interventional radiology, ophthalmology and optometry, hand surgery, and orthopedic surgery, reflect decreases in payments relative to payment to other specialties, largely resulting from the redistributive effects of the implementation of the Year 4 update to clinical labor pricing and/or the proposed adjustments to transfer of post-operative care for global surgical procedures. The services furnished by these specialties were negatively affected by the redistributive effects of increases in work RVUs for other codes, and/or rely primarily on supply/equipment items for their practice expense costs and, therefore, were affected negatively by the updated Year 4 clinical labor pricing under budget neutrality. These decreases are also due to the revaluation of individual procedures based on reviews, including consideration of AMA RUC review and recommendations, as well as decreases resulting from the continued phase-in implementation of the previously finalized supply and equipment pricing updates. The estimated impacts also reflect decreases due to the continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 110), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 110 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As discussed previously, we have reviewed our suite of public use files

and have worked on new ways to offer interested parties additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2023 utilization data, Total RVUs change between −1 percent and 1 percent for more than 80 percent of practitioners, representing approximately 75 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Specialties, such as gastroenterology, exhibit little variation in changes in total RVUs per practitioner. Table 110 (CY 2025 PFS Estimated Impact on Total Allowed Charges by Specialty) indicates an overall change of 0 percent for this specialty, and the practitioner-level distribution shows that 98 percent of these practitioners will experience a change in Total RVUs between -1 percent and 1 percent. The specific service mix within a specialty may vary by practitioner, so individual practitioners may experience different changes in total RVUs. For example, Table 110 indicates a 1 percent increase in RVUs for the physical/occupational therapy specialty as a whole; however, 24 percent of physical/occupational therapy specialty practitioners—representing over 21 percent of Total RVUs for the specialty—will experience a 1 percent or more increase in Total RVUs. Meanwhile, 13 percent of physical/occupational therapy specialty practitioners will experience 1 percent or more decreases in Total RVUs, and these practitioners account for 14 percent of Total RVUs for this specialty. We also note the code level RVU changes are available in the Addendum B public use file that we make available with each rule (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

The specialty impacts displayed in Table 110 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from finalized policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) (such as the updated proposals associated with the transfer of post-operative care for global surgical procedures in CY 2025 or the clinical labor pricing update phase-in that began in CY 2022) but does not include any changes in spending which result from finalized policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 2.50 percent temporary payment increase for CY 2023 and the 1.25 and 2.93 percent temporary payment increases that applied for portions of CY 2024 are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table 110. Section 1848(t)(2)(C) specifies that these temporary payment increases are not to be taken into account in determining fee schedules for physicians' services furnished in years after the respective increases end. As such, these temporary increases are not subject to the PFS budget neutrality adjustment.

b. Impact

Column F of Table 110 displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2025 PFS final rule website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.* We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

D. Impact of Changes Related to Telehealth Services

We are finalizing the addition of several codes to the Medicare Telehealth Services List on a provisional basis, including HCPCS codes G0541–G0543, and G0539–G0540, and CPT Codes 97550, 97551, 97552, 96202, and 96203. We are also finalizing the addition of several codes to the Medicare Telehealth Services List on a permanent basis, including HCPCS codes G0011, G0013, and G0560. We are finalizing maintaining certain Telecommunications technology-related flexibilities through 2025, including that we will continue to use a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using real-time audio and video interactive telecommunications. We are also finalizing delaying implementation of the telehealth frequency limitations for subsequent nursing facility and inpatient hospital visits for an additional year, to include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home, and to continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. While we note that certain other Medicare telehealth flexibilities related to the PHE for COVID–19 are expiring, including the removal of statutory geographic and location limitations for most Medicare telehealth services, the beneficiary's home continues to be a permissible originating site for certain types of services including those furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including a Substance Use Disorder (SUD), and for monthly End Stage Renal Disease (ESRD) related clinical assessments described in section 1881(b)(3)(B). However, expiration of certain flexibilities for Medicare telehealth services is not expected to impact broader utilization of these services because reasonable and necessary services for the diagnosis or treatment of an illness or injury continue to be covered. Despite the fact that some services will no longer be furnished under telehealth, we expect that they will continue to be furnished in-person. We therefore anticipate that our provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2025 at levels comparable to observed utilization of these services during CY 2024.

E. Other Provisions of the Regulation

1. Impact of Provisions for Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services

In section II.J.2. of this final rule, we are adding to the list in § 411.15(i)(3)(i) of clinical scenarios under which FFS Medicare payment may be made for dental services inextricably linked to covered services to now include certain dental services associated with dialysis services for beneficiaries with end-stage renal disease (ESRD). Specifically, payment is permitted under Medicare Parts A and B for dental or oral examination performed as part of a comprehensive workup prior to, or contemporaneously with, Medicare-covered dialysis services when used in the treatment of ESRD; and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with covered dialysis services in the

treatment of ESRD. We do not anticipate any significant increase in utilization or payment impact for additional dental services given the historically low utilization of these therapies.

Based on the Renal Management Information System (REMIS) and Enrollment Data Base (EDB) gathered from the Integrated Data Repository (IDR) we estimate Fee-For-Service (FFS) Part B ESRD enrollment to have averaged roughly 240,000 enrollees during CY 2023. Based on United States Renal Data System (USRDS) from the NIH, we estimate that roughly 40,000 of these enrollees are on the kidney transplant waitlist in any given year and that roughly 10,000 of these patients on the waitlist would typically receive a transplant. Since we already include dental services associated with kidney transplant patients in § 411.15(i)(3)(i)(A) as an example of services for which payment can be made for certain dental services, we removed these patients from the estimate, which left roughly 30,000 FFS beneficiaries.

For a variety of reasons outlined previously, we have historically observed low FFS dental utilization in instances when coverage could apply (<1 percent of potential users). FFS dental billing patterns have shown a cost per covered utilizer of about $525 in recent years. To illustrate the potential cost of the payment for dental services inextricably linked to dialysis services for beneficiaries with ESRD we applied three scenarios of utilization (0.1 percent, 1 percent, 3 percent) and cost per patient of approximately $525 to the 30,000 patients. Under all of these scenarios the policy is projected to represent a negligible cost to the Medicare program (<$1,000,000) in any given year.

Therefore, we do not anticipate a significant payment impact for these provisions. It is important to note that there is some uncertainty in these take-up rate assumptions, but they are consistent with the current utilization of dental services, including after the regulation changes made in the CYs 2023 and 2024 PFS final rules. Additionally, given that our addition to the list of clinical scenarios under which payment may be made for dental services inextricably linked to covered services is not a change in coverage or payment policy, the cost impact of this provision is negligible and therefore it is not necessary to adjust the conversion factor under the PFS budget neutrality requirement.

2. Impact of Changes Related to Supervision of Outpatient Therapy Services in Private Practices

As outlined in section II.H. of this final rule, we proposed to change our regulatory requirements for OTs and PTs who are enrolled as suppliers in Medicare as OTs and PTs in private practice (OTPPs and PTPPs, respectively) to allow for general supervision of their occupational therapy assistants (OTAs) and physical therapist assistants (PTAs) to the extent permitted under State law. The requirement for OTPPs and PTPPs to provide direct supervision of OTAs and PTAs, which has been in place since 2005, requires the OTPP/PTPP to be present in the office suite or in the patient's home, and immediately available to furnish assistance and direction throughout the performance of the procedure performed by the OTA/PTA (or by an OT or PT they are supervising who is not enrolled in Medicare as a supplier). In contrast, the proposal to allow for general supervision will mean that the procedure is furnished under the OTPP's/PTPP's overall direction and control, but the OTPP/PTPP need not be present in the treatment location or immediately available.

As discussed in section II.H. of this final rule, we are finalizing our proposal, as proposed, because we continue to believe that the change to allow for general supervision of OTAs/PTAs by OTPPs and PTPPs will have a positive impact on patient access to outpatient therapy services; and will align with the currently required general supervision of PTAs/OTAs by PTs and OTs who work for Medicare institutional providers, such as rehabilitation agencies, outpatient hospitals, and SNFs. It will also reflect the supervision level specified in 44 State physical therapy practice acts [909] and all but one State occupational therapy practice act.

The financial impact of changing the supervision level in private practices from direct to general is difficult to estimate. While it is generally agreed that direct supervision of support personnel generally creates more access issues for patients compared to general supervision, the reverse is also true, that general supervision allows more access to services since the supervising therapist, in this case, does not have to be present onsite when the therapy services occur. We heard from several commenters that stated by changing the supervision level to from direct to general in private practices of PTs and OTs, that Medicare would save up to an estimated $271 million over a 10-year period.[910] The basis for this projected savings, as one commenter believes, even if the supervision change resulted in a modest increase in therapy service, is that some services of the therapist would shift to the therapy assistant. This would result in a greater number of claims for services furnished by OTAs/PTAs being paid at 85% of what we otherwise make to the therapist under the PFS when those services are furnished in whole or in part by a PTA/OTA; and depending on the amount of such services, along with the workforce shortage of both therapists and assistants, there may be a small percentage of costs or savings resulting from our finalized policy.

3. Impacts of Changes Related to Advanced Primary Care Management Services

In section II.G.2 of this final rule, ''Advanced Primary Care Management (APCM) Services,'' we proposed to create three HCPCS codes to use for reporting the APCM services (HCPCS codes G0556, G0557, and G0558) to recognize the resources involved in furnishing services using an advanced primary care delivery model under the PFS. As described in sections II.G.2.b and II.G.2.c of this final rule, the APCM services incorporate elements of existing services with the understanding that some patients will require more resources and some fewer based on variability in patient complexity and needs. As we ordinarily do, we proposed to base the PFS valuation for APCM codes on the resources involved in furnishing the typical case of the service which may not necessarily reflect the actual resources involved in furnishing every individual service. To value APCM, we compared the service elements described by the APCM codes to the values we have established for the specific care management services and communication technology-based services (CTBS) codes on which we modeled the service elements of the APCM codes and which we built into the service descriptors for G0556, G0557, and G0558 (see also Table 111

[909] Federation of State Boards of Physical Therapy Jurisdiction Licensure Reference Guide, *https://www.fsbpt.net/lrg/Home/SupervisionRequirementLevelsBySetting.*

[910] September 2022 report by Dobson DaVanzo & Associates commissioned by 8 therapy organizations to evaluate the financial impact and medical consequences of various provisions included in the Stabilizing Medicare Access to Rehabilitation and Therapy or SMART Act, (H.R. 5536) at: *https://www.dobsondavanzo.com/index.php?src=directory&view=Publications&submenu=_pubs&category=Cost%20Estimation&srctype=Publications_lister_redesign.*

and sections II.G.2.b. through II.G.2.d. of this final rule). Specifically, the APCM services incorporate elements of chronic care management (CPT codes 99487, 99489, 99490, 99491, 99439, 99437), principal care management (CPT codes 99424, 99425, 99426, 99427)), transitional care management (CPT codes 99495 and 99496), interprofessional internet consultation (CPT code 99446, 99447, 99448, 99449, 99451, 99452), remote evaluation of patient videos/images (HCPCS code G2250), virtual check-ins (HCPCS code G2251 and G2252), and online digital E/M or e-visits (CPT codes 98970, 98971, 98972, 99421, 99422, 99423) into this new bundled PFS payment beginning for CY 2025.

As outlined throughout section II.G.2 of this final rule, the elements of APCM services reflect the comprehensive approach to care management involved in care delivery using the advanced primary care model. This is a model of primary care that is being integrated into current medical practice. As such, we stated that it would be appropriate to use the current valuation and uptake of the codes on which we modeled the APCM codes to inform our valuation of APCM services. Using Medicare FFS claims data and evidence from the CMS Innovation Center's testing of a series of advanced primary care models (see section II.G.2.a.(1) of this final rule), we sought to understand how these different services have been used historically and relate that information to the way we think about the service elements for APCM and the valuation of the three APCM code levels. We know that for Medicare beneficiaries who receive care management services during a year, the non-complex CCM base code is billed on average for five months and with three add-on codes during those five months. We also know that initial information from practitioner interviews conducted as part of our CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold time for billing the non-complex CCM base code; typically, these practitioners reported spending between 45 minutes and an hour per month on CCM services for each patient, with times ranging between 20 minutes and several hours per month (81 FR 80244). However, this does not account for the care management services that are provided beyond one time-based billing interval and without reaching the next; nor does it account for the resources involved in maintaining certain advanced primary care practice capabilities and continuous readiness and monitoring activities, including patient population monitoring and care needs assessment, to fully furnish and bill APCM services as is medically reasonable and necessary for any individual patient during any calendar month. Finally, this does not account for changes to utilization of APCM that may occur as a result of the billing and documentation requirements for APCM services when compared to the current coding and payment for care management and CTBS services.

We are estimating a utilization of approximately 300,000 claims for the HCPCS code G0556, 1.3 million claims for the HCPCS code G0557, and 400,000 claims for the HCPCS code G0558, and solicited comment on our assumptions. To estimate utilization for G0556, we first calculated an eligible G0556 population by estimating the number of Medicare beneficiaries without multiple chronic conditions who have an established relationship with a primary care provider using Welcome to Medicare and Annual Wellness Visit claims and estimating the uptake of APCM Level 1 based on average uptake of CCM/PCM/TCM in CY 2022 claims data; then, we adjusted this estimate to account for increased frequency of billing (multiplied by 12 to account for 12 months of assumed practitioner billing for the APCM service). To estimate utilization for G0557, we first calculated estimated ratios to represent the average utilization of CCM/PCM/TCM services in the first year of policy implementation compared to CY 2022 claims; then, we applied a reduced utilization ratio to CY 2022 claims for CPT codes 99490 and 99487 (10.4 percent) and multiplied by the eligible G0557 population of Medicare beneficiaries with multiple chronic conditions who are non-QMB; finally, as described for G0556, we adjusted this estimate to account for increased frequency of billing (increase from an average of five months of CCM claims per beneficiary to 12 months of assumed practitioner billing for the APCM service, or 237.3 percent). To estimate utilization for G0558, we took the estimated number of G0557 claims for CPT codes 99490 and 99487 and multiplied by the eligible G0558 population of Medicare beneficiaries with multiple chronic conditions who are QMB; again, we adjusted this estimate to account for increased frequency of billing (same percentage applied to G0557).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

A few commenters were concerned about an inconsistency between the assumptions underlying valuation and those underlying CMS' utilization estimates for the services. For purposes of estimating utilization, CMS assumed that beneficiaries who receive APCM services will do so for 12 months each year; however, the valuation methodology assumed beneficiaries receive only a fraction of that—for example, CMS' proposed inputs for HCPCS code G0557 were based on CPT code 99490 multiplied by 5/12, CPT add-on code 99439 multiplied by 1/6, CPT add-on code 99489 multiplied by 1/12, and CPT code 99487 multiplied by 1/12. From the commenters' perspective, it seemed unreasonable to expect practices to maintain APCM capabilities and provide APCM services for 12 months per year while setting the value of those capabilities and services at a fraction of that time.

Response: We continue to reiterate that because the APCM codes are a bundle of existing care management and other services and the estimates of utilization of services are divided across the span of 12 months, we feel that this valuation reference is one way to estimate the work, time, and intensity of HCPCS code G0557. We also reiterate our assumption that beneficiaries receiving APCM may not require any services one month and may have increased utilization the next month. We are attempting to account for the varying care needs of the beneficiary, with an understanding that needs often ebb and flow. As discussed previously, we appreciate that APCM services require different practice capabilities as compared to other care management services and may revisit valuation of all APCM services in future rulemaking.

Comment: A few commenters commented on our predicted reduction in utilization for existing service codes. One commenter was concerned that the reduction in utilization for existing codes will not be sufficient to offset the significant cost increase. Another commenter asked whether CMS intended that the reduction in utilization of communication technology-based services (CTBS) will impact the value and payment for CTBS codes when separately reported by nonphysician qualified health care professionals. This commenter pointed out that, in Addendum B, the non-facility and facility PE RVUs for HCPCS code G2251 show a significant reduction from 0.15 to 0.00, and asked CMS to clarify whether this is a data entry error or an intentional change related to the proposed APCM codes. This commenter believes that the PE

RVU for HCPCS code G2251 should be restored to the original value of 0.15, as it should remain separately reportable when a virtual check-in is not associated with APCM services.

Response: We thank commenters for pointing out the error in Addendum B. The error has been corrected in this final rule.

After consideration of public comments, we are finalizing the impacts of APCM services as proposed. We look forward to continuing to engage with interested parties as these codes are billed.

We anticipate that these coding and payment policies for APCM services will result in slight reductions in utilization of existing care management and CTBS services during CY 2025 when compared to observed utilization of these services during CY 2024. Specifically, we estimated an approximate 11.4 percent reduction in utilization from CY 2024 across the 20 service codes which are incorporated into the APCM services (see previously). The estimated total net increase is approximately 700,000 claims, and we do not anticipate a significant payment impact for these provisions. We believe that the cost impact of this proposal is negligible and therefore it is not necessary to adjust the conversion factor under the PFS budget neutrality requirement.

4. Impact of Changes Related to Strategies for Improving Global Surgery Payment Accuracy

As discussed in section II.L. of this final rule, beginning for services furnished in 2025, we are finalizing our proposal to broaden the applicability of transfer of care modifier -54 for 90-day global packages as proposed. Beginning with services furnished in CY 2025, modifier -54 is required for all 90-day global surgical packages in any case when a practitioner plans to furnish only the surgical procedure portion of the global package (including both formal and other transfers of care). We are not finalizing any changes regarding the use of modifier -55 and modifier -56 for CY 2025. Modifiers -55 and -56 will continue to be billed exclusively in cases where there is a documented formal transfer of care.

Since we believe that this will result in expanded use of the transfer of care modifier -54, which will have a corresponding effect on the payment for the affected services, we have reflected this in our utilization estimates accordingly (see download file for this final rule titled CY 2025 PFS final rule 2023 Utilization Data Crosswalked to 2025 at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending*) and anticipate more global surgical packages to be billed separately using modifier -54, which could have payment consequences for a selection of high-volume global surgery codes. We assume that the same number of global surgery codes will be billed; however, we anticipate more codes will be billed using transfer of care modifier -54. We do not expect that the utilization of separately billable post-operative E/M services will change. Rather than modify our utilization estimates for these codes, our utilization estimate includes only 90-day high volume and/or high-cost procedure codes where reporting post-operative visits with CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*) is required. This is a relatively small set of codes (approximately 180) versus the full range of approximately 4,000 global surgical codes; however, this subset of codes accounts for about 73 percent of total Medicare 90-day procedure volume. The full list of affected codes is available in the file titled ''CY 2024 Analytic Crosswalk to CY 2025'' on the CMS website under downloads for the CY 2025 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For this select list of global surgical codes, we are estimating that the transfer of care modifier, modifier -54, will be employed 20 percent of the time. We believe that this is a conservative estimate given the frequency with which these global surgical services involve a transfer of post-operative care. RAND's research has indicated that a post-operative transfer of care is common for 90-day global surgical procedures but that these transfers of care are almost never reported with the appropriate modifier. Then, for the 20 percent of cases where we believe the transfer of care modifier will be employed, we proposed to apply the payment reduction associated with the modifier -54 for post-operative care and apply it to the utilization estimate for the associated procedures billed using the transfer of care modifiers. These percentages can be found in the PFS Relative Value Files under the columns labeled ''pre op, intra op, post op'' at *https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files.* For example, CPT code 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) is a high-volume knee replacement procedure where the post-operative portion of the total payment is 21 percent. We estimated that there will be a post-operative transfer of care 20 percent of the time for CPT code 27447, and in those 20 percent of cases, there will be a corresponding 21 percent decrease in payment. This is reflected in a utilization crosswalk of 0.958 for CPT code 27447 as a result of this 4.2 percent reduction (20 percent times 21 percent) to capture this estimated reduction in spending associated with our proposal to require the use of the transfer of care modifier (modifier -54).

We note that for purposes of estimating the utilization of the transfer of care modifier, our estimates include increased reporting of the transfer of care modifier for codes that are subject to the RAND data collection exercise, with the exception of cases where the modifier is already used 5 percent of the time or more. We recognize that this policy will apply more broadly and solicited comment on this.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter said the reference to ''expected'' in the CMS proposal should have no impact on the utilization rates of Modifier -55 because Modifier -55 should not be appended to a claim unless post-operative management of patient care has actually occurred. Commenters expressed general concern about the ability of CMS to extrapolate any meaningful data for purposes of updating global code values based on changes in utilization of the transfer-of-care modifiers if this policy is finalized.

Response: We appreciate the commenter noting the appropriate use of modifier -55 and agree that our utilization assumptions focused on the use of modifier -54. We understand the concerns surrounding the data and want to reiterate that modifier -54 and its use is an iterative step in the process of accurately valuing the global surgical packages.

After consideration of public comments, we are finalizing as proposed. We note that the impact of this estimated reduction in spending associated with this policy is redistributed across the PFS via an

increase in the budget neutrality adjustment to the conversion factor.

We also proposed and are finalizing a new HCPCS code, G0559, to capture the additional practitioner time and resources spent in providing follow up post-operative care by a practitioner who did not perform the surgical procedure. Additionally, we expect the global surgical add-on code, HCPCS code G0559, will be billed during the post-operative period of 90 days following the procedure. We expect that this code will be billed once during the global period when the patient is seen for an office/outpatient (O/O) evaluation and management (E/M) visit that is related to the recent surgical procedure. We believe that this code will be billed by a physician or other practitioner (other than the proceduralist or another practitioner in the same practice) who is seeing the patient for a visit during the post-operative period and did not furnish the surgical procedure. We believe that there is additional time, resources, and complexity involved in the first O/O E/M visit following a procedure that should be captured during the post-operative period and may be billed in certain instances when a transfer of care modifier was not appended to the claim.

We estimated a utilization of approximately 40,000 total claims in the first year for the add-on code, HCPCS code G0559. We calculated this utilization estimate based on claims data for procedure codes with a post-operative diagnosis code and an observed to expected ratio (that is the ratio of visits that are included in the global surgical package compared to the number of visits actually furnished) of less than 25 percent. We anticipate that uptake of HCPCS code G0559 will be low initially, consistent with initial uptake of other new services we have finalized under the PFS. We solicited comment on these assumptions and welcomed input from the public.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter asked about the impact on budget neutrality regarding the new proposed add-on code, HCPCS code G0559. Another commenter was also concerned about the unbalanced impact this would have on budget neutrality, negatively affecting those who have no opportunity to bill for this code.

Response: We appreciate the commenters question on budget neutrality and note that HCPCS code G0559, as finalized, does affect budget neutrality since we are adding a new service with utilization and work RVUs, but that the impact is relatively small.

Comment: A few commenters stated that they anticipated uptake and utilization of the new add-on code will be slow.

Response: We appreciate commenters noting that uptake and utilization of the new add-on code may be slow. We would like to reiterate that improving global surgery payment accuracy is an iterative process and we believe that use of the add-on code, as well as the transfer of care modifiers, are an important first step in that process.

After consideration of public comments, we are finalizing as proposed.

5. Drugs and Biological Products Paid Under Medicare Part B

a. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023 and 2024 final rules, we finalized several policies to implement the provision. These policies are described in section III.A.1 of this final rule.

In section III.A.1 of this final rule, we are finalizing additional clarifications for implementing the provision, including: a change in how we will identify certain drugs that are excluded from the definition of refundable drug for those which payment has been made under Part B for fewer than 18 months; how we identify drugs from a single-dose container; the requirement to use the JW modifier if a billing supplier is not administering a drug, but there are discarded amounts during the preparation process before supplying the drug to the patient. We also discuss an application (CMS 10835, OMB 0938–1435) for increased applicable percentage.

In the CY 2024 PFS final rule (88 FR 79485 through 79490), we analyzed JW modifier data from 2021 as if the data represented dates of service on or after the effective date of section 90004 of the Infrastructure Act (that is, January 1, 2023).[911] Similar to our regulatory impact analysis in the CY 2023 PFS final rule (87 FR 70187 through 70188), we used the 2021 JW modifier data to estimate refund amounts as described in section 1847A(h)(3) of the Act. In this final rule, we performed the same analysis on the 2022 JW modifier data. First, we subtracted the percent units discarded by 10 percent (the applicable percentage for most refundable drugs), except for drugs with an increased applicable percentage as described in § 414.940(d). We note that since the data indicating which drugs will have an increased applicable percentage of 26 percent for the unique circumstances of rarely utilized orphan drugs (§ 414.940(d)(5)) will not be available until the data is analyzed for the initial report, we entered 26 percent for orphan drugs furnished to fewer than 100 beneficiaries in CY 2022 based on data on the CMS website.[912] Therefore, the drugs with increased applicable percentage under § 414.940(d)(5) may change each year based on claims data; it is applied in this analysis for estimation purposes only. Then, we multiplied that percentage by the CY 2022 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. This analysis remains appropriate for this final rule because we are applying the finalized policies from the CY 2023 and 2024 PFS final rules to the most recent publicly available data for the JW modifier data from CY 2022.

Overall, according to data on the CMS website [913] for Medicare Part B discarded drug units in the 2022 calendar year, Medicare paid over $800 million for discarded amounts of drugs from a single-dose container or single-use package paid under Part B. In that year, there were 55 billing and payment codes with 10 percent or more discarded units based on JW modifier data. Of these, 10 did not meet the definition of refundable single-dose container or single-use package drug in section 1847A(h)(8) of the Act because they are not single source drugs or

[911] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

[912] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.*

[913] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-discarded-drug-units.*

biologicals; 5 were excluded from the definition of refundable single-dose container or single-use package drug (as specified in section 1847A(h)(8)(B) of the Act) because they are identified as radiopharmaceuticals or imaging agents in FDA-approved labeling; and 3 are products referred to as skin substitutes, which were removed because we anticipate making changes to coding and payment policies regarding those products in future rulemaking. After these exclusions, there were 35 billing and payment codes that met the definition of refundable single-dose container or single-use package drug. Of these, 29 codes have discarded units above the relevant finalized applicable percentage, and 6 codes have discarded units that would fall below increased applicable percentages in this final rule.

We estimated refund amounts as described in section 1847A(h)(3) of the Act based on this data by subtracting the percent units discarded by 10 percent (the applicable percentage), except for drugs with higher applicable percentages finalized in the CY 2023 or 2024 final rules. Then, we multiplied the appropriate percentage by the CY 2022 total allowed amount to estimate the annual refund for a given billing and payment code. The quarterly refund was estimated by dividing the annual estimate by 4. Based on this data, there will be approximately $98.7 million in refunds due from manufacturers for the calendar year of 2022 ($24.7 million each calendar quarter).

There are several limitations to this analysis that could substantially affect the total quarterly refund. Since new drugs are continually being approved, this estimate does not consider newer drugs that will meet the definition of refundable single-dose container or single-use package drug on or after the effective date of January 1, 2023. Since section 1847A(h)(8)(B)(iii) of the Act excludes drugs approved by FDA on or after November 15, 2021, and for which payment has been made under Part B for fewer than 18 months from this definition, we expect an impact on refund amounts after the 18-month exclusion has ended if the drug otherwise meets the definition. We also note that this estimate is based on CY 2022 data for discarded drug amounts, which, for reasons discussed in the CY 2023 PFS final rule (87 FR 69716), we believe to be an underestimate due to the frequent omission of the JW modifier. Claims edits for both the JW and JZ modifiers will likely increase accurate reporting of discarded drug amounts. Other substantial changes to this estimate may occur if a billing and payment code no longer meets this definition. For example, if a generic version of one of these drugs is marketed, the billing and payment code will become a multiple source drug code and will no longer meet the definition of refundable single-dose container or single-use package drug. Subsequently, the manufacturers will not be responsible for refunds under this provision. There may be changes in the percent discarded units for a given refundable single-dose container or single-use package drug if the manufacturer introduces additional vial sizes or modifies the vial size to reduce the amount discarded. Lastly, since data from the CMS website only includes billing and payment codes on the ASP drug pricing file[914] and implementation of section 90004 of the Infrastructure Act is not restricted to billing and payment codes included on the file, there may be other applicable data that were not assessed as part of this estimate.

b. Impacts Related to the Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales

In section III.A.2 of this final rule, CMS is finalizing how payment limits will be calculated when manufacturers report negative or zero ASP data for a drug to CMS, beginning with the payment limits included in the January 2025 ASP Drug Pricing file. We are revising § 414.904(i) to reflect CMS' approach to setting a payment limit for circumstances in which negative or zero ASP data is reported by a manufacturer for a drug.

Specifically, we are codifying that in cases where negative or zero ASP data is reported for some, but not all, NDCs of a multiple source drug, we will calculate the payment limit using the positive ASP data reported for the drug, except for the existing carryover policy for multiple source drugs that we will apply when missing data results in a significant change in the ASP payment limit. We are finalizing to move this carryover policy for multiple source drugs within § 414.904(i) to fit within the structure of the new set of payment limit methodologies. We are also codifying that in the case of a multiple source drug for which negative or zero ASP data is reported for all NDCs, we will set the payment limit using the most recently available positive ASP data from a previous quarter until at least one NDC for the drug has positive ASP data for a quarter.

We are codifying that in cases where negative or zero ASP data is reported for some, but not all, NDCs of a single source drug that is not a biosimilar, we will calculate the payment limit using the positive ASP data reported for the drug. We are codifying that for single source drugs that are not biosimilars with all negative or zero ASP data for a given quarter, the payment limit will be, until at least one NDC for the drug has positive manufacturer ASP data for a quarter, the lesser of 106 percent of the volume-weighted average of the most recently available positive manufacturer ASP data for at least one NDC from a previous quarter and 106 percent of the WAC, and we will use 106 percent of the lowest WAC per billing unit if there is more than one WAC per billing unit.

We are also finalizing our proposal to codify that in cases where negative or zero manufacturer's ASP data is reported for some, but not all, NDCs of a biosimilar, we will calculate the payment limit using the positive manufacturer's ASP data reported for the biosimilar. Lastly, we are finalizing a modification to our proposal to codify a methodology for calculating payment limits when the manufacturer reports negative or zero manufacturer's ASP for all NDCs for a biosimilar for a given quarter. We are adopting the approach proposed for circumstances when no other biosimilars have been approved for the same reference product or no other biosimilars with the same reference product report positive manufacturer's ASP data for the given quarter for all circumstances, regardless of whether positive ASP data is reported for other biosimilars that reference the same reference product. In other words, we are finalizing for all biosimilars with all negative or zero manufacturer's ASP data that we will set the payment limit equal to the sum of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter plus 6 percent (or 8 percent for a qualifying biosimilar biological) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product for the given quarter.

With regard to estimating changes in expenditures for CY 2025, because drugs and biologicals that report negative or zero ASP data vary by quarter and we cannot predict those that will report such data, we used historic claims data to perform an illustrative analysis of how program spending would have changed had the proposed policies been in place in CY 2023. In the analysis, we identified single source and multiple source billing and payment codes associated with negative or zero

[914] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice.*

ASP data for which we published payment limits based on other applicable pricing data (that is, the manufacturer or published wholesale acquisition cost) in the four calendar quarters of 2023. For each such billing and payment code, we used claims data to identify: (1) the number of allowed billing units in a calendar quarter (that is, the number of billing units of a drug or biological paid for by Medicare); (2) the payment limit per billing unit we applied to that drug or biological under our current policies; and (3) the payment limit per billing unit our finalized policy would apply to the billing and payment code. We then subtracted the product of the allowed billing units for the payment limit under current policy by the product of the allowed billing units and the payment limit under our finalized policy, and the difference between the two is what the difference between what Medicare spending on the billing and payment codes would have been if our proposed payment limit methodologies were used in that calendar quarter of 2023 and what Medicare actually spent. These data and net reductions (or increases) in program spending are illustrated in Table 112.

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TABLE 112: Theoretical Changes in Medicare Spending on Drugs and Biologicals with Negative or Zero ASP Data Based on CY 2023 Claims Data

1Q2023	Allowed Billing Units	Current Policy (WAC+6)	Finalized Policy	Δ Between Current and Finalized Policy
A9600	2	$4,156.57	$4,156.57	$0.00
J0600	388	$5,708.59	$5,592.56	$45,020.27
J0641	743725	$0.35	$0.27	$59,146.41
J0720	116	$41.26	$40.41	$97.51
J1000	1448	$29.70	$26.45	$4,698.57
J1020	47177	$4.61	$1.49	$147,172.43
J2770	15	$493.97	$337.47	$2,347.56
J3300	361410.5	$4.19	$3.90	$101,778.80
J9214	62	$32.57	$31.85	$45.11
J9302	601	$63.96	$62.23	$1,035.92
Total				**$361,342.58**
2Q2023	**Allowed Billing Units**	**Current Policy (WAC+6)**	**Finalized Policy**	**Δ Between Current and Finalized Policy**
J0285	79	$46.32	$41.82	$355.81
J0287	408	$11.13	$10.30	$339.24
J0600	435	$5,708.59	$5,592.56	$50,473.78
J1020	51493.5	$4.61	$1.49	$160,638.09
J1952	83966	$98.43	$88.75	$812,631.54
J3300	382291	$4.19	$3.90	$107,603.64
J9071	69321	$3.87	$1.99	$130,365.00
J9214	31	$32.57	$31.85	$22.56
J9268	114	$2,585.41	$2,320.12	$30,243.93
J9302	1201	$63.96	$62.23	$2,069.85
Total				**$1,294,743.45**
3Q2023	**Allowed Billing Units**	**Current Policy (WAC+6)**	**Finalized Policy**	**Δ Between Current and Finalized Policy**
J0216	67	$2.57	$2.23	$22.12
J0287	156	$11.13	$10.30	$129.71
J0636	74598	$0.80	$0.76	$2,512.18
J1572	2231	$56.12	$44.54	$25,827.58
J1738	242	$3.32	$3.13	$46.94
J2360	13873	$16.54	$5.38	$154,795.59
J3244	650	$2.65	$0.60	$1,337.45
J3300	348934	$4.27	$3.90	$127,484.96
J7342	23	$30.02	$30.01	$0.25
J9046	42577	$48.55	$8.65	$1,698,614.91
J9071	77971	$3.87	$1.99	$146,632.18
J9198	438.5	$40.28	$24.64	$6,857.90
J9214	21	$32.57	$31.85	$15.28
J9296	3567	$9.66	$9.74	-$284.99

J9393	27710	$21.20	$3.07	$502,406.57
Q4248	29844	$1,107.70	$1,003.00	$3,124,704.07
Total				**$5,791,102.73**
4Q2023	**Allowed Billing Units**	**Current Policy (WAC+6)**	**Finalized Policy**	**Δ Between Current and Finalized Policy**
J0595	281	$2.54	$5.05	-$703.96
J0893	12700	$2.12	$2.24	-$1,524.98
J1000	1027	$32.67	$30.68	$2,040.73
J1980	1106	$35.46	$33.23	$2,468.40
J9071	146276	$3.87	$1.19	$392,283.72
J9198	232	$40.28	$24.26	$3,716.66
J9394	57142	$53.00	$1.65	$2,934,066.27
Total				**$3,332,346.84**

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As illustrated in Table 112, the application of the payment limit calculation approaches will have reduced program spending for all but three drugs that reported negative or zero ASP data in calendar quarters in 2023 and reduced spending by a total of $10,779,535.60 over the year.

We separately analyzed theoretical changes in program spending for one biosimilar product (ZIEXTENZO®, Q5120) that has reported negative ASP data for all NDCs for four consecutive quarters beginning with the second calendar quarter of 2022, and calculated the payment limit under our method for biosimilars with negative or zero ASP data and changes in program spending for the four impacted quarters had our proposed payment approach been applied, as well as payment limits and theoretical changes in program spending under the two alternatives considered under the rule. Under the first alternative, we would include the ASP data and billing units sold of the reference biological for a given quarter along with those of the other biosimilars in the volume-weighted average calculation. Under the second alternative, which we finalized in section III.A.2 of this rule, we will set the payment limit for a given quarter using the biosimilar's most recently available positive ASP data and either 6 percent (or 8 percent for qualifying biosimilar biologicals) of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter. The calculated payment limits under the proposal and the two alternatives, as well as the estimated reductions in program expenditures, are illustrated in Table 113.

TABLE 113: Theoretical Changes in Medicare Spending on Q5120 for 4Q 2023 through 2Q 2024

Ziextenzo (Q5120)	Allowed Billing Units	Current Policy (WAC+6)	Payment limit: Proposal	Payment limit: First Alternative	Payment limit: Second Alternative (Finalized Policy)
4Q2023	2,359	$346.755	$118.369	$95.267	$29.24
1Q2024	1,299	$346.755	$117.313	$86.053	$27.40
2Q2024	750	$346.755	$149.574	$127.623	$31.86
3Q2024	207	$346.755	$144.007	$119.946	$27.74
			Spending Δ: Proposal	Spending Δ: First Alternative	Spending Δ: Second Alternative (Finalized Policy)
4Q2023			$538,762.136	$593,260.72	$749,026.64
1Q2024			$298,045.708	$338,651.29	$414,835.93
2Q2024			$147,885.610	$164,348.76	$236,168.86
3Q2024			$41,968.943	$46,949.41	$66,036.05
Total Savings			**$984,693.455**	**$1,096,260.775**	**$1,400,031.436**

We note that the spending change estimates reflect preliminary claims data. Providers and suppliers have a 12-month period to submit Medicare Part B claims, including claims for drugs payable under Part B, so a lag exists between the date of service when a drug is administered and when the claim is submitted and adjudicated. An evaluation of July 2010 Medicare Part B claims in the Physician/Supplier-Carrier setting showed that 91.68, 96.84, and 98.32, and 99.13 percent of claims were final at 3, 6, 9, and 12 months, respectively, following the date of service. At 24 and 48 months, 99.83 and 100 percent of the claims, respectively, were considered to be final. Therefore, for the allowed billing units and estimated program expenditure reduction for the first 3 calendar quarters of CY 2024 are significantly lower than we would expect after claims mature for a full year. Over the 4

calendar quarters (4Q2023, 1Q2024, 2Q2024, and 3Q2024), our proposed approach for calculating the payment limit for biosimilars with only negative or zero manufacture's ASP data, our first alternative approach, and our finalized policy would have reduced program expenditures by at least $984,693.455, $1,096,260.775, and $1,400,031.436, respectively.

After assessing the effect of applying the proposed alternative payment limit calculation approaches to recent Medicare FFS claims experience over 2023 and 2024, we estimate an average annual gross Part B effect of $12.2 million dollars in reduced program spending for 2025 and approximately $122 million over 2025 to 2034, as shown in Table 114. Historically we have observed that negative or zero ASP pricing data may occasionally occur for a drug when it is discontinued or substituted away for another product and assume this to occur in the future. Moreover, given the infrequency of negative or zero ASP data, we do not expect in all years that alternative pricing approaches will be necessary or to affect payment amounts for drugs with material levels of utilization. Therefore, for a low estimate we project the policy to have a negligible effect on program spending for the projection window. To illustrate a potential high impact estimate scenario, the affected utilization from 2023 was doubled relative to the observed data. Please note that the actual effect of the policy will be specific to the affected drugs in any given year and considerations that affect their utilization and pricing, therefore actual experience may deviate considerably from these projections.

TABLE 114: Projected Impacts Related to Proposed Payment Limit Methodologies in Circumstance in which Manufacturers Report Negative or Zero Average Sales Price Data

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	-12.2	-12.2	-12.2	-12.2	-12.2	-12.2	-12.2	-12.2	-12.2	-12.2	**-122**
Estimate Range:											
Low Estimate	0	0	0	0	0	0	0	0	0	0	**0**
High Estimate	-24.4	-24.4	-24.4	-24.4	-24.4	-24.4	-24.4	-24.4	-24.4	-24.4	**-244**

c. Impacts Related to the Payment of Radiopharmaceuticals in the Physician Office

In section III.A.3. of this final rule, we are finalizing to codify in regulations at § 414.904(e)(6) that, for radiopharmaceuticals furnished in a setting other than the hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing. The clarification does not necessarily change the payment methodology in place for a MAC but rather clarifies that any payment methodology that was being used by any MAC prior to the enactment of the MMA can continue to be used by any MAC. Therefore, we believe that this clarification will have no impact on Medicare spending.

d. Impacts Related to Immunosuppressive Therapy

In section III.A.4 of this final rule, we are finalizing modifications to regulations to include orally and enterally administered compounded formulations with active ingredients derived only from FDA-approved drugs where approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue, or that have been determined by a Medicare Administrative Contractor (MAC) to be reasonable and necessary for a specific purpose in immunosuppressive treatment included in the immunosuppressive drug benefit. In addition, we are finalizing two changes regarding supplies of immunosuppressive drugs to align with current standards of practice and reduce barriers to medication adherence: to allow payment of a supply fee for a prescription of a supply of up to 90 days and to allow prescriptions for these immunosuppressive drugs to be refillable.

CMS has limited insight into how many patients who are currently prescribed compounded immunosuppressive drugs will have their immunosuppressive medication paid for under Part B as a result of the finalized changes to the immunosuppressive drug benefit. Medicare Part D claims data for CY 2023 indicates there were 2,662 prescriptions filled that year for compounded immunosuppressive drugs that could have been administered through oral or enteral routes (that is, that would likely be paid under Part B if the immunosuppressive drug benefit revision is finalized as proposed). We estimate that this number of prescriptions correlates to up to 2,000 Part D enrollees that were prescribed compounded immunosuppressive drugs that will be covered under the finalized policy. However, we do not know how many Part B beneficiaries currently have their compounded immunosuppressive drugs paid for by means other than a Part D policy. And finally, and perhaps most importantly, compounded drugs are priced by each A/B and DME MAC and have no estimable payment limit. Thus, we are unable to estimate the cost shift from Part D and other plans to Part B that will result from the finalization of the immunosuppressive drug benefit policies, including allowing payment of supply fees for prescriptions fills for supplies of up to 90 days and for immunosuppressive drugs to be refillable.

e. Impacts Related to Clotting Factors

In section III.A.5. of this final rule, we are finalizing to update § 410.63(b) to clarify existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee

applies. We are also clarifying that therapies that enable the body to produce clotting factor and do not directly integrate into the coagulation cascade are not themselves clotting factors for which the furnishing fee applies. Additionally, we are finalizing to clarify at § 410.63(c) that the furnishing fee is only available to entities that furnish blood clotting factors, unless the costs associated with furnishing the clotting factor are paid though another payment system, including the PFS. That is, we are finalizing to clarify through revisions to § 410.63 that clotting factors (as specified in section 1861(s)(2)(I) of the Act) and those eligible to receive the clotting factor furnishing fee (as specified in section 1842(o)(5) of the Act) are the same subset of products. Accordingly, the clarification will not be adding a furnishing fee to any new products. Therefore, we believe that this clarification will have no impact on Medicare spending.

6. Impacts Related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, we are finalizing with a modification that starting in 2025, RHCs and FQHCs will report the individual CPT and HCPCS that describe care coordination services instead of the single HCPCS code G0511. We are also allowing RHCs and FQHCs to come into compliance by at least until July 1, 2025, to enable those RHCs and FQHCs to be able to update their billing systems. We are also finalizing a policy that permits billing of the add-on codes associated with these services. In addition, beginning in CY 2025, we finalizing the coding and policies regarding Advanced Primary Care Management (APCM) services, as outlined in section II.G of this final rule. In terms of estimated impacts to the Medicare program, we believe that the proposals discussed in section III.B.2 of this final rule will have no impact on Medicare spending.

In section III.B.3. of this final rule, we are finalizing the policy to continue to adopt the definition ''immediate availability'' as including real-time audio and visual interactive telecommunications for the direct supervision of services and supplies furnished incident to a physician's service through December 31, 2025, for RHCs and FQHCs. We also finalizing, on a temporary basis, a policy allowing payment for medical care non-behavioral health visits furnished via telecommunication technology in a manner similar to with the payment mechanisms mandated by statute through December 31, 2024. RHCs and FQHCs will continue to bill for RHC and FQHC services furnished using telecommunication technology services by reporting HCPCS code G2025 on the claim through December 31, 2025. In addition, we are finalizing a policy which extends the delay the in-person visit requirement for mental health services furnished via communication technology by RHCs and FQHCs to beneficiaries in their homes until January 1, 2026. We believe these RHC/FQHC proposals related to telecommunication technology will have a negligible impact on Medicare spending.

In section III.B.4. of this final rule, we are finalizing a payment rate when four or more IOP services per day are provided in the RHC and FQHC setting. We are also finalizing to aligning with the four or more services per day payment rate for hospital outpatient departments, which will be updated annually. In terms of impact, we believe that this proposal will have negligible impact on Medicare spending.

In section III.B.5. of this rulemaking, we are finalizing our proposal to allow RHCs and FQHCs to bill for Part B preventive vaccines and the administration at the time of service. We state that payments for these claims will initially be made according to Part B preventive vaccine payment rates in other settings, but that they will be annually reconciled with the facilities' actual vaccine costs on their cost reports, which is current practice and statutorily mandated. Therefore, we believe that this proposal will have no impact on Medicare spending.

In section III.B.6. of this final rule, we outline our proposal relating to RHC productivity standards. We are finalizing our proposal to remove productivity standards for RHCs effective for cost reporting periods beginning on or after January 1, 2025, and believe that this will have no impact on Medicare spending.

In section III.B.7 of this final rule, we are finalizing the rebasing of the FQHC market basket to reflect a 2022-base year. The CY 2025 FQHC market basket update is 0.1 percentage point lower using the 2022-based FQHC market basket (3.4 percent) compared to the 2017-based FQHC market basket (3.5 percent). Therefore, the economic impact of finalizing the FQHC market basket rebasing for CY 2025 is approximately $1 million and we consider this impact to be negligible. We determined this amount by applying a factor of -0.001 to the FQHC baseline, which was approximately $1,000 million in calendar year 2024. Over the next 10 years the rebasing methodology results in the same estimated market basket percentage increase for every year except CY 2034 when it is expected to be 0.1 percentage point lower compared to the 2017-based FQHC market basket update. Therefore, the estimated impact of the rebasing of the FQHC market basket over the next 10 years is negligible.

In section III.B.8. of this final rule, we clarified that when RHCs and FQHCs furnish dental services that align with the inextricably linked policies and operational requirements in the physician setting, we will consider those services to be a qualifying visit and the RHC will be paid at the RHC AIR and the FQHC will be paid under the FQHC PPS. We believe this clarification related to dental services furnished in RHCs and FQHCs will have a negligible impact on Medicare spending. Even though this policy expands payment under Medicare Part B, it will only cover dental services inextricably linked to specific medical services as described in section II.J. of this final rule.

7. Changes in the RHC and FQHC CfCs: Provision of Services (§ 491.9(a)(3) and (c)(2)(ii) and (vi))

Provision of Services (§ 491.9)

At § 491.9(a), we proposed to explicitly require RHCs and FQHCs to provide primary care services and to codify the statutory requirement that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. After consideration of public comments, we are finalizing our proposal to require RHCs to provide primary care services. However, we are not finalizing this requirement for FQHCs. We are also withdrawing the proposed requirement at § 491.9(a)(2)(ii) to codify the statutory requirement that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. We believe that finalizing the proposal to require RHCs to provide primary care services supports our goal of clarifying the services that RHCs may provide and safeguarding access to primary care services while avoiding unintended consequences that may create barriers to accessing care. We believe the requirement at § 491.9(a)(3) (finalized in this rule) to require RHCs to provide primary care services will result in real, but difficult to estimate, long-term benefits to patients receiving services at RHCs, as well as economic benefits to the clinic. Regarding the estimated impacts on the Medicare program, the

provisions discussed in section III.C.2 of this final rule will have no impact on Medicare spending.

This change will provide RHCs with additional flexibility to provide outpatient specialty services on-site or hire additional providers with specialized expertise to meet the needs of their community, including specialized areas of internal medicine, pediatrics, geriatrics, obstetrics and gynecology, dermatology, cardiology, neurology, endocrinology, and ear, nose and throat. As a result, RHCs will be able to improve access to care by serving more patients in communities served by RHCs, including rural communities, and not requiring patients to travel longer distances to receive specialty services. Patients could have access to specialists within their own communities, improving overall access for Medicare beneficiaries. Moreover, CMS will no longer determine or enforce the standard of RHCs ''being primarily engaged in furnishing primary care services.'' [915] which has been enforced via the sub-regulatory guidance contained in the *State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs).* Resources that clinics are currently using to evaluate if they are meeting this requirement could be devoted to other administrative tasks. Therefore, we believe that there will be no burden imposed on RHCs related to this proposal.

We also proposed to remove hemoglobin and hematocrit (H&H) lab tests from the list of specific tests RHCs must provide, as well as update the language regarding the primary culturing requirement to reflect current standards of practice at § 491.9(c)(2)(ii) and newly designated (vi), respectively. We are finalizing these provisions as proposed. Additionally, based on a comment citing that 82 percent of RHCs indicate that the lab requirement for the ''Examination of stool specimens for occult blood'' at § 491.9(c)(2)(iv) is no longer frequently ordered or considered the best clinical practice. Therefore, we are finalizing the removal of this requirement from the list of laboratory services RHCs must provide.

As stated in section III.C.2.b of this final rule, RHCs report that the H&H lab requirement and the examination of stool specimens for occult blood (these specific tests) are particularly burdensome and costly for clinics due to purchasing and maintaining the equipment that is seldom or never used.

This change will reduce the overall burden for RHCs by reducing the number of diagnostic tests they must provide. RHCs will no longer be required to purchase or maintain H&H lab tests or stool examination equipment or supplies, freeing up resources for other essential services. H&H lab tests are most often ordered as part of a larger panel of labs that is not provided at the RHC. When this is the case, patients will receive the H&H as part of that larger panel at an outside lab that offers the larger panel of labs. These patients may be inconvenienced by having to travel to another laboratory, but this limits the number of specimens they must provide for the laboratory tests, reducing the number of times a patient's veins must be accessed for blood draws. RHCs report that when laboratory tests are ordered that are not provided by the RHC, such as a comprehensive blood count (CBC), their patients are often sent to the nearest hospital that would have a full-service laboratory available to perform the test. A CBC test looks at a patient's overall health and can detect a wide range of conditions that the hemoglobin and hematocrit tests cannot. This ensures comprehensive patient care and may result in a decreased need for follow-up testing and decreased patient turnaround time.[916]

Examination of stool specimens for occult blood, frequently referred to as fecal occult blood tests (FOBTs), are used to detect gastrointestinal bleeding as an indicator for colorectal cancer. FOBTs that are performed in the outpatient setting are typically self-administered at home and submitted to a laboratory.[917] The national guidelines, including those of the US Preventive Services Task Force and American Cancer Society, explicitly specify that colorectal cancer (CRC) screening using FOBT should be done at home.[918] [919] The patient may be inconvenienced by having to mail the test themselves, but at-home tests provide the patient the ability to collect more samples, which may limit the chances of false test results.[920]

Currently, there are approximately 5,462 Medicare-certified RHCs. Applying the most recent data from 2021, 66 percent (3,605) of RHCs are designated as ''provider-based,'' which are owned and operated as an integral part of a hospital, nursing home, or home health agency. The remaining 34 percent (1,857) of RHCs are ''independent clinics'' and, though uncommon, may be owned and/or operated by a healthcare system. Therefore, we assume that, at most, half of the independent clinics, for a total of 929 RHCs, will continue to provide H&H tests because it is less likely that they are a part of a healthcare system. As a result, we assume that 4,534 (3,605 provider-based RHCs + 929 independent clinics) RHCs will continue to refer patients to a fully certified laboratory rather than directly provide the H&H test or examine stool specimens for occult blood on site. Because the regulatory requirements at § 491.9 states that RHCs must provide these tests on-site, RHCs must have and maintain the appropriate equipment to perform these tests, even if the equipment is not utilized. There are variations in the H&H testing equipment RHCs may use; however, we note that the average cost of an H&H meter or analyzer costs approximately $1,200 for the system and is replaced on average every 3 years. The systems also have an approximate $100 annual maintenance fee. We estimate that over the next 3 years, 4,534 RHCs will each save approximately $1,500. This would result in a total annual savings of $2,267,000 ((4,534 RHCs that typically refer patients to a fully certified laboratory × $1,500)/3). After 3 years, the RHC program will save a total of $6,801,000 (4,534 × $1,500).

Likewise, there are various FOBTs used to screen for colorectal cancer. One study reviewed a hospital's medical records over a 4-year period and found

[915] Centers for Medicare & Medicaid Services. (2020, February 21). State Operations Manual Appendix G—Guidance for Surveyors: Rural Health Clinics (RHCs) (pp. 63–64). *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf.*

[916] Mayo Foundation for Medical Education and Research. (2023, January 14). *Complete blood count (CBC).* Mayo Clinic. *https://www.mayoclinic.org/tests-procedures/complete-blood-count/about/pac-20384919.*

[917] Wielandt, A.M., Hurtado, C., Moreno, M., Zárate, A., & López-Köstner, F. (2021). Test de sangre oculta en deposiciones para programas de cribado de cáncer colorrectal: actualización [Fecal occult blood test for colorectal cancer screening]. *Revista medica de Chile, 149*(4), 580–590. *https://doi.org/10.4067/s0034–98872021000400580.*

[918] US Preventive Services Task Force, Bibbins-Domingo, K., Grossman, D. C., Curry, S.J., Davidson, K.W., Epling, J.W., Jr, García, F.A.R., Gillman, M.W., Harper, D.M., Kemper, A.R., Krist, A. H., Kurth, A.E., Landefeld, C.S., Mangione, C.M., Owens, D.K., Phillips, W.R., Phipps, M.G., Pignone, M.P., & Siu, A.L. (2016). Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA, 315*(23), 2564–2575. *https://doi.org/10.1001/jama.2016.5989.*

[919] Smith, R.A., Andrews, K.S., Brooks, D., Fedewa, S.A., Manassaram-Baptiste, D., Saslow, D., Brawley, O.W., & Wender, R.C. (2018). Cancer screening in the United States, 2018: A review of current American Cancer Society guidelines and current issues in cancer screening. *CA: a cancer journal for clinicians, 68*(4), 297–316. *https://doi.org/10.3322/caac.21446.*

[920] Collins JF, Lieberman DA, Durbin TE, Weiss DG. Accuracy of screening for fecal occult blood on a single stool sample obtained by digital rectal examination: a comparison with recommended sampling practice. *Ann Intern Med.* 2005;142(2):81-85.

that the laboratory cost for an FOBT is approximately $5 per test.[921] We have received the following Medicare statistical information from CY2021—CY2023 Medicare claims. The annual average number of Medicare beneficiaries who received a colorectal cancer screening using FOBT from an RHC is 264. Therefore, the annual savings removing the ''Examination of stool specimens for occult blood'' requirement will save RHCs $1,320 (264 tests × $5).

8. Clinical Laboratory Fee Schedule

In section III.D. of this final rule, we outline statutory revisions to the data reporting period and phase-in of payment reductions under the CLFS. In accordance with section 502 of the FCAOEA, 2024, we proposed certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for CDLTs that are not ADLTs, we proposed to update certain definitions and revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2025. Section 502(b) of the FCAOEA, 2024 delayed the next data reporting period under the CLFS for CDLTs that are not ADLTs by 1 year, that is, it required the next data reporting period for these tests to take place during the period of January 1, 2025, through March 31, 2025. Subsequently, the next private payor rate-based CLFS update for these tests would be effective January 1, 2026, instead of January 1, 2025. In addition, we proposed conforming changes to our requirements for the phase-in of payment reductions to reflect section 502(a) of the FCAOEA, 2024. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2024, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

However, CAEA, 2025 (Pub. L. 118–83) was passed on September 26, 2024, after the publication of the proposed rule and close of the comment period. Section 221 of that law delayed data reporting requirements for CDLTs that are not ADLTs, as well as the phase-in of payment reductions under the CLFS from private payor rate implementation under section 1834A of the Act. Specifically, as amended by section 221(b), section 1834A(1)(B) of the Act now provides that, in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that: (i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2025; (ii) reporting is required during the period beginning January 1, 2026, and ending March 31, 2026; and (iii) reporting is required every 3 years after the period described in subparagraph (ii). Essentially, data reporting will now be required during the period of January 1, 2026, through March 31, 2026, instead of January 1, 2025, through March 31, 2025. The 3-year data reporting cycle for CDLTs that are not ADLTs will resume after that data reporting period.

Section 221 of the CAEA, 2025 does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, the next data reporting period for CDLTs that are not ADLTs (January 1, 2026, through March 31, 2026) will continue to be based on the data collection period of January 1, 2019, through June 30, 2019.

Section 221(a) of the CAEA, 2025 further amends the provisions in section 1834A(b)(3) of the Act pertaining to the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2028. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2025 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2025 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2024. Finally, section 221(a) further amends section 1834A(b)(3)(B)(iii) of the Act to specify that the applicable percent of 15 percent will apply for CYs 2026 through 2028.We are finalizing the self-implementing conforming changes to the data reporting and phase-in of payment reductions at 42 CFR part 414, subpart G in accordance with section 221 of the CAEA, 2025.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016, through June 30, 2016) and data reporting period (January 1, 2017, through March 31, 2017). In addition, as outlined in section III.D. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the FCAOEA, 2024 and CAEA, 2025 amendments to the data reporting period will delay using updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, it is uncertain whether the delay in data reporting will result in a measurable budgetary impact. In other words, to assess the impact of delayed reporting and subsequent implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delays in data reporting after collecting actual updated applicable information from applicable laboratories and calculating the updated CLFS rates.

Regarding the conforming changes to our requirements for the phase-in of payment reductions, we note that for CYs 2026 through 2028, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. Based on data reported in the 2017 data collection period, we estimated 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2026.

9. Effects of Proposals Being Finalized Relating to the Medicare Diabetes Prevention Program Expanded Model

a. Effects on Beneficiaries

We proposed to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) align MDPP terminology and definitions with the proposed 2024 Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) Standard [922] definitions

[921] Gupta, A., Tang, Z., & Agrawal, D. (2018). Eliminating In-Hospital Fecal Occult Blood Testing: Our Experience with Disinvestment. *The American journal of medicine, 131*(7), 760–763. *https://doi.org/10.1016/j.amjmed.2018.03.002.*

[922] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

for ''in-person with a distance learning component,'' ''combination with an online component,'' and ''online''; (2) remove the MDPP bridge payment; (3) provide a more effective option for a beneficiary to self-report their weight in an MDPP distance learning session, by submitting 2 photos; (4) facilitate Medicare Administrative Contractors (MACs) in processing claims for a MDPP make-up session held on the same day as a regularly scheduled session by requiring use of an existing HCPCS modifier; and (5) align current rule language with previous rulemaking.

MDPP is a non-pharmacological behavioral intervention consisting of up to 22 sessions using a CDC approved National Diabetes Prevention Program (National DPP) curriculum.[923] CDC administers a national quality assurance program recognizing eligible organizations that furnish the National DPP through its evidence based DPRP Standards, which are updated every three years. The 2024 CDC DPRP Standards replace the 2021 CDC DPRP Standards in June 2024.[924]

The Calendar Year (CY) 2021 PFS final rule allowed virtual delivery of MDPP during the COVID–19 Public Health Emergency (PHE) (85 FR 84830). Improvements to MDPP in the Calendar Year 2024 final rule included a simplified payment structure to allow for fee-for-service (FFS) payments for beneficiary attendance, while retaining the performance-based payments for diabetes risk reduction (that is, weight loss) (88 FR 79241). This policy also extended certain PHE flexibilities including the option to deliver some or all MDPP sessions via distance learning, until December 31, 2027 (88 FR 79241). Another PHE flexibility extended through December 31, 2027, at 42 CFR 410.79(e)(3)(iii), is for MDPP suppliers to obtain weight measurements for beneficiaries using one of the following options: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the at-home digital scale of the MDPP beneficiary.

The 2024 CDC DPRP Standards were proposed after the CY 2024 PFS was finalized. To align with 2024 CDC DPRP Standards, we proposed to update the MDPP definition for ''online'' delivery to align with the proposed 2024 CDC DPRP definition. We also proposed to add terms and definitions for CDC's new modalities including ''in-person with a distance learning component'' and ''combination with an online component'' and to remove the existing ''combination'' term and definition. Lastly, we specified that MDPP make-up sessions must be provided in-person or via distance learning delivery, as required by the CY 2024 PFS final rule.[4]

Furthermore, the MDPP bridge payment (G9880), which is a payment made to the subsequent supplier for the first session when a beneficiary switches MDPP suppliers, is no longer necessary in MDPP's CY 2024 FFS payment structure and may increase risk for fraud, waste, or abuse. We proposed to remove the bridge payment from the MDPP CY 2025 Fee Schedule. In addition, we have identified a more effective option for a beneficiary to self-report their weight in an MDPP distance learning session. We have also identified the need to require suppliers to use Current Procedural Terminology (CPT) Modifier 76 to allow Medicare Administrative Contractors (MACs) to identify a claim for an MDPP make-up session held on the same day as a regularly scheduled session. Finally, we proposed to align current rule language with previous rulemaking pertaining to MDPP terminology, requirements, and payment structure.

All the changes finalized for MDPP in CY 2025 are conforming or administrative and expected to have a modest impact on beneficiaries' access to MDPP services. Aligning with 2024 CDC DPRP Standards for MDPP delivery modes may help expand beneficiary access by streamlining data submission for MDPP suppliers and increasing the number of MDPP eligible organizations that enroll in Medicare as MDPP suppliers. Additionally, allowing for MDPP make-up sessions to be scheduled on the same day as regularly scheduled sessions will increase flexibility for both MDPP suppliers and beneficiaries and may help expand access for beneficiaries with transportation and other scheduling issues that prevent scheduling sessions more than one day a week or month. Increased flexibility in scheduling MDPP sessions may help to address a lack of MDPP suppliers in certain communities and challenges related to beneficiary logistics concerning course attendance.

Additionally, we proposed to provide a more effective option to beneficiaries to self-report weight for a MDPP distance learning session, by allowing beneficiaries to submit two (2) photos to capture both the beneficiary weight on the digital scale and the beneficiary visible in their home. Current MDPP supplier standards at § 424.205 require beneficiary weight to be reported at each MDPP session attended. This change will help to address concerns voiced by MDPP suppliers who have reported that many of their beneficiaries are unable to take a picture while standing on their home scales due to risk of injury and physical health limitations. This new flexibility may promote more consistent collection of weight for MDPP sessions.

Lastly, we do not expect removing the MDPP bridge payment to have an impact on beneficiary access. This payment for the first session attended with a new supplier when a beneficiary switches MDPP suppliers is not necessary in MDPP's CY 2024 FFS payment structure that includes payment for every session attended and historically has been submitted by few MDPP suppliers.

Overall, these modifications address MDPP supplier and beneficiary needs based upon available monitoring and evaluation data received to date, feedback from Medicare Advantage plans and existing MDPP suppliers, and feedback from beneficiary focus groups. The changes are also in response to comments from interested parties made through public comments in response to prior rulemaking.

b. Effects on the Market

We anticipate that the conforming and administrative changes proposed in this rulemaking are likely to result in modest increases of MDPP suppliers and beneficiary access to the set of MDPP services. We anticipate that this will assist in contributing to a reduction of the incidence of diabetes among eligible Medicare beneficiaries. As of April 2024, there are approximately 810 in-person organizations nationally that are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes DPRP status. However, only 36 percent of these eligible in-person organizations are participating in MDPP.[925] Aligning with CDC DPRP delivery modes, particularly adding the new ''in-person with a distance learning component'' mode, is expected to help increase recruitment of new DPRP organization as MDPP suppliers, who currently would need to obtain both in-person and distance learning CDC DPRP recognition to deliver sessions via both modalities. Furthermore, only about one-third of MDPP suppliers have

[923] *https://www.cdc.gov/diabetes/prevention/resources/curriculum.html.*

[924] Centers for Disease Control and Prevention Diabetes Prevention Recognition Program. Standards and Operating Procedures. Requirements for CDC Recognition. June 2024. *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

[925] Centers for Disease Control and Prevention. Diabetes Prevention Recognition Program Application. Registry of All Recognized Organizations. *https://dprp.cdc.gov/Registry.*

submitted MDPP-related claims.[926] Our proposed change to remove the MDPP bridge payment will help to further simplify the payment structure, which is expected to have a positive impact on supplier claim submissions. While requiring MDPP suppliers to add a modifier to indicate that a claim is for a MDPP same day make-up session does add complexity because we proposed to use an existing CPT modifier in use and recognized by the MACs, we expect this addition to require minimal changes in claim processing systems. Additionally, this modifier is only to be used for same day make-up sessions, which are only allowed once per week, and, while an important tool to increase access for beneficiaries with barriers to participation in MDPP, are not expected to be used for most session attendance claims. In summary, we believe that having more flexibility in how the set of MDPP services are delivered will make MDPP more accessible to beneficiaries, particularly those who live in rural areas or in communities with gaps in MDPP supplier locations.

c. Payment for MDPP Services

Regulations at § 414.84 specify that MDPP suppliers may be eligible to receive payments for furnishing MDPP services and meeting performance targets related to beneficiary weight loss and attendance. We anticipate that the change to the MDPP payment structure will have minimal impact on total payment for MDPP services. A smaller proportion of MDPP suppliers, only 9.8 percent since the start of the program through April 2024, have submitted claims for the MDPP bridge payment, with an even smaller proportion of 2.7 percent having received payment for a bridge payment claim. According to CDC DPRP data, less than 1 percent of MDPP sessions are same day make-up sessions.[927] The total maximum payment per beneficiary for MDPP of $768 will remain unchanged by our finalized proposals.

d. Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

The changes this year for implementation in the CY PFS 2025 are expected to have no impact on Medicare spending.

[926] Unpublished MDPP monitoring data. 2023.

[927] Diabetes Prevention Recognition Program. Unpublished data. April 2024.

10. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As outlined in section III.F.2 of this final rule, we are finalizing to permanently allow periodic assessments to be furnished via audio-only communication when two-way audio-video communications technology is not available to the beneficiary, to the extent that it is authorized by SAMHSA and DEA at the time the service is furnished and all other applicable requirements are met. We also are finalizing to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone to the extent that the use of audio-video telecommunications technology to initiate treatment with methadone is authorized by DEA and SAMHSA at the time the service is furnished, an OTP determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform, and all other applicable requirements are met. We believe the Part B cost impact of these flexibilities for the use of telecommunications will be minimal because we do not expect that these flexibilities will significantly increase the frequency with which medically necessary intake activities and periodic assessments are furnished, and since the payment rate for these services will be the same regardless of if an OTP furnishes these services via telecommunications or in-person.

In section III.F.3 of this final rule, CMS finalized to update the payment rate for both intake activities (HCPCS code G2076) and periodic assessments (HCPCS code G2076) by adding in the value of the non-facility rate for SDOH risk assessments described by HCPCS code G0136 (*Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5–15 minutes, not more often than every 6 months*). We believe updating the payment amount for intake activities with an addition of HCPCS code G0136 will serve as a reasonable proxy to reflect the value and resources required by new SAMHSA standards for initial assessment service activities at § 8.12(f)(4)(i) that OTPs are required to provide, including an assessment to identify a patient's unmet HRSNs or the need for harm reduction intervention and recovery support services that are critical to the treatment of an OUD. Similarly, an update in the payment amount for periodic assessments will support OTPs in continuing to assess any changes in unmet HRSN, or harm reduction intervention and recovery support services needs throughout the duration of MOUD treatment. Currently, the CY 2024 payment rate for the intake add-on code (G2076) is $201.73 and adding the value of a crosswalk to the CY 2024 non-facility rate of $18.97 will result in a payment rate of approximately $220.70. The CY 2024 payment rate for periodic assessments (G2077) is $123.96 and adding the value of $18.97 will result in a payment rate of approximately of $142.93. These payment rates will continue to be updated annually by the percentage increase in the Medicare Economic Index (MEI) and the Geographic Adjustment Factor (GAF) as codified in § 410.67(d)(4)(ii) through (iii). According to historical claims data for intake activities (HCPCS code G2076) and periodic assessments (HCPCS code G2077) furnished by OTPs from the beginning of CY 2020 through the end of CY 2023, the number of claims for intake activities and periodic assessments are low. Due to low utilization of the intake activities and periodic assessments add-on codes, CMS estimates that an increase in the add-on payment amount to HCPCS codes G2076 and G2077 by $18.97 per claim will still result in a negligible cost to the Medicare program. Furthermore, we are finalizing new add-on codes for coordinated care and referral services (G0534), patient navigational services (G0535), and peer recovery support services (G0536). Coordinated care and/or referral services are based on a crosswalk to the CY 2024 PFS non-facility rate of the community health integration base HCPCS code G0019 and divided by two; patient navigational services are based on a crosswalk to the CY 2024 PFS non-facility rate of the principal illness navigation base HCPCS code G0023 and divided by two; and peer recovery support services are based on a crosswalk to the CY 2024 PFS non-facility rate of the principal illness navigation—peer support base code HCPCS code G0140 divided by two. All these codes are based on at least 30 minutes of services provided and will be updated annually by the percentage increase in the Medicare Economic Index (MEI) and the Geographic Adjustment Factor (GAF) as codified in § 410.67(d)(4)(ii) through (iii). Since there is not yet sufficient utilization data available on the frequency of which coordinated care and referral services (HCPCS codes G0534), patient navigational services (HCPCS codes G0535), and peer recovery support services (HCPCS codes G0536) are

furnished by an OTP, and since CMS is still collecting utilization data on the new CHI, PIN, and PIN–PS codes established in CY 2024 which HCPCS codes G0534, G0535, and G0536 are based on, we cannot estimate the financial impact of these new codes on the Medicare program.

Lastly, in section III.F.4 of this final rule, we finalized to establish payment for new opioid agonist and antagonist medications that were recently approved by the FDA. We finalized to include a new add-on code to the bundled payment for a new opioid overdose reversal product, nalmefene hydrochloride nasal spray product (Opvee®), which includes one carton of two, 2.7 mg nasal sprays of nalmefene. We will price the drug component of this add-on code for nalmefene according to the ASP payment methodology set forth in section 1847A, except that the payment amount shall be ASP+0. The non-drug component of this add-on code will also include overdose education furnished in conjunction with nalmefene, and it will be updated annually by the percentage increase in the MEI and GAFs consistent with other opioid antagonist medications in § 410.67(d)(4)(ii) through (iii). We are limiting Medicare payment to OTPs for nalmefene to one add-on code every 30 days; however, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of nalmefene dispensed by the OTP, to the extent that it is medically reasonable and necessary to furnish additional doses of nalmefene. We also finalized payment for the weekly formulation of the new extended-release injectable buprenorphine product Brixadi®, via a new weekly bundled payment code that includes a drug and non-drug component. We finalized to price the drug component consistent with our payment methodology for implantable and injectable medications codified § 410.67(d)(2)(i)(A), and we finalized to limit the payment amount to 100-percent of ASP and to use a crosswalk to the weekly Brixadi® formulation described by HCPCS code J0577 (*Injection, buprenorphine extended release (brixadi), less than or equal to 7 days of therapy*). The non-drug component (individual and group therapy, SUD counseling, toxicology testing) will also include administration of an injection based on CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*); updated annually by the percentage increase in MEI and GAFs. CMS further finalized to update the drug-component of the existing HCPCS code (G2069) for monthly injectable buprenorphine to include the monthly formulation of Brixadi® based on a crosswalk to HCPCS code J0578 *(Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy*). We are finalizing to continue using the existing payment methodology for the non-drug component of G2069, but we will instead calculate the drug component by volume-weighting the ASP for all the NDCs crosswalked to HCPCS codes for monthly Brixadi® and Sublocade®. Since the payment methodology for the new add-on code for Opvee® (G0532), the weekly bundled payment for weekly Brixadi® (G0533), and the update to the monthly bundled payment for injectable buprenorphine (HCPCS code G2069) is based on comparable and existing drugs billed under the Medicare OTP benefit, and assuming an OTP may provide these new drugs to a Medicare beneficiary in lieu of the comparable and existing drugs under the Medicare OTP benefit (e.g, Opvee® instead of Narcan® or Kloxxado®, or the weekly or monthly formulation of Brixadi® instead of Sublocade®), then CMS estimates the financial impacts of these new drugs would be negligible.

11. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2024, 10.8 million Medicare beneficiaries receive care from a health care provider in one of the 480 ACOs participating in the Shared Savings Program, one of the largest value-based care programs in the country. The modifications to Shared Savings Program policies we are finalizing with this final rule advance Medicare's value-based care strategy of growth, alignment, and equity, with many provisions supporting more than one of these goals. The policies in this final rule are designed, in part, to further improve the quality of care furnished by ACOs by revising the quality performance standard and reporting requirements, broaden program participation, particularly by ACOs in and providing care to underserved communities, and promote the continued integrity and fairness of Shared Savings Program financial calculations.

As described in section III.G.7.b of this final rule, under the benchmarking methodology for agreement periods beginning on January 1, 2024, and in subsequent years, established in earlier rulemaking, CMS calculates two adjustments in establishing the historical benchmark, a regional adjustment (refer to § 425.656) and a prior savings adjustment (refer to § 425.658). Under this approach, we determine which adjustment is applied to the benchmark, either the regional adjustment, prior savings adjustment, or no adjustment (refer to § 425.652(a)(8) and (c)). One of the changes to the Shared Savings Program financial methodology finalized with the CY 2024 PFS final rule (see 88 FR 79185 through 79195, see also 88 FR 79494 and 79495) was to mitigate the impact of the negative regional adjustment on the benchmark for ACOs in agreement periods beginning on January 1, 2024, and in subsequent years. We explained our belief that this change would further encourage continued participation among high-cost ACOs that serve medically complex beneficiaries by eliminating the potential of a lower benchmark due to an overall negative regional adjustment, and may also encourage ACOs serving such populations that may have otherwise been discouraged from participating in the Shared Savings Program by the prospect of a lower benchmark to join (see 88 FR 79188, see also 88 FR 79494 and 79495). Under this approach, an ACO with an overall negative regional adjustment that was not eligible for a prior savings adjustment would ultimately receive no adjustment, upward or downward, to its benchmark (see § 425.652(a)(8)(iii) and see also 88 FR 79190). The Health Equity Benchmark Adjustment (HEBA) we are finalizing with modifications, described in section III.G.7.b of this final rule, will add a third avenue for ACOs to receive a positive adjustment to their historical benchmark, and will be most impactful for new ACOs serving medically complex, high-cost populations in underserved communities.

We combined an analysis of the impact of the HEBA on currently participating ACOs with the projected impact of HEBA on new ACOs not yet participating in the Shared Savings Program, to generate an overall impact estimate of the HEBA. The HEBA would likely have a limited impact on currently participating ACOs. Only about 34 percent of the 456 ACOs participating in performance year 2023 were estimated to have a proportion of assigned beneficiaries who were enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid equal to or greater than 15 percent, which is the new HEBA eligibility threshold that is being finalized in this final rule. The 15 percent threshold will have to be met

for an ACO to be eligible for the HEBA under the final policies (as discussed in section III.G.7.b. of this final rule, and specified in § 425.662(b)(3) as finalized by this final rule). Of the 34 percent of ACOs participating in performance year 2023 that were estimated to have a proportion of assigned beneficiaries who were enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid equal to or greater than 15 percent, only about one-in-five of such ACOs were estimated to not already be eligible for a higher benchmark adjustment from either a positive regional adjustment or a prior savings adjustment. That is, about 7 percent of ACOs participating in performance year 2023 were estimated to benefit from the HEBA policy at rebasing (with a median effect of about a 1 percent increase to the benchmark), because an ACO would receive the HEBA only if the HEBA were higher than the existing ''higher of'' adjustment method (see discussion in section III.G.7.b of this final rule, and see § 425.652(a)(8)(ii)(B)(*1*) as revised by this final rule, and § 425.662(c) as added by this final rule). This represents roughly a 60 percent increase in the number of existing ACOs estimated to benefit from the HEBA under an eligibility threshold of 15 percent, compared to the 20 percent threshold originally proposed in the CY 2025 PFS proposed rule. Although the HEBA is projected to increase program spending for existing ACOs by about $140 million over 10 years, an overall net savings is projected after also including the impact estimated from new ACOs, as detailed in the following discussion.

The number of ACOs that would be incentivized to participate in the Shared Savings Program by the HEBA is uncertain. Changes to the Shared Savings Program finalized in the CY 2023 and CY 2024 PFS final rules were already projected to increase program participation among ACOs with higher spending and provide more opportunities for improving care and reducing spending (see 87 FR 70191 through 70196, and 88 FR 79494 and 79495). Therefore, we can reasonably estimate that at least some new ACOs may join and succeed in the Shared Savings Program regardless of the benefit afforded to them by the HEBA. Savings to the Shared Savings Program are expected to grow to the extent that the HEBA were to cause new, high-spending ACOs to participate—that is, ACOs whose assigned beneficiary populations have risk-adjusted spending that is significantly higher than corresponding regional benchmark spending at baseline. We project in the 2034 performance year, the HEBA would likely increase program participation by 25 additional ACOs (but our estimates of increased program participation range from 0 to 100 additional ACOs), as compared to program participation today, and on net increase Federal Medicare program savings by $400 million over the 2025–2034 period because of this increased program participation.

The estimated impact of the HEBA, accounting for both its impact on currently participating ACOs that are assumed to renew their participation in the Shared Savings Program over the next 5 years and new ACOs that are expected to participate in the program for the first time over the next 10 years, is shown in Table 115. Mean Shared Savings Program spending is expected to be reduced by $260 million over the next 10 years as a result of the HEBA. However, uncertainty regarding the number of high spending ACOs that will participate in light of a HEBA, combined with uncertainty regarding high spending ACOs' savings potential, results in a wide range of potential impacts in total over that 10 year period, from $2.2 billion in net savings at the 10th percentile (that is, only 10 percent of stochastic trials reduced Federal spending by a greater magnitude than $2.2 billion) to $1.2 billion in net spending at the 90th percentile.

TABLE 115: Projected Impact of Health Equity Benchmark Adjustment ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	20	30	30	20	10	-20	-60	-80	-100	-110	**-260**
Estimate Range:											
Low Estimate (10th Percentile)	-10	-20	-40	-80	-140	-220	-310	-390	-450	-500	**-2,160**
High Estimate (90th Percentile)	50	70	90	120	140	140	140	150	160	180	**1,240**

For the calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts used in Shared Savings Program financial calculations, upon reopening a payment determination pursuant to § 425.315(a) (described in section III.G.7.c of this final rule), some ACOs will selectively elect to request reopening for a prior performance year. As a result, we project at least some degree of higher program spending for increased shared savings payments (or reduced loss recoupments) in cases for which CMS decides to reopen the payment determination and issue a revised initial determination to account for the impact of improper payments. However, because reopening will not be limited to adjusting performance year and benchmark year expenditures for ACO assigned beneficiaries but will also impact other potentially offsetting calculations including regional and national expenditure trends used to update ACO benchmarks, and because, in addition to the reopening, CMS will also adjust the historical benchmark calculated for a potential subsequent

agreement period, the frequency of requests, and the net impact of any given request, are likely to be limited. The reopening policy is projected to increase program spending by $60 million in total over the 2025 to 2034 period, ranging from $30 million at the 10th percentile to $90 million at the 90th percentile, as shown in Table 116.

TABLE 116: Projected Impact for Modifications to Specify the Calculation Methodology to Account for Improper Payments in Recalculating Expenditures and Payment Amounts used in Financial Calculations, Upon Reopening a Payment Determination ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	10	0	0	0	0	10	10	10	10	10	**60**
Estimate Range:											
Low Estimate (10th Percentile)											**30**
High Estimate (90th Percentile)											**90**

Note: Projections at the 10th and 90th percentile are shown in aggregate but not at the annual level because scenarios contributing to the high estimate projection generally involve elevated spending in a limited number of years rather than consistently higher spending across the projection period.

The methodology for excluding payment amounts for HCPCS and CPT codes exhibiting SAHS billing activity, as described in section III.G.7.d of this final rule, is anticipated to be utilized only in rare and extreme cases where a number of criteria are satisfied, including that the level of billing represents a significant claims increase representing a deviation from historical utilization trends that is unexpected and not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services during a limited time period. Even in cases where CMS may apply the adjustment to Shared Savings Program calculations for SAHS billing activity, for CY 2024 or subsequent calendar years, there is no expectation that it will necessarily increase or decrease overall shared savings or shared losses because the policy will be applied systematically across all ACOs in the Shared Savings Program in a method that adjusts both performance year and benchmark year expenditures for ACO assigned beneficiaries and regional and national expenditures used in benchmark calculations. However, this policy would have the benefit of reducing potential costs generated by selective reopening requests under the reopening policy, because it would prevent extreme cases of SAHS billing activity from injecting variation in the distribution of ACO shared savings and loss calculations which could lead to an elevated number of selective reopening requests from ACOs predicting that reopening would improve their financial outcome. For this reason, without the policy to adjust Shared Savings Program calculations for SAHS billing activity during CY 2024 or subsequent calendar years, the estimated impact shown in Table 116 would have included between $100 to $300 million in additional projected spending from selective reopening requests.

We estimate that there would be no additional program expenditures stemming from the implementation of the prepaid shared savings payment option, which will provide eligible ACOs with additional cash flow to encourage their investment in activities that could potentially reduce costs for the Medicare program and beneficiaries and improve the quality of care furnished to their assigned beneficiaries. Any risk of higher program spending as a result of finalization of our prepaid shared savings policy would be fully mitigated by the fact that eligibility will be limited to ACOs that CMS estimates are most likely to earn shared savings, and any prepaid shared savings payments an ACO receives will have to be repaid to CMS. CMS will be protected by the ACOs' repayment mechanisms in the event that an ACO does not earn shared savings or cannot otherwise repay the amount owed to CMS. On the other hand, there is a high degree of uncertainty regarding whether (a) a meaningful number of ACOs will choose this option given the requirements for how prepayments must be spent, and (b) the potential impact (if any) that participation in this option will have on the cost of care.

As to this uncertainty, our analysis assumed that up to 30 ACOs would opt to receive prepaid shared savings per year (with the probability distribution skewed toward zero participants), with a 33 percent chance that ACOs receiving prepaid shared savings would respond by reducing spending for assigned beneficiaries by between 0 to 2 percentage points (with the probability distribution skewed toward zero impact) as compared to their current spending on assigned beneficiaries.[928] This projection accounts for annual prepaid shared savings (offset by eventual recoupments and/or repayments) of

[928] The assumptions allow for a limited possibility that performance by ACOs receiving prepaid shared savings could generate shared savings comparable to the savings generated by certain ACOs in the ACO Investment Model. Abt Associates, Evaluation of the Accountable Care Organization Investment Model, Final Report (September 2020), available at *https://www.cms.gov/priorities/innovation/data-and-reports/2020/aim-final-annrpt.*

roughly $2 million per ACO participating in the payment option. The associated impact on ACO spending was projected to be nominal. Both at the mean and at the 90th percentile the projected net impacts on Medicare spending round to zero. At the 10th percentile (the optimistic end of the range), we project small net savings of $20 million in total to the Medicare Program over 10 years, as shown in Table 117.

TABLE 117: Projected Impact for the Prepaid Shared Savings Option ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	0	0	0	0	0	0	0	0	0	0	**0**
Estimate Range:											
Low Estimate (10th Percentile)											**-20**
High Estimate (90th Percentile)											**0**

Note: Projections at the 10th and 90th percentiles are shown in aggregate but not at the annual level because scenarios contributing to the $20 million savings at the 10th percentile are too small to round above zero in any given year.

The remaining changes to the Shared Savings Program regulations are not estimated to have an impact on program spending at the aggregate level. These changes include requiring Shared Savings Program ACOs to report the APP Plus quality measure set beginning in performance year 2025, that will incrementally grow to comprise of 11 measures, consisting of the 6 measures in the existing APP quality measure set and 5 new measures from the Adult Universal Foundation measure set that will be incrementally incorporated into the APP Plus quality measure set over performance years 2025 through 2028 or the performance year that is one year after eCQM specifications become available for Quality ID: 487 Screening for Social Drivers of Health and Quality ID: 493 Adult Immunization Status, whichever is later; focusing the collection types available to Shared Savings Program ACOs for reporting the APP Plus quality measure set in performance years 2025 and 2026 to include eCQM/MIPS CQM/Medicare CQM collection types, and in 2027 and subsequent performance years, to include eCQM/Medicare CQM collection types; requiring Shared Savings Program ACOs that report the APP Plus quality measure set to report on all required measures in the APP Plus quality measure set, as applicable; establishing a Complex Organization Adjustment for Virtual Groups and APM Entities, including Shared Savings Program ACOs, when reporting eCQMs; scoring Medicare CQMs using flat benchmarks in their first 2 performance periods in MIPS; and extending the eCQM reporting incentive in order to promote the adoption of eCQMs and also extending the reporting incentive to ACOs reporting MIPS CQMs in performance years 2025 and 2026 to support ACOs in meeting the Shared Savings Program quality performance standard. Additional changes include permitting continued participation by ACOs whose number of assigned beneficiaries falls below 5,000 during their agreement period; ensuring clarity of provisions on application procedures; revisions to the definition of primary care services under § 425.400(c) for purposes of beneficiary assignment; refining advance investment payment policies; providing clarity and consistency in provisions of the Shared Savings Program regulations on calculation of the ACO risk score growth cap in risk adjusting the benchmark each performance year and the regional risk score growth cap in calculating the regional component of the three-way blended benchmark update factor; and modifying beneficiary notification requirements.

The combined impacts for all Shared Savings Program provisions are shown in Table 118.

TABLE 118: Projected Impact of Medicare Shared Savings Program Provisions (Individually Shown in Tables 115, 116 and 117) ($ Millions; Negative Values Represent Savings to the Program)

	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Impact Estimate	30	30	30	20	10	-10	-50	-70	-90	-100	**-200**
Estimate Range:											
Low Estimate (10th Percentile)	0	-20	-40	-80	-140	-210	-300	-380	-440	-490	-2,100
High Estimate (90th Percentile)	60	70	90	120	140	150	150	160	170	190	1,300

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and new policies adopted in section III.G. of this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: allowing eligible ACOs to receive prepaid shared savings, as described in section III.G.5 of this final rule; using a calculation methodology to account for the impact of improper payments in recalculating expenditures and payment amounts for certain Shared Savings Program financial calculations, upon reopening an ACO's payment determination and issuing a revised initial determination pursuant to § 425.315(a), as described in section III.G.7.c of this final rule; using a methodology for certain Shared Savings Program financial calculations to mitigate the impact of SAHS billing activity occurring in CY 2024 or subsequent calendar years, as described in section III.G.7.d of this final rule; and making technical changes to the provision describing how we calculate the weights applied when capping growth in regional risk scores as part of the regional component of the three-way blended benchmark update factor, as described in section III.G.7.f of this final rule. When considered together these changes to the Shared Savings Program's payment methodology are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the ability for ACOs to sustain effective participation particularly in serving medically complex, high-cost populations in underserved communities, and promoting integrity and fairness and ensuring the accuracy of Shared Savings Program financial calculations. These changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule, we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that required section 1899(i)(3) of the Act authority (see 87 FR 70195 and 70196). The marginal impact of the proposed changes in the CY 2024 PFS final rule were estimated to lower net spending by $330 million over the subsequent 10-year period for all new policies combined, including the cap an ACO's regional service area risk score growth, the addition of a new third step to the beneficiary assignment methodology, and the revised approach to identify the assignable beneficiary population (88 FR 79496). The marginal impact of the changes in this final rule are estimated to lower net spending by an additional $200 million in total through 2034. Although the provisions in this final rule that require section 1899(i) of the Act authority are estimated to increase spending by only $60 million over 10 years, the cumulative impact of all policies (including those in this final rule) are estimated to result in more than $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies that require section 1899(i)(3) of the Act authority. Therefore, we estimate that program expenditures associated with the implementation of the implementation of the provisions in this final rule would not be greater than those that would result under the statutory payment model, consistent with the requirements of section 1899(i)(3)(B) of the Act.

We will continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. Additional Shared Savings Program data beginning to accumulate after the end of the COVID–19 public health emergency, along with emerging information on the characteristics of new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024 and January 1, 2025, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. In the event that we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

12. Medicare Part B Payment for Preventive Services

In section III.H.2. of this final rule, based on the proposals in section III.M of this final rule, we clarify that a physician's order is no longer required for the administration of a hepatitis B vaccine in Part B, which will facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We also finalize a policy that payment for hepatitis B vaccines and their administration be made at 100 percent of reasonable cost in RHCs and FQHCs, separate from the FQHC PPS or the RHC All-Inclusive Rate (AIR) methodology, in order to streamline payment for all Part B vaccines in those settings. We believe that Medicare spending impacts from both of these proposals will be negligible, as hepatitis B vaccines are already available to all Medicare enrollees under either Part B or Part D. While we believe that there will be an uptake of hepatitis B vaccines under Part B as shifted from Part D, we believe that this impact on the Part B program will be negligible for several reasons, including the fact that a portion of current beneficiaries have already received the hepatitis B vaccine through either Part B or Part D, and since a significant number of individuals will likely receive this vaccine by the time they are Medicare age due to current CDC recommendations (please see section III.M of this final rule for more information).

In section III.H.3. of this final rule, we finalize a fee schedule for Drugs Covered as Additional Preventive Services (DCAPS), per section 1833(a)(1)(W)(ii) of the Act. We also set payment limits for supply and administration fees for DCAPS drugs that are similar to those fees for drugs paid under the ASP payment methodology set forth in section 1847A of the Act, and we set payment limits for DCAPS drugs and any supply and administration fees in RHCs and FQHCs according to this same fee schedule. We believe impacts from these policies will be minimal as well. While no drugs are currently covered as DCAPS, DCAPS drugs are likely to be covered under Part D before coverage under the Part B additional preventive services benefit would commence.

13. Impact of Provisions for Medicare Prescription Drug Inflation Rebate Program

In this final rule, we are codifying existing policies established in program guidance as well as revised and new policies to implement the Medicare Part B Drug Inflation Rebate Program, including the requirement for manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation; criteria for the identification of Part B rebatable drugs; computation of the beneficiary coinsurance adjustment for Part B rebatable drugs; determination of the rebate amount for Part B rebatable drugs; reduction of the rebate amount for Part B rebatable drugs in shortage and when there is a severe supply chain disruption; removal of units subject to discarded drugs; provision of rebate reports to each manufacturer of a Part B rebatable drug; reconciliation; and establishment of enforcement provisions via civil money penalties.

Additionally, we are codifying existing policies established in program guidance as well as revised and new policies to implement the Medicare Part D Drug Inflation Rebate Program, including the requirement for manufacturers to pay rebates for certain Part D drugs and biological products; covered under Part D; criteria for the identification of Part D rebatable drugs; determination of the rebate amount for Part D rebatable drugs; reduction of the rebate amount for shortages and when there is a severe supply chain disruption or likely shortage; provision of rebate reports to each manufacturer of a Part D rebatable drug; reconciliation; and establishment of enforcement provisions via civil money penalties.

We do not expect these policies to have a material impact on inflation rebates, as the majority of these policies codify existing guidance. New policies or changes to existing policies in guidance are technical provisions that we do not expect to have a material impact on the calculation of total rebates in aggregate. Additionally, no data is available at this time to estimate the amount of billing units that will be subject to discarded drug refunds.

As outlined in section III.I. of this final rule, for Part D drug inflation rebates, we will implement at § 428.203(b)(2) section 1860D–14B (b)(1)(B) of the Act, which requires the Secretary to exclude 340B units from the total number of units used to calculate the total rebate amount owed by a manufacturer, beginning on January 1, 2026. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026.

In the proposed rule (89 FR 61969), we proposed to use an estimation methodology to remove a percentage of units from the total number of units used to calculate the total rebate amount to remove 340B units from Part D drug inflation rebate calculations. That percentage would be equal to the total number of units purchased under the 340B Drug Pricing Program for an NDC–9, divided by the number of total units sold of that NDC–9. After further consideration and taking into account the comments received on the proposed estimation methodology, we did not finalize the estimation policy for the applicable period that begins on October 1,2025. Instead, we plan to explore the establishment of a Medicare Part D claims data repository to use for removal of 340B units from the calculation of Part D inflation rebates starting January 1, 2026. We plan to continue exploring the development of detailed policies and requirements related to any such repository for future rulemaking related to this topic and the exclusion of 340B units starting January 1, 2026.

CMS does not currently have data on 340B claims for the Part D program or at the drug level in general, which prevents CMS from quantifying the impact of this provision. While we expect that the exclusion of 340B units from Part D inflation rebates will reduce the amount of rebates collected through this program, the magnitude of this reduction is unknown due to the lack of data on 340B claims for the Part D program.

14. Modifications to Coverage of Colorectal Cancer Screening

In section III.K. of this rulemaking we discuss that we are finalizing as proposed, provisions to update and expand coverage for CRC screening by (1) removing coverage for the barium enema procedure in regulations at § 410.37, (2) adding coverage for the computed tomography colonography (CTC) procedure in regulations at § 410.37, and (3) expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (described and authorized in NCD 210.3) returns a positive result.

We do not anticipate our provision removing coverage for the barium enema procedure will result in a significant financial impact on the Medicare program. An internal claims analysis found that Medicare Fee for Service only paid 62 claims for the screening barium enema procedure in calendar year 2021 and only 72 claims for the screening barium enema procedure in calendar year 2022.

We do not anticipate our provision adding coverage for the CTC procedure for CRC screening will result in a significant financial impact on the Medicare program. CTC could be an appropriate option for patients and clinicians who seek a visualization procedure as a first step in CRC screening that is less invasive and less burdensome on the patient (including those who are medically fragile or have complex or usual anatomy) compared to optical colonoscopy. We expect that patients will often choose CTC as an alternative to colonoscopy for CRC screening and that future increased utilization of CTC will be balanced, in part, by avoided screening colonoscopies. Our goal is that the patient and their clinician make the most appropriate choice in CRC screening, which includes considerations of the risks, burdens and tradeoffs for each covered test or procedure. We expect that utilization of CTC for CRC screening will be modest, especially considering that CTC requires bowel preparation and travel to an outpatient clinical services site (similar to a colonoscopy) and also considering the availability of non-invasive stool-based tests that can be administered at home and mailed to a lab. A 2015 study titled ''Medicare cost of colorectal cancer screening: CT colonography vs. optical colonoscopy'' concluded that CTC is 29 percent less expensive than colonoscopy (accounting for related procedures) for the Medicare population in the base scenario. Although the CTC cost advantage is increased or reduced under alternative scenarios, it is always positive.[929]

We do not anticipate our provision expanding a ''complete colorectal cancer screening'' in § 410.37(k) to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test returns a positive result will produce a significant financial impact on the Medicare program. We expect that patients will choose either a stool-based test or a blood-based biomarker test for a non-invasive first option in CRC screening and that patients who choose a blood-based biomarker test within the context of a complete colorectal cancer screening under our proposal will be offset, in part, by the avoided utilization of a stool-based test.

In conclusion, we anticipate that updating and expanding coverage for CRC screening will result in some additional utilization, but that additional utilization will be balanced, in part or in whole, by avoided utilization of alternative types of tests as well as benefits and savings resulting from increased prevention and early detection (allowing for less invasive and more effective treatment). We did not receive public comments on this impact analysis.

15. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

In section III.L of this final rule, we finalized two updates to the CMS EPCS Program. We finalized that prescriptions written for a beneficiary in a LTC facility will not be included in determining compliance under the CMS EPCS Program until January 1, 2028. We also finalized that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility will commence on or after January 1, 2028. Without these changes, if we keep the existing date of January 1, 2025, as the beginning date for which these prescriptions will be considered for compliance purposes for the CMS EPCS Program and on which we would begin to take compliance actions based on these prescriptions, we estimate at least 6,800 prescribers would become non-compliant due to CMS including prescriptions written for beneficiaries in LTC in the CMS EPCS Program compliance threshold calculation. This estimate is based on data from calendar year 2022 and is prior to considering emergency and disaster exceptions and waivers, which could reduce these numbers. This policy change allows prescribers additional time to adopt the new e-prescribing standard, NCPDP SCRIPT standard version 2023011, and utilize EPCS. Additionally, this policy will prevent an increased number of prescribers from potentially applying for a waiver for circumstances beyond their control due to difficulty of reliably conducting EPCS for beneficiaries in LTC facilities by the current deadline of January 1, 2025.

We do not believe this proposal will cause additional costs as we are only extending the deadline by which we will include prescriptions written for beneficiaries in LTC facilities in the CMS EPCS Program compliance threshold calculation and not modifying the requirement to become compliant. We also note that beneficiaries in LTC facilities may not receive the full benefits of EPCS, which we describe in the CY 2022 PFS final (86 FR 65362), until a later date, but we believe the delay is necessary due to the logistical challenges of prescribers electronically prescribing controlled substances prescriptions for beneficiaries in LTC facilities.

We solicited public comments on our impact assumptions.

We did not receive public comments on our assumptions, and therefore, we are finalizing our impact assumptions without modification.

16. Expand Hepatitis B Vaccine Coverage

In section III.M. of this rulemaking, we are finalizing our proposal to expand Hepatitis B vaccine coverage by revising our regulatory definition for intermediate risk groups by adding a new paragraph to include individuals who have not previously received a completed hepatitis B vaccination series or whose vaccination history is unknown (§ 410.63(a)(2)).

Hepatitis B vaccine is currently covered under Medicare Part B for enrollees who are at intermediate or high risk of contracting hepatitis B virus, and, for Part D enrollees who do not fall into those categories the vaccine may be covered under Medicare Part D.[930] In 2021, about 51 million of 65 million Medicare beneficiaries were enrolled in Part D and 21,629 received the vaccine. In 2019, Part B covered 300,000 doses of hepatitis B vaccine for beneficiaries who were at high or intermediate risk for the disease.[931] Since the vaccine has been available for several decades, we are not able to determine how many Medicare beneficiaries have already received the vaccine.

[929] Pyenson, B., Pickhardt, P.J., Sawhney, T.G. et al. Medicare cost of colorectal cancer screening: CT colonography vs. optical colonoscopy. Abdom Imaging 40, 2966–2976 (2015). *https://doi.org/10.1007/s00261-015-0538-1.*

[930] Sayed, BA, Finegold, K, Ashok, K, Schutz, S, De Lew, N, Sheingold, S, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. (Issue Brief No. HP–2023–05). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2023. Retrieved from *https://aspe.hhs.gov/sites/default/files/documents/407d41b6534e7af6702eb280b3945d00/aspe-ira-vaccine-part-d.pdf.*

[931] Medpac 2021. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 7. Medicare vaccine coverage and payment. Retrieved from *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/jun21_ch7_medpac_report_to_congress_sec.pdf.*

Overall vaccination rates among adults, including older adults, are generally low.[932] [933] A Centers for Disease Control and Prevention (CDC) analysis of data from the National Health Interview Survey found that fewer than half of all adults (less than 45 percent) received age-appropriate recommended vaccinations in 2019.[934] An estimated 20 percent of adults aged ≥60 years have been vaccinated against hepatitis B; and approximately 34 percent of adults aged ≥19 years have been vaccinated against hepatitis B.[935] We do not anticipate our proposal to result in significant economic impact on the Medicare program.

As of January 1, 2023, the Inflation Reduction Act (IRA) eliminated out-of-pocket costs for vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP).[936] Before the IRA, beneficiaries incurred out of pocket costs for Part D vaccines. While we would expect that after the IRA, more beneficiaries will receive covered vaccines because of eliminating out of pocket costs, existing research shows that cost-sharing is only one factor among other determinants. Trust in vaccines, access to health care, health literacy, perceived risk, socio-demographic factors and awareness of vaccine recommendations, all shape whether individuals obtain a recommended vaccine.[937] If the number of people receiving the hepatitis B vaccine under Part D is any indication, we assume that even by increasing access, there will not be immediate or significant change in the number of covered hepatitis B vaccines paid under Medicare Part B. For these reasons, we do not anticipate that expanding the definition of intermediate risk for hepatitis B vaccine will result in a significant financial impact to the Medicare Program. We did not receive any public comments on our impact analysis.

[932] CDC. (2022, February 17). Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2019–2020. Centers for Disease Control and Prevention. Retrieved February 27, 2023, from *https://www.cdc.gov/adultvaxview/publications-resources/vaccination-coverage-adults-2019-2020.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html.*

[933] Gellin, B.G., Shen, A.K., Fish, R., Zettle, M.A., Uscher-Pines, L., & Ringel, J.S. (2016). The National Adult Immunization Plan: Strengthening Adult Immunization Through Coordinated Action. American journal of preventive medicine, 51(6), 1079–1083. *https://doi.org/10.1016/j.amepre.2016.04.014.*

[934] CDC. (2022, February 17). Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2019–2020. Centers for Disease Control and Prevention. Retrieved February 27, 2023, from *https://www.cdc.gov/adultvaxview/publications-resources/vaccination-coverage-adults-2019-2020.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2019-2020.html.*

[935] CDC. 2023. Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021. Retrieved from *https://www.cdc.gov/adultvaxview/publications-resources/vaccination-coverage-adults-2021.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2021.html.*

[936] Sayed, BA, et al. 2023. Inflation Reduction Act Research Series.

[937] Sayed, BA, et al. 2023. Inflation Reduction Act Research Series.

17. Low Titer O+ Whole Blood Transfusion Therapy During Ground Ambulance Transport

As outlined in section III.N of this final rule, we are finalizing our proposal to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion. In addition, we are also modifying the definition of ALS2 at § 414.605 by adding the administration of low titer O-whole blood transfusion therapy, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, collectively termed prehospital blood transfusion (PHBT) as a new number 8.

We would also reflect this change in the Medicare Benefit Policy Manual, Chapter 10, Ambulance Services, section 30.1.1, Definition of Ground Ambulance Services. Under this proposal, a ground ambulance transport that provides one of the PHBT will itself constitute an ALS2-level transport.

We believe that many ground ambulance transports providing PHBT already qualify for ALS2 payment, given that patients requiring such transfusions are generally critically injured or ill and often suffering from cardio-respiratory failure and/or shock and are therefore likely to receive one or more procedures currently listed as ALS procedures in the definition of ALS2, such as endotracheal intubation, central venous line, chest decompression, and placement of an intraosseous line. For impact analysis, for ground ambulance transports that provide PHBT only and currently do not qualify for ALS2 payment, we assume that these transports are reported as ALS1 (advanced life support, level 1) emergencies.

In order to help identify the number of ground ambulance transports that could potentially be affected by this proposal, we analyzed inpatient hospital claims related to multiple-trauma that started with an ALS1 emergency ambulance transport and also included a blood transfusion done in the hospital. The inpatient admissions were identified by DRG code ''813'' and diagnosis code of ''24,'' the ambulance transport is identified by HCPCS ''A0427,'' and the blood transfusion administered to these patients in the hospital setting is identified by the presence of covered charges, patient liability amounts, and replacement units for blood.

Since payments vary for urban, rural, and super-rural ground ambulance transports, we calculated the average Medicare payment amount for ALS2 (HCPCS A0433) and ALS1 (HCPCS A0427) over the last several years. The average payment differential over calendar years 2019 and 2023 is estimated to be roughly $162 per transport. It is difficult to make an assumption for the number of transports that will be impacted by this proposal, but the potential number over the last several years, based on an analysis of actual experience, is very few. Even if all of these ALS1 emergency transports shifted to being ALS2 transports, which is very unlikely, the impact would be negligible.

We did not receive any public comment on our impact analysis and therefore, we are finalizing our proposal to modify the definition of ALS2 at § 414.605 by adding the administration of low titer O+ whole blood transfusion. In addition, we are also modifying the definition of ALS2 at § 414.605 by adding the administration of low titer O-whole blood transfusion therapy, packed red blood cells (PRBCs), plasma, or a combination of PRBCs and plasma, collectively termed prehospital blood transfusion (PHBT) as a new number 8.

18. Updates to the Quality Payment Program

In this section of this final rule, we estimated the overall and incremental impacts of the Quality Payment Program policies. We estimated participation, final scores, and payment adjustment for eligible clinicians participating through traditional MIPS, MVPs, and the Advanced APMs. We also presented the incremental impacts to the number of expected Qualified Participants (QPs) and associated APM Incentive Payments that result from our policies relative to a baseline model that reflects the status quo in the absence of any modifications to the previously finalized policies.

A. Overall MIPS Modeling Approach and Data Assessment

(1) MIPS Modeling Approach

For this final rule, we used a similar modeling approach as the CY 2024 PFS final rule (88 FR 79504 through 79506). We created two MIPS RIA models: a baseline and policy model. Our baseline model includes previously finalized policies that will be in effect for the CY 2024 performance period/2026 MIPS payment year in the absence of any of the new policies in this final rule. Examples of previously finalized policies included in the baseline model include: updated QP and partial QP thresholds, and the previously finalized list of MVPs.

The policies model builds off the baseline model and incorporates the MIPS policies for the CY 2025 performance period/2027 MIPS payment year included in this final rule. By comparing the baseline model to the policies model, we are able to estimate the incremental impact of the specific policies in this final rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This modeling approach enables our model to align as much as possible with actual MIPS scoring and minimizes differences between our projections and policy implementation. These limitations of our model are outlined later in this RIA.

(2) Data Used To Estimate Future MIPS Performance

In the CY 2024 PFS final rule (88 FR 79504), we explained our decision to use CY 2022 performance period submissions data. We noted that using CY 2022 performance data presents the most current data and aligns our participation, final scoring, and payment adjustment analysis around the same common data set. CY 2022 performance data were the most recently available data in time for us to construct our simulation model for this final rule and for the same reasons discussed in the CY 2024 PFS final rule (88 FR 79504), we are considering it to construct the baseline and policies model in this final rule. As more data becomes available, we will assess the feasibility and validity of that data for use in RIA simulations.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Beginning in payment year 2019, through the Medicare, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs for the applicable QP Performance Period for a year and the corresponding payment year. In payment years 2019 through 2024 these QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the calendar year immediately preceding the payment year. In payment year 2025, QPs will receive a lump-sum APM Incentive Payment equal to 3.5 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. In payment year 2026, QPs will receive a lump-sum APM Incentive Payment equal to 1.88 percent payment of their estimated aggregate paid amounts for covered professional services furnished during CY 2025. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs but meet a lower threshold to become Partial QPs for the year may elect to report to MIPS and, if they elect to report, will then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, there are two separate PFS CFs—one for eligible clinicians who are QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the non-qualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, while the update to the non-qualifying APM CF for a year is 0.25 percent.

In addition, the thresholds to achieve QP status beginning in the 2025 QP Performance Period will increase to 75 percent for the payment amount method, and 50 percent for the patient count method. Overall, we estimated that for the 2025 QP Performance Period between 380,100 and 488,700 eligible clinicians will become QPs, and therefore be excluded from MIPS reporting requirements and payment adjustments.

In section IV.A.4.m.(2) of the CY2025 PFS proposed rule, we proposed to modify the definition of ''attribution-eligible beneficiary'' to include any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination. However, we are not finalizing this proposal and therefore no impact of this policy is included in the estimated number of QPs provided above.

We projected the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2025 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2025 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that will attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2025 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- ACO REACH Model (formerly Global and Professional Direct Contracting) Model;
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track); and
- Enhancing Oncology Model (EOM); and
- Primary Care First (PCF) Model.

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see § 414.1425(a) for information on the APM Participant Lists and QP determinations) for the 2023 QP performance period third snapshot QP determination date to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM

Incentive Payments for the 2025 QP Performance Period. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries were attribution eligible through the APM Entity.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2025 Performance Period/2027 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Proposed Policies Models

For this final rule, we applied the same assumptions as in the CY 2024 PFS final rule (88 FR 79505) to estimate our initial population of clinicians based on CY 2022 performance period/ 2024 MIPS payment year data.

We used the same CY 2022 final reconciled eligibility determination file described in the CY 2024 PFS final rule (88 FR 79505). This file reconciles eligibility from two determination periods and aligns with the CY 2022 performance period submissions data on which we based this model. Our analysis included 1,820,899 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims we applied the same eligibility assumptions and determination process described in the CY 2024 PFS final rule (88 FR 79505). We did not propose any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and final policies model.

For our RIA model, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all 3 criteria and is subject to a MIPS payment adjustment. We based this estimate on the CY 2022 performance period data described in this section of this final rule, which includes the three low volume criteria. Within this category we divide clinicians into two groups- clinicians who report data and clinicians who do not report data.

Our next two eligibility assumptions concern clinicians and groups who may participate in MIPS but are not required to participate. First, we estimate group eligibility. These are the clinicians who have a group submission, and their group exceeds the low-volume threshold in all 3 criteria. Next, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in 1 criterion but not all 3 may elect to opt-in. Based on the CY2022 data we determine which individuals opted-in to MIPS and for the purposes of our model estimate that these clinicians will continue to opt-in to MIPS.

After applying the process outlined in this section of this final rule, we next estimated the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These are clinicians who are not MIPS eligible individually but who may either opt-in because they exceed the low volume threshold in at least one criterion but not all three or who could report as part of a group which exceeds all three low volume criteria.

Finally, we estimated the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. First, we estimated the number of MIPS eligible clinicians who are below all three low-volume criteria (both as an individual and as a group) again using the CY 2022 performance period data as outlined in this section of this final rule.

Next, we estimated the number of QPs (not MIPS eligible). In section VII.E.17.b. of this final rule, we estimated a range of QPs. For the purposes of our RIA population, we estimated a specific number of QPs. This is because it is necessary to establish a specific population of clinicians to use to simulate the impacts of our final policies on participation, final scores, and payment adjustments. Finally, we estimated the number of clinicians who are excluded for other reasons including that they are a non-eligible clinician type or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimated 686,645 MIPS eligible clinicians with $5.5 billion in allowed charges. However, this number may be as high as 1,270,806 MIPS eligible clinicians and $7 billion allowed charges if *all potentially* MIPS eligible [938] clinicians either opt-in or report as a group. This is an unlikely scenario, but it establishes the full range of possible MIPS eligible clinicians in our initial population.

(b) MIPS Eligibility Estimates

Eligibility among many clinicians is contingent on submission to MIPS as a group or election to opt-in: therefore, we will not know the number of MIPS eligible clinicians who submit until the submission period for the CY 2023 performance period is closed. For the remaining analysis, we used the estimated population of 686,645 MIPS eligible clinicians described previously in this section of this final rule. Table 119 summarizes our eligibility estimates for the policies model after applying our assumptions outlined in this section of this final rule.

[938] We define potentially MIPS eligible clinicians as those clinicians who are not required to participate in 13MIPS but *may* either opt-in or join a group that exceeds the low-volume threshold in all three criteria.

TABLE 119: Description of MIPS Eligibility Status for CY 2025 Performance Period/2027 MIPS Payment Year Using the CY 2025 PFS Proposed Rule Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians *	Number of Clinicians	PFS allowed charges ($ in mil)**
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	105,843	$29,530
MIPS eligible	Did not Report to MIPS	40,813	$11,951
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	533,473	$13,108
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	6,516	$350
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**686,645**	**$54,564**
Not MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	178,216	$5,517
Potentially MIPS Eligible	Group Eligible; Did not Report	405,945	$9,502
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	129,806	$795
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	60,471	$501
Qualified Participant (QP)***	Not applicable	359,816	$17,602
Total Number of Clinicians Not MIPS Eligible		1,134,254	**$33,916**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,820,899	**$88,481**

* Participation excludes facility-based clinicians who do not have scores in the 2022 MIPS submission data.
** Allowed charges estimated in 2022 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.
*** Our QP estimate differs from that reported in section VII.E.17.b of this final rule because, for purposes of establishing the population used in our modeling, we estimate an absolute number of QPs rather than a range.

d. Modeling Approach and Methods for MIPs Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this final rule, we present several proposals which impact the measures and activities, the performance category scores, final score calculation, and the MIPS payment adjustment of MIPS eligible clinicians. We outlined these changes in more detail in section VII.E.17.d.(3). of this final rule as we described our methodology to estimate MIPS payment adjustments for the CY 2025 performance period/2027 MIPS payment year. We then presented the impact of the policies in the CY 2025 performance period/2027 MIPS payment year and compared select metrics to the baseline model. By comparing the baseline model to the policies model, we are able to estimate the incremental impact of the policies

for the CY 2025 performance period/2027 MIPS payment year.

MIPS eligible clinician's final scores are calculated based on the clinician's performance on measures and activities under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity, clinicians participating in MIPS through the APM Performance Pathway (APP), or through an MVP. MIPS APM participants can participate in the APP as an individual, group, virtual group, APM Entity and are only scored on three MIPS performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the proposed and previously finalized policies to the existing MIPS scoring engine.

In the CY 2022 PFS final rule (86 FR 65394 through 65397), we finalized policies at § 414.1365 for implementing MIPS Value Pathways beginning in the CY 2023 performance period/2025 MIPS payment year. We incorporated MVP participation and scoring rules in this RIA where applicable as described in the following section.

(2) Methodology To Assess Impact for MIPS Value Pathways

(a) MVP Participant Assumptions

At § 414.1365(b), we required MVP Participants (which can be a group, individual, subgroup, or APM entity) to register prior to submitting an MVP. We assessed whether to use CY 2024 MVP registration data to estimate MVP participation but elected to again use the approach described in the CY 2024 PFS final rule (88 FR 79507) for two reasons. First, we do not presently have MVP scoring data, thus do not know the information of MVP registrants that may submit MVP data to MIPS. Secondly, our model is based on CY 2022 performance data. This data does not contain MVP scores and reconciliation between multiple years introduces uncertainty and complexity into our model. As MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation and final scores.

We assumed for purposes of this model, that MVP Participants are MIPS eligible individual clinicians or groups that submit the required MVP measures. For the baseline model, we used the measures from the 16 MVPs finalized in the CY 2024 PFS final rule Appendix 3 (88 FR 79978 through 80047).

In section IV.A.4.a. and Appendix 3 of this final rule, we proposed modifications to all 16 existing MVPs and 6 new MVPs. The 6 new MVPs are:

- Complete Ophthalmologic Care
- Dermatological Care
- Gastroenterology Care
- Optimal Care for Patients with Urologic Conditions
- Pulmonology Care
- Surgical Care

For the policies model, we incorporated the measure revisions for the existing MVPs described in Appendix 3 of this final rule. Due to data availability, we are unable to simulate scores for the following measures and improvement activity: ABG44, PIMSH13, UREQA10, 485, 486, 487, 488, 489, 490, 492, 493, 495, 496, 497, 499, 500, 501, 502, 503, 504, 505, AAD16, AAD17, AAD18, ABG44, GIQIC26, IA_PM_XX, IRIS61, MSK6, MSK7,MSK8,MSK9,MUC2023–141, MUC2023–161, MUC2023–162, MUC2023–190, MUC2023–211.

For these MVP Participants, we calculated both an MVP and a traditional MIPS score and took the highest score consistent with the existing scoring hierarchy which was finalized in the CY 2023 PFS final rule (86 FR 65537).

Our MVP Participant assumptions have limitations: the measure list used to simulate MVP participation does not align completely with what is finalized in section IV.A.4.a. of this final rule, we are not incorporating subgroups due to a lack of data, not all of the assumed participants may elect to register for an MVP, and we may have additional clinicians or groups register for an MVP. However, we believe this is a reasonable approach to simulate the impact of MVPs and we sought comment on this assumption but did not receive any feedback.

(b) MVP Scoring Methods and Assumptions

We simulate an MVP score using the same data sources as we did for traditional MIPS. We scored according to § 414.1365(d) and (e) using the MVP reporting requirements listed in § 414.1365(c) with one exception. We did not restrict the improvement activities to the activities listed in the MVP inventory. We believed this would lower our estimated MVP score as clinicians and groups were not required to select from a limited inventory in the CY 2022 performance period (upon which our model is based). Therefore, we scored any improvement activities the MVP Participants submitted in 2022 as if those improvement activities are in the MVP inventory. Additionally, in section IV.A.4.b.(1)(b) of this final rule, we are finalizing to score all available population health measures for a clinician participating in an MVP and select the highest scoring of those measures for use in determining their category score. We incorporated this policy into our simulation.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we generally used the CY 2022 performance period's data, including data submitted or calculated for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for the new quality performance category measures, and other data sets. We calculated a hypothetical final score for the CY 2025 performance period/2027 MIPS payment year for the baseline and policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, and the application of our final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We used the CY 2024 PFS final rule final policies model as the starting point of our baseline model. Since there are no previously finalized policies impacting the quality performance category that were not already included in the CY 2024 PFS final rule policies model, we did not make any modifications to the quality performance category and the baseline model is identical to the CY 2024 PFS final rules policies model with respect to the quality category.

Our policies model incorporates the following policies from this final rule as outlined in section IV.A.4.e.(1) of this final rule:

In section IV.A.4.f.(1)(b)(i) of this final rule, to facilitate fairer scoring, we are finalizing to remove the scoring cap and change the benchmarking approach for certain topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities. We did not simulate the addition of quality measures described in section IV.A.4.e.(1)(d)(i) since we use existing quality measure data from the CY 2022 performance period which does not include new measures. We did not simulate the removal of quality

measures described in section IV.A.4.e.(1)(d)(ii) since we cannot predict how clinician behavior and measure selection will change in response.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a methodology similar to the methodology described in the CY 2024 PFS final rule (88 FR 79508) for the baseline and the proposed policies RIA models with the modifications described below.

For this final rule, the baseline policies RIA model used the same methodology as the final policies RIA model in the CY 2024 PFS final rule (88 FR 79508). The policies RIA model incorporated and implemented the following changes:

- In section IV.A.4.e.(2)(a) of this final rule, we are adopting 6 new episode-based cost measures and modify 2 existing episode-based cost measures. We incorporated measure test data with the specifications for the new and modified measures.
- In section IV.A.4.f.(1)(d) of this final rule, we are modifying our cost scoring methodology. The median cost for a measure will be assigned achievement points equal to 10 percent of the performance threshold (7.5 in the CY 2024 performance period/CY 2026 payment year). The cut-offs for benchmark ranges will be calculated as standard deviations from the median. This policy is incorporated into our model based on the specifications explained in section IV.A.4.f.(1)(d)(ii)(B) of this final rule.

(c) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated Promoting Interoperability performance category score by using the same methodology that we used in the CY 2024 PFS final rule (88 FR 79508). We did not incorporate any changes to this category in our model. In section IV.A.4.e.(4)(f) of this final rule, we are finalizing minimum criteria for a qualifying data submission for the Promoting Interoperability performance category. We conducted an analysis of this policy and determined that the impact on final scores and payment adjustments was negligible and therefore did not incorporate it into our model.

(d) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline and policies model we used the same method to estimate the improvement activities performance category score as described in the CY 2024 PFS final rule (88 FR 79508) including alignment with the clarification provided regarding IA automatic weighting for APM participants (88 FR 79366).

In section IV.A.4.e.(3)(b)(IV) of this final rule, we are removing weighting of improvement activities. We conducted an analysis of this policy and determined that the impact on final scores and payment adjustments was negligible and therefore did not incorporate it into our model.

(e) Methodology To Estimate the Complex Patient Bonus Points

For the baseline and policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology To Estimate the Final Score

We did not make any changes for how we calculated the MIPS final score. Our baseline and policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance category to zero percent of their final score, and the category's weight redistributed to other performance category(ies), for the CY 2022 performance period/2024 MIPS payment year (which was the data source used in our model) in accordance with our reweighting policies under § 414.1380(c)(2), then we continue to apply that reweighting in our model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted. Although it is unlikely (but possible) that the exact same clinicians will apply for and receive reweighting in both the CY 2022 performance period/2024 MIPS payment year (which our data is based on) and the CY 2025 performance period/2027 MIPS payment year (which we are simulating), we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same clinicians may not receive reweighting 2 years in a row, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting 2 years in a row, the absolute number of reweighting and the characteristic of practices who receive reweighting is likely to remain similar. Secondly, if we were to not assign reweighting to those clinicians, many of them will receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is realistic to assume that, in the absence of reweighting, those clinicians will continue to not submit data. For these reasons, clinicians who received reweighting in the CY 2022 performance period/2024 MIPS payment year also are approved for reweighting in the CY 2025 performance period/2027 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and final policies RIA models, we applied the hierarchy as finalized in the CY 2022 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we applied the performance threshold of 75 points finalized in the CY 2024 PFS final rule (88 FR 79373). In section IV.A.4.g.(2)(c) of this final rule, we are finalizing to again set the performance threshold at 75. Therefore, for both the baseline and final policies models we used a performance threshold of 75 to calculate the exchange function used for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and final policies model. This is due to the scaling factor used to determine positive adjustments

is dependent on the total dollar amount of negative payment adjustments and those adjustments differ as final scores are not identical between both models.

For both the baseline and policies models, we used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in this section of the final rule, we created a baseline and policies simulation. Using this simulation, we estimated the impact of the policies of this final rule.

(a) Impact to Clinician Eligibility

In section VII.E.17.c.(2) of this final rule, we noted that we did not modify clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact to Clinician's Final Scores

TABLE 120: CY 2025 Final Score Estimates by Practice Size

Practice Size*	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate**	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	18,867	75.00	31.05%	22.00%	46.95%
2) 2-15	71,908	81.79	60.47%	14.97%	24.56%
3) 16-99	150,377	81.76	64.79%	10.32%	24.89%
4) 100+	445,493	82.80	74.84%	4.32%	20.84%
Overall	686,645	82.20	69.93%	7.23%	22.84%
			Final Policies		
1) Solo	18,867	75.00	32.41%	21.94%	45.65%
2) 2-15	71,908	86.02	64.29%	14.78%	20.93%
3) 16-99	150,377	85.87	72.41%	9.98%	17.61%
4) 100+	445,493	87.19	83.28%	4.13%	12.59%
Overall	686,545	86.42	77.51%	7.02%	15.47%

*Practice size is defined as the number of NPIs in a TIN

** The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.

The median final score is 82.20 in our baseline model and 86.42 in our policies model. There is an increase in the number of clinicians receiving a positive payment adjustment for all practice sizes and an increase in the median final score for all practice sizes except for solo practitioners.[939] We project that 69.93 percent of MIPS eligible clinicians will receive a positive adjustment in our baseline model and 77.51 percent of MIPS eligible clinicians will receive a positive adjustment in our policies model. This increase is largely due to our change to the cost scoring methodology discussed in section IV.A.4.f.(1)(d)(ii)(B) of this final rule. Table 121 shows the median cost score for MIPS eligible clinicians who are scored on the cost performance category for our baseline and final policies model. There is a substantial difference in median cost scores between our two models. This is true across all practice sizes. The median cost category score is 59.16 in our baseline model and 73.85 in our policies model.

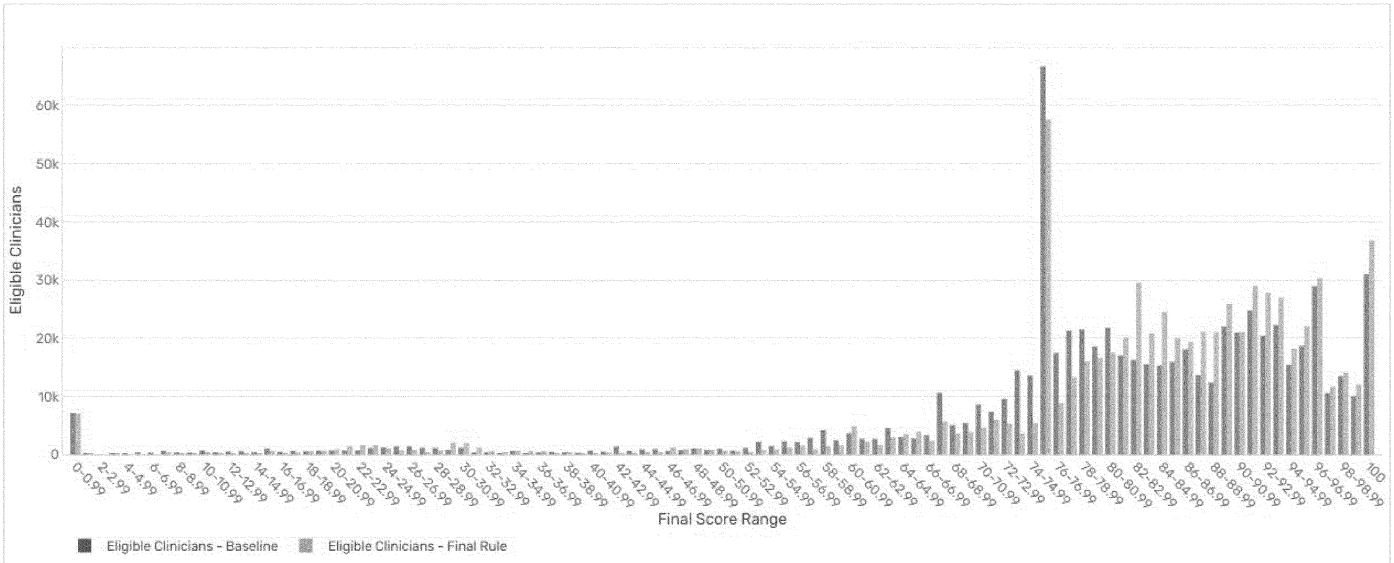
[939] See section VII.E.17.d.(b)(b)(i) of this final rule for a discussion of the performance of solo practitioners specifically.

TABLE 121: CY 2025 Cost Score Estimates by Practice Size

Practice Size	MIPS Eligible Clinicians Receiving Cost Score	Total Number of MIPS Eligible Clinicians	Proportion of MIPS Eligible Clinicians Receiving Cost Score	Median Cost Score Estimate
		Baseline		
1) Solo	7,380	18,867	39.12%	62.15
2) 2-15	32,476	71,908	45.16%	59.89
3) 16-99	65,428	150,377	43.51%	60.30
4) 100+	226,035	445,493	50.74%	59.02
Overall	331,319	686,645	48.25%	59.16
		Final Policies		
1) Solo	7,636	18,867	40.47%	75.24
2) 2-15	33,242	71,908	46.23%	74.34
3) 16-99	66,311	150,377	44.10%	74.35
4) 100+	227,601	445,493	51.09%	73.78
Overall	334,790	686,545	48.76%	73.85

Figure D–B1 shows the distribution of final scores for all MIPS eligible clinicians. Note that there are a relatively large number of MIPS eligible clinicians with a final score of 75. As stated in section VII.E.17.d.(3)(f) of this final rule MIPS eligible clinicians whom we approved for reweighting of all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is skewed to the right indicating that clinicians tend to receive final scores on the higher end of the distribution with many final scores clustered near the performance threshold of 75. Our policies have the effect of shifting final scores to the right. Many clinicians with final scores just below the performance threshold in the baseline model see their scores increased to a value just above the performance threshold in the policies model.

FIGURE D-B1: Count of MIPS Eligibles Clinicians by Final Score



(i) Impact to Small and Solo Practices

18,867 MIPS eligible clinicians or 2.7 percent of all MIPS eligible clinicians are solo practitioners in both the baseline and final policies models. The median final score for solo practitioners is exactly equal to the performance threshold in both the baseline and final policies model although the portion of solo practitioners receiving a positive adjustment is higher in the final policies model than in the baseline model. As stated in section VII.E.17.d.(3)(f) of this final rule, clinicians receiving reweighting under our current policies at § 414.1380(c)(2) are assigned a final score exactly equal to the performance threshold if we approved for reweighting of all MIPS performance categories.

As discussed in section VII.E.17.d.(3)(f) of this final rule, clinicians receiving reweighting under our current policies at § 414.1380(c)(2) are assigned a final score exactly equal to the performance threshold if we

approved for reweighting of all MIPS performance categories.

These practitioners have a lower median final score than other practice sizes. This is largely due to the fact that many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.45 percent of solo practitioners submit data to MIPS compared to 93.68 percent of all clinicians. The median final score in our baseline and final policies model is 75.00 for all solo practitioners, but for solo practitioners who submit data the median final score is 84.35 in the baseline and 87.03 in the final policies model. These findings indicate that the lower final scores among solo practitioners is likely due to not reporting data to MIPS. Figure D–B2 shows the distribution of final scores for solo practitioners as a box plot. While the median final score is 75 in both models, the bottom quartile increases from 17.52 to 22.33 between the baseline and proposed policies model. Figure D–B3 shows the final score distribution for all practice sizes. The first quartile of final scores is 75 in the baseline model and 77.45 in the final policies model. The range between Q1 and Q3 is significantly narrower for all practice sizes than it is for solo practitioners. Figure D–B4 shows the distribution of final scores for solo practitioners who submit data to MIPS. This distribution is much closer to the distribution of final scores in the overall population with the first quartile at 73.45 in the baseline and 75.00 in the final policies model. This is similar to the median final score for all practice sizes which is 86.42. This indicates that, while many solo practitioners do not submit data to MIPS, those who do submit data perform similarly or better than the overall population of MIPS eligible clinicians. This is further evidence that the main factor causing low final scores among solo practitioners is the high proportion who do not submit data.

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FIGURE D-B2: Distribution of Final Scores for Solo Practitioners

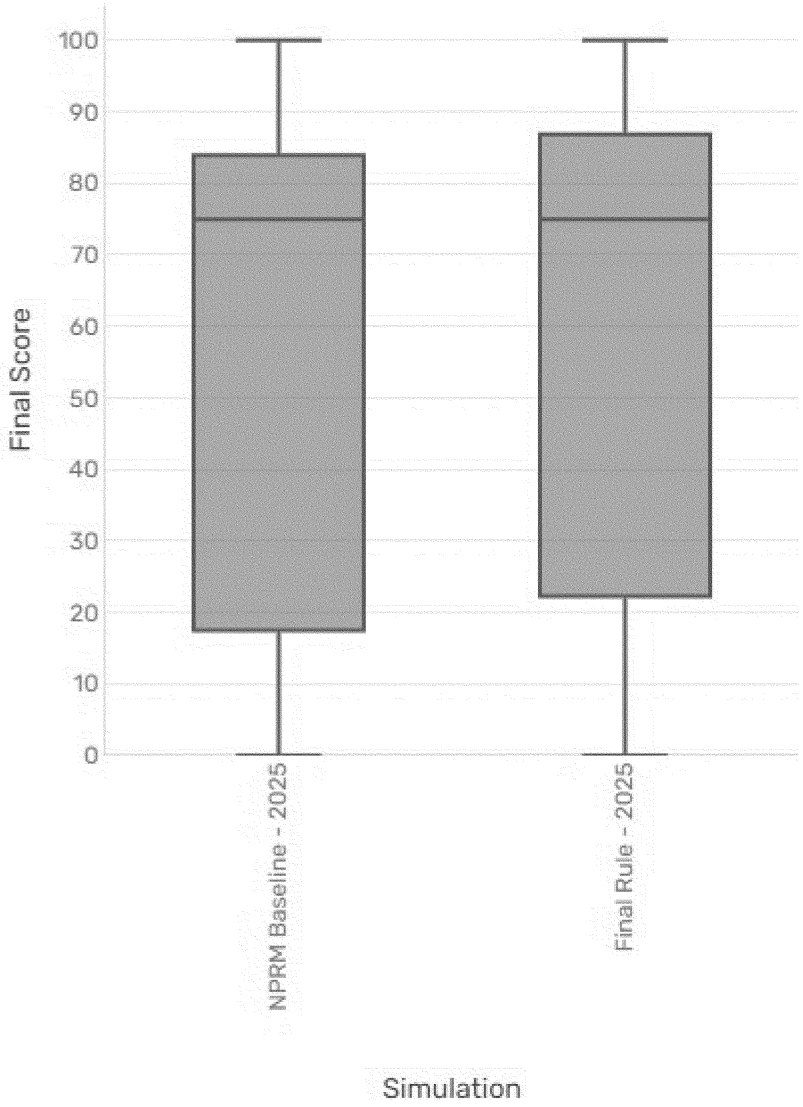


FIGURE D-B3: Distribution of Final Scores for All Practice Sizes

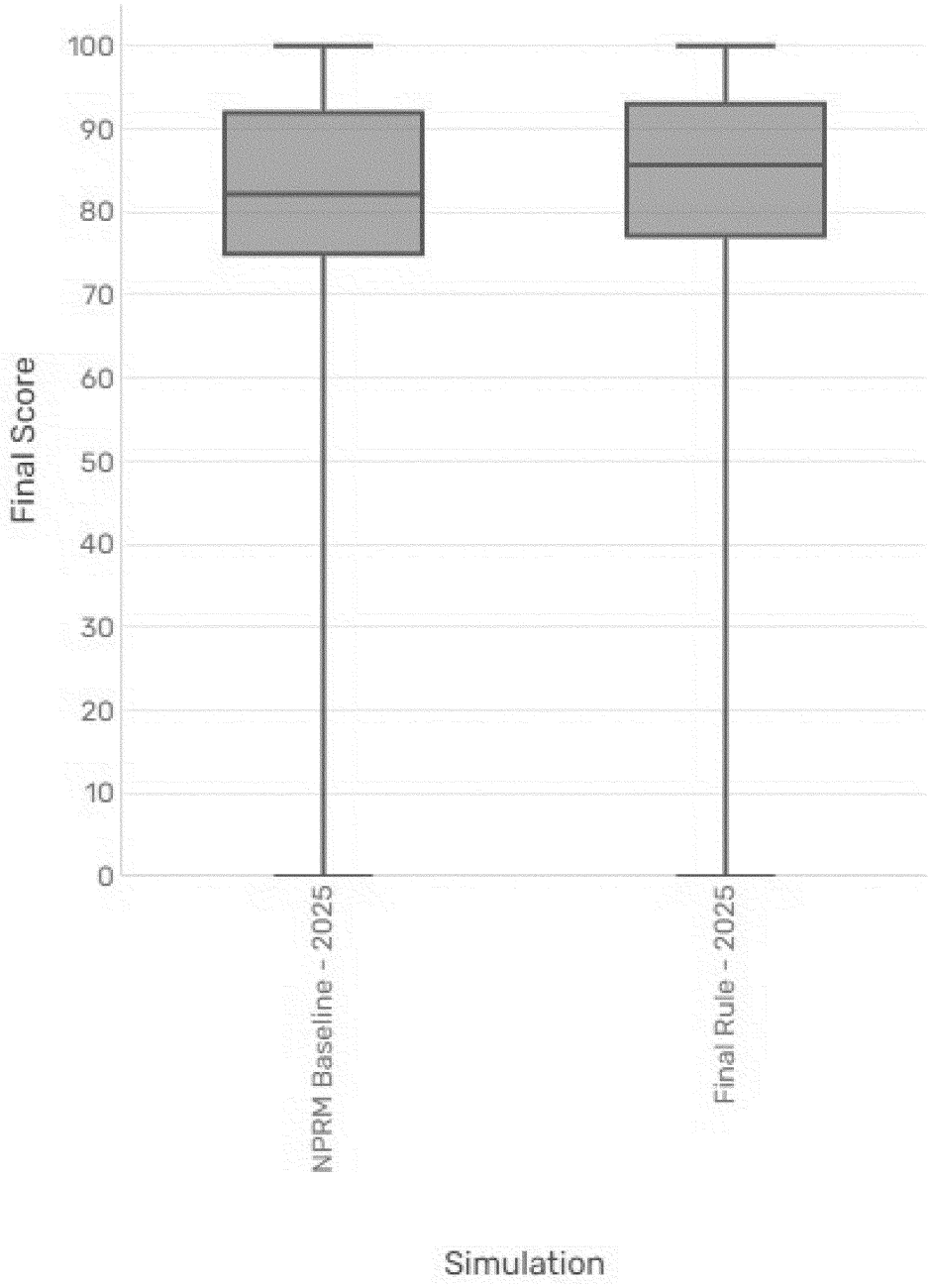
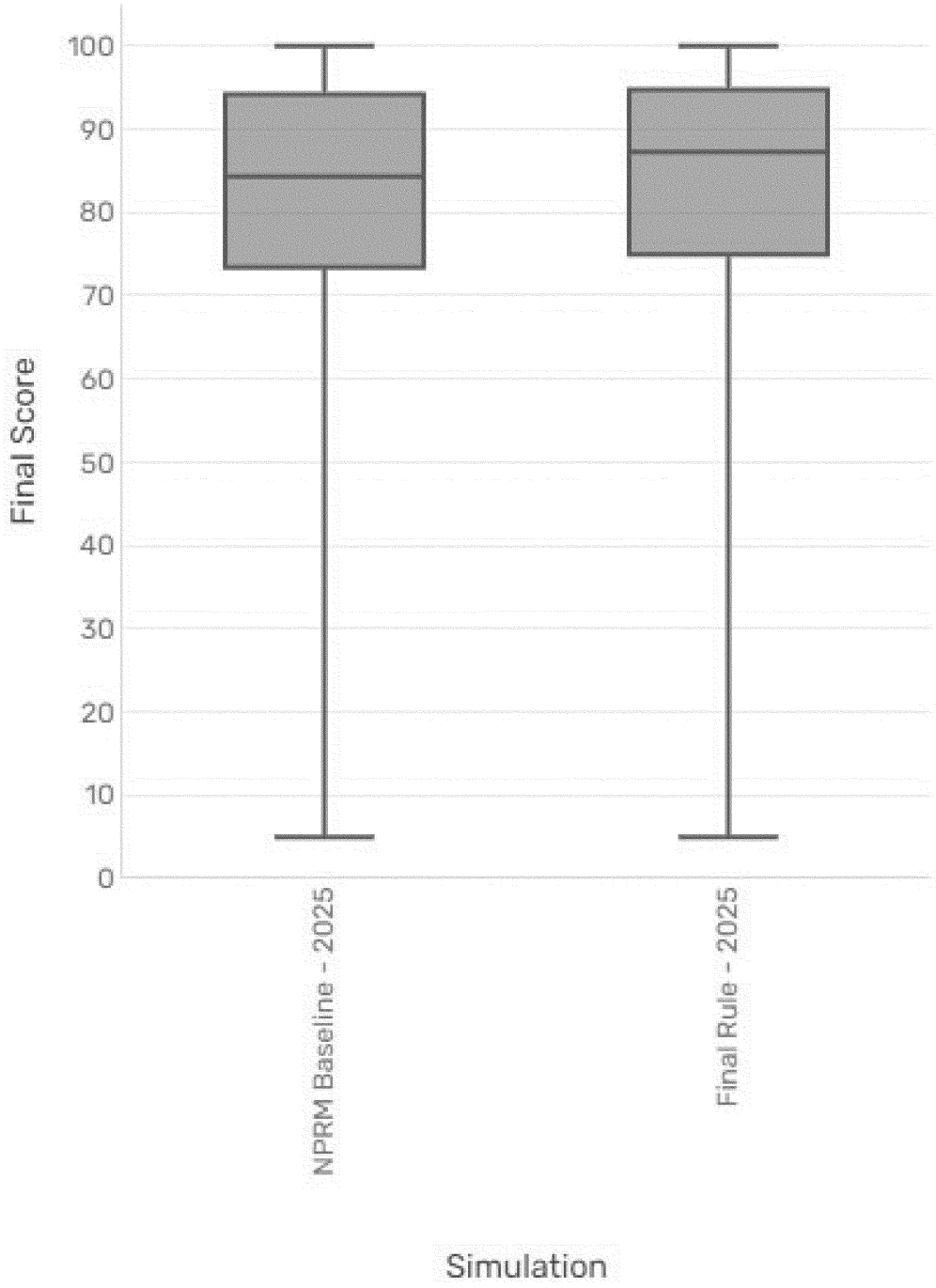
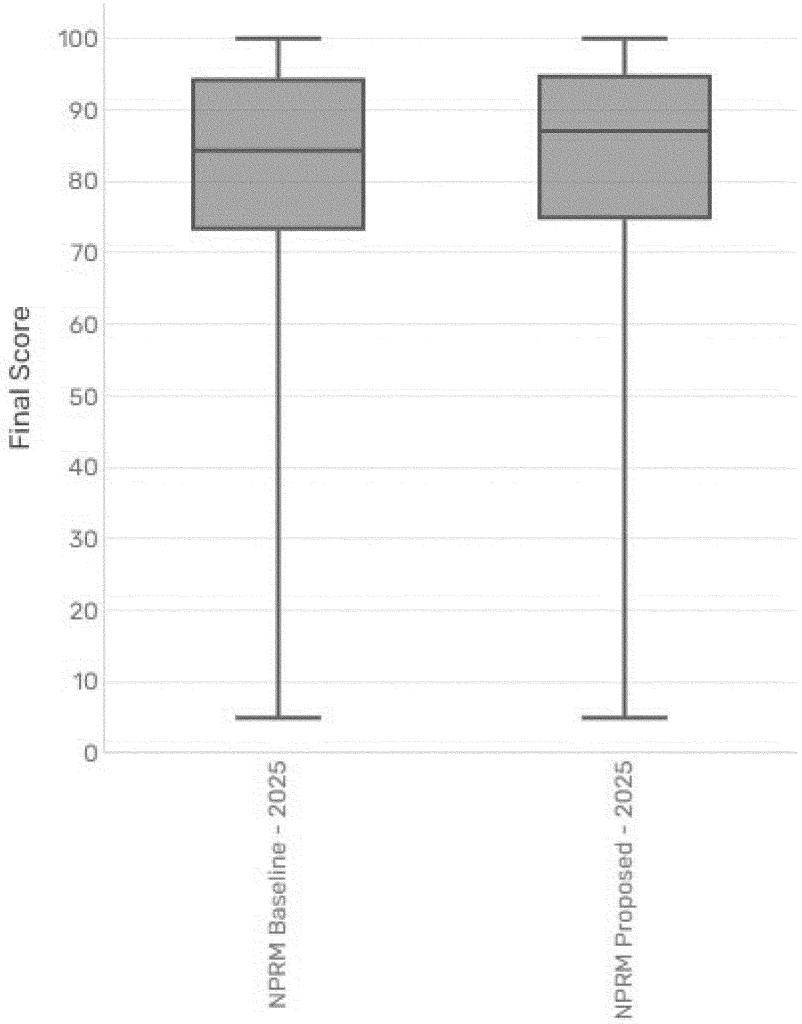


FIGURE D-B4: Distribution of Final Scores for Solo Practitioners who Submit Data





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Small practices, defined as groups with a range between 2 and 15 clinicians, have a median final score of 81.79 in the baseline and 86.02 in the policies model. This is similar but slightly lower than the median final score for all practice sizes of 86.42. Among small practices who submit data the median final score is 89.81 in the policies model (and 86.83 in the baseline). This is significantly higher than the median final score for all clinicians who submit data which is 87.53. This indicates that small practices perform similarly to other practice sizes although a slightly larger proportion of small practices do not submit data. Table 124 shows the percentage of clinicians by practice size who either do or do not submit data to MIPS and the corresponding median final score. Note that the median final score for clinicians who do not submit data is 75 for all practice sizes except for solo practitioners. This indicates that many clinicians belonging to small, medium, or large practices (but not solo practitioners) who do not submit data to MIPS have been approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, many solo practitioners who do not submit data do so despite not being eligible for application of our reweighting policies or not applying for reweighting under those policies.

A large majority of all practice sizes except solo practitioners submit data to MIPS. It is possible that the small percentage of MIPS eligible clinicians in those practice sizes who do not submit data to MIPS are primarily MIPS eligible clinicians who have received reweighting under our policies at § 414.1380(c)(2). It should be noted that median final scores increase for solo and small practitioners between our baseline and policies model indicating that the net effect of our policies is an increase in their final scores.

TABLE 122: Percentage of MIPS Eligible Clinicians who Submit Data and Median Final Score

	Percentage **of MIPS** Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	**Median Final Score of MIPS Eligible Clinicians who Do not submit data.**
		Baseline	
1) Solo	49.39%	84.35	19.35
2) Small (2-15)	79.32%	86.83	75
3) Medium (16-99)	91.69%	83.42	75
4) Large(100+)	98.23%	83.15	75
Overall	93.47%	83.46	75
		Final Policies	
1) Solo	49.45%	87.03	22.89
2) Small (2-15)	79.46%	89.81	75
3) Medium (16-99)	92.03%	87.27	75
4) Large(100+)	98.41%	87.31	75
Overall	93.68%	87.53	75

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Analysis of this group of clinicians indicates that their final scores are similar to the overall population of MIPS Eligible Clinicians across all practice sizes. Table 123 shows the median final score and the percentage of eligible clinicians with a positive or neutral or negative adjustment by practice size.

TABLE 123: CY 2025 Final Score Estimates by Practice Size for *Rural Practitioners Only*

Practice Size	**Total Number of MIPS Eligible Clinicians**	**Median Final Score Estimate**	**Percent Eligible Clinicians with Positive Payment Adjustment**	**Percent Eligible Clinicians with Neutral Payment Adjustment**	**Percent Eligible Clinicians with Negative Payment Adjustment**
			Baseline		
1) Solo	2,694	75.00	34.89%	17.37%	47.74%
2) 2-15	11,760	83.89	65.94%	10.48%	23.58%
3) 16-99	30,444	85.05	71.38%	6.80%	21.82%
4) 100+	43,286	80.43	69.02%	5.08%	25.90%
Overall	88,184	81.29	68.38%	6.77%	24.85%
			Final Policies		
1) Solo	2,694	75.00	36.53%	17.33%	46.14%
2) 2-15	11,762	87.34	69.82%	10.42%	19.76%
3) 16-99	30,409	87.53	76.90%	6.37%	16.73%
4) 100+	43,281	84.27	81.78%	4.94%	13.28%
Overall	88,146	85.41	77.12%	6.54%	16.34%

The median final score for all rural practitioners is 81.29 in our baseline model and 85.41 in our policies model. This is slightly lower than the median final score for all practitioners which is 82.20 in our baseline model and 86.42 in our policies model. However, the median final score is identical for solo practitioners and higher for small and medium practices. Large rural providers have a slightly lower median final score compared to large practices generally. The lower overall median final scores for rural practitioners are driven by large rural practices who perform slightly worse than other practice sizes and when compared to large practices generally. It should be noted that median final scores increase for rural providers of all practice sizes between our baseline and proposed policies model indicating that the net effect of our proposed policies is an increase in their final scores.

(iii) Impact to Safety Net Providers

(a) Updated Definition of Safety Net Providers

In the CY 2023 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the CY 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to the top 20 percent (80th percentile) of social risk we can identify the providers who are caring for the largest proportion of low-income or otherwise socially vulnerable individuals.

Table 126 shows the final score estimates for safety net providers under this new definition. Safety net provers have higher median final scores than the overall population of MIPS eligible clinicians across all practice sizes with the exception of small and solo practitioners. When our analysis is restricted to providers who submit data to MIPS this discrepancy disappears and small and solo safety net providers who submit data have higher median final scores than the overall population of small and solo MIPS eligible clinicians who submit data. However, only 43.65 percent of solo and 72.90 percent of small safety net providers submit data compared to 49.45 percent and 79.46 percent of the overall population of solo and small MIPS eligible clinicians respectively. These results are shown in Table 124. This indicates that the lower scores among small and solo safety net practitioners is likely due to a larger number of these practitioners not submitting data. It should be noted that median final scores increase for solo and small safety net providers between our baseline and policies model indicating that the net effect of our policies is an increase in their final scores.

TABLE 124: CY 2025 Final Score Estimates by Practice Size for *Safety Net Practitioners Only*

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	5,347	62.31	26.95%	20.07%	52.98%
2) 2-15	14,202	80.84	55.01%	15.56%	29.43%
3) 16-99	37,246	85.12	66.77%	12.97%	20.26%
4) 100+	82,916	86.18	83.59%	5.64%	10.77%
Overall	139,711	85.35	74.04%	9.15%	16.81%
			Final Policies		
1) Solo	5,347	65.78	27.70%	20.05%	52.25%
2) 2-15	14,208	84.50	57.18%	15.52%	27.30%
3) 16-99	37,212	88.31	70.48%	12.79%	16.73%
4) 100+	82,839	89.23	87.11%	5.53%	7.36%
Overall	139,606	88.59	77.36%	9.03%	13.61%

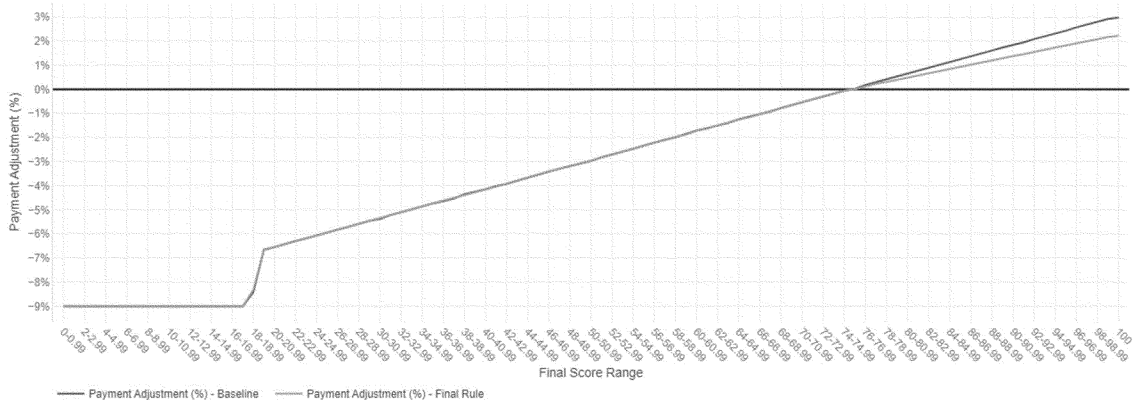
TABLE 125: CY 2025 Median Final Scores for *Safety Net Practitioners Who Submit Data*

Practice Size	Percent of MIPS Eligible Clinicians who Submit Data	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
			Baseline		
1) Solo	43.63%	86.12	61.77%	10.84%	27.39%
2) 2-15	72.90%	89.51	75.46%	7.06%	17.48%
3) 16-99	91.73%	86.54	72.78%	8.45%	18.77%
4) 100+	98.47%	86.18	84.88%	4.45%	10.67%
Overall	91.97%	86.37	80.48%	5.85%	13.67%
			Final Policies		
1) Solo	43.65%	89.06	63.45%	10.84%	25.71%
2) 2-15	72.94%	92.29	78.39%	7.04%	14.57%
3) 16-99	91.90%	89.53	76.67%	8.44%	14.89%
4) 100+	98.58%	89.31	88.35%	4.45%	7.20%
Overall	92.08%	89.57	83.99%	5.83%	10.18%

(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We did not increase in the performance threshold in this final rule. However, payment adjustments differ between the baseline and final policies model. This is because our policies increase final scores of MIPS eligible clinicians [940] and therefore a larger proportion of MIPS eligible clinicians receive a final score greater than the performance threshold and thus a positive payment adjustment. The parameters of the exchange function used to determine payment adjustments depends on the final score distribution of MIPS eligible clinicians. As the proportion of MIPS eligible clinicians receiving a negative payment adjustment decreases the budget neutral funds available for redistribution also decrease. In the baseline model we project redistributing $517 million and in the policies model we project redistributing $458 million. This decrease means that the scaling factor for positive adjustments is reduced.

FIGURE D-B5: Payment Adjustment Function



We also report the median positive and negative payment adjustments by practice size in Table 126.

[940] This increase is largely due to the change in our cost performance category scoring policies discussed in section IV.A.4.f.(1)(d)(ii)(B) of this final rule.

TABLE 126: CY 2025 Median Positive and Negative Payment Adjustment Estimates by Practice Size

Practice Size	Median Positive Payment Adjustment*	Median Negative Payment Adjustment*
Baseline		
Solo (1)	2.06%	-9.00%
Small (2-15)	1.82%	-4.69%
Medium (16-99)	1.65%	-1.25%
Large (>99)	1.59%	-0.88%
Overall	1.65%	-1.10%
Final Policies Model		
Solo (1)	1.55%	-6.42%
Small (2-15)	1.46%	-5.88%
Medium (16-99)	1.35%	-1.44%
Large (>99)	1.28%	-1.08%
Overall	1.31%	-1.48%

*The median positive payment adjustment is defined as the medium payment adjustment among clinicians with a final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal the performance threshold.

For all practices sizes except for solo practitioners the median negative payment adjustment increases in magnitude. This is because many MIPS eligible clinician's final scores are clustered near the performance threshold. An increase in median final scores will cause many of those clinicians who have a minor negative adjustment to meet or exceed the performance threshold and therefore be removed from the population of clinicians with a negative adjustment. The remaining population of MIPS eligible clinicians with negative adjustments are more likely to have negative payment adjustments higher in magnitude. In contrast to other practice sizes. fewer solo practitioners with negative payment adjustments have a final score near the performance threshold and an increase in the final score of these MIPS eligible clinicians will reduce the size of their negative payment adjustment but is less likely to shift their final scores above the performance threshold in the manner described earlier. As discussed in section VII.E.17.d.(4)(b)(i) of this final rule, this is largely because many of these solo practitioners do not submit data to MIPS despite being MIPS eligible clinicians. Our analysis indicates that 49.45 percent of solo practitioners submit data to MIPS in our policies model compared to 93.70 percent of all MIPS eligible clinicians. In Table 127, we report the proportion of MIPS eligible clinicians who either did or did not submit data with the maximum negative adjustment (−9 percent).

TABLE 127: CY 2024 CY 2024 Clinicians with The Maximum Negative Adjustment

Practice Size	Percent of **Clinicians who Did NOT Submit Data** with Maximum Negative Adjustment	Percent of **Clinicians Who Submit Data** With Maximum Negative Adjustment
Baseline (-9%)		
Solo (1)	48.94%	2.90%
Small (2-15)	35.75%	0.84%
Medium (16-99)	17.88%	0.37%
Large (>99)	11.71%	0.12%
Overall	29.35%	0.28%
Final Policies Model (-9%)		
Solo (1)	35.57%	2.26%
Small (2-15)	25.23%	0.72%
Medium (16-99)	12.52%	0.35%
Large (>99)	5.50%	0.10%
Overall	20.77%	0.24%

Across all practice sizes the proportion of clinicians who do not submit data who receive the max negative payment adjustment decreased between the baseline and proposed policies model. A larger proportion of solo practitioners (2.26 percent) who submit data receive the maximum negative adjustment.

The median positive adjustment for solo practitioners is 1.55 percent which is higher than the median positive adjustment for all practice sizes overall. This indicates that, while many solo practitioners do not submit data to MIPS, those solo practitioners who do report data to MIPS and receive a positive adjustment receive a similar median adjustment to other practice sizes.

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are finalizing several policies that impact burden for the CY 2025 performance period/2027 MIPS payment year. In section V.B.6. of this final rule, we outline estimated costs to MIPS eligible clinicians for Quality Payment Program ICRs that have updated estimates due to policy provisions in section IV.A. of this final rule. In section V.B.6. of this final rule, we applied the impacts of both policy provisions and updated data sources when estimating burden. In Table 128, we summarize the incremental burden of the policy provisions for these ICRs.

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TABLE 128: Incremental Estimated Burden from Associated Finalized Policies
(Asterisks refer to paragraph directly following table)

Burden Description and Associated Provisions	Burden Hours	Burden Dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year with updated data and assumptions (outlined in section V.B.6.a.(1)(a) of this final rule).	594,447	$71,079,848
Burden change for MVP registration ICR due to the provision of additional MVPs (outlined in section V.B.6.c.(5).(a).(i) of this final rule). *	+626	+$66,759
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(2) of this final rule). *	-7,697	-$898,035
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(3) of this final rule). *	-6,866	-$823,269
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(4) of this final rule). *	-9,664	-$1,176,109
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(5).(a).(iii) of this final rule). *	+16,031	+$1,917,478
Total change in burden due to policy for CY 2025 performance period/2027 MIPS payment year	-7,570	-$913,176
Total burden set forth in the CY 2025 PFS final rule	586,877	70,166,672
Burden Description and Associated Provisions	**Burden Hours**	**Burden Dollars**
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year with updated data and assumptions (outlined in section V.B.8. of this final rule).	594,447	$71,079,848
Burden change for MVP registration ICR due to the provision of additional MVPs (outlined in section V.B.8.e.(7)(a)(i). of this final rule). *	+626	+$66,759
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.8.e.(4). of this final rule). *	-7,697	-$898,035
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.8.e.(5) of this final rule). *	-6,866	-$823,269
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.8.e.(6). of this final rule). *	-9,664	-$1,176,109
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (outlined in section V.B.8.e.(7)(a)(iii). of this final rule). *	+16,031	+$1,917,478
Total change in burden due to policy for CY 2025 performance period/2027 MIPS payment year	-7,570	-$913,176

Burden Description and Associated Provisions	Burden Hours	Burden Dollars
Total burden set forth in the CY 2025 PFS final rule	586,877	70,166,672

The total change in burden due to this policy provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the addition of six new MVPs. Therefore, there is a decrease in burden in the MIPS CQM and QCDR, eCQM, and Medicare Part B ICRs due to respondents who previously submitted MIPS through those collection types submitting data with reduced quality submission requirements as an MVP Participant. Total change in burden also reflects an increase in submission burden due to the additional MVP registrants. See section V.B.6.c.(2) of this final rule for additional detail.

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(2) Additional Impacts to Clinicians

We provide additional burden discussions for policy provisions that we are not able to quantify.

(a) Impact on Third Party Intermediaries

In section IV.A.4.j.(1)(b) of this rulemaking, we are finalizing our proposal that Consumer Assessment of Healthcare Providers & Systems (CAHPS) vendors will provide information on the range of costs for their services as part of CAHPS vendor registration process, beginning with the CY 2026 performance period/2028 MIPS payment year. This policy is in addition to the previously established registration requirements. We recognize that there may be additional minimal burden associated with the cost information requirement for the CAHPS vendor registration. However, we assume that this information is brief and readily available to vendors completing the registration process. We are unable to quantify the additional impact for the CAHPS vendor cost requirement.

(b) Modifications to the Improvement Activities Inventory

As outlined in section IV.A.4.e.(3)(b)(iii) of this final rule, we are finalizing our proposed changes to the improvement activities inventory for the CY 2025 performance period/2027 MIPS payment year and future years as follows: adding two new improvement activities; modifying one existing improvement activity; and removing four previously adopted improvement activities. We are also finalizing, with modification, our proposed changes to the improvement activities inventory for the CY 2026 performance period/2028 MIPS payment year: removing four improvement activities; and modifying one improvement activity. We do not expect these changes to the improvement activities inventory to affect our currently approved information collection burden for the number of estimated respondents or response time. Most of the improvement activities in the Inventory remain unchanged for the CY 2025 performance period/2027 MIPS payment year. We refer readers to section IV.A.4.e.(3)(b)(iii). of this final rule for additional information on changes to the improvement activities inventory.

(c) Modifications to Improvement Activities Scoring and Reporting Policies

As discussed in section IV.A.4.e.(3)(b)(iv), we are finalizing two scoring and reporting policy changes for the improvement activities performance category effective for the CY 2025 performance period/2027 MIPS payment year and subsequent years. As noted in section V.B.6.e. of this final rule, we established our currently approved estimate that it will take a computer analyst 5 minutes to log in and manually attest that improvement activities were completed in the CY 2019 PFS final rule (83 FR 60016). In the CY 2024 PFS final rule (88 FR 79454 and 79455), this estimate included scenarios where MIPS eligible clinicians might submit 1, 2, 3, or 4 activities for the improvement activities category, based on medium- or high-weighted activities and any additional scoring scenarios such as for MIPs Value Pathways (MVP) participants. We believe this policy will decrease burden for MIPS eligible clinicians who previously reported medium-weighted activities. As MIPS eligible clinicians who previously only reported high-weighted activities will have the same attestation requirements under this policy, we will continue our currently approve estimates of 5 minutes per response. We expect reduced reporting burden for clinicians who previously reported at least one medium-weighted activity; however, we are unable to estimate the aggregated impact of this policy given the current weighting and scoring rules that affect the number of activities each clinician submits to receive full credit for the improvement activities performance category.

(d) MVP Maintenance Process

In section IV.A.4.a of this final rule, we are finalizing a modification to the public-facing MVP maintenance webinar process previously established in the CY 2022 PFS final rule (86 FR 65410) and modified in the CY 2023 PFS final rule (87 FR 70037). We had communicated in the CY 2023 PFS final rule that if we identified any potentially feasible and appropriate submitted maintenance recommendations that we would host a public facing webinar open to interested parties and the general public through which they could offer their feedback on the potential maintenance updates we have identified.

Due to the low volume of submitted maintenance recommendations in past years, we are finalizing changes to provide us more flexibility in how we communicate maintenance recommendations prior to proposing them in rulemaking. Allowing flexibility in communicating recommendations through alternative webinar formats or other public communication channels will offer similar opportunities for public review and feedback as a live public webinar. For example, in lieu of a live webinar, we may choose to communicate submitted maintenance recommendations via a pre-recorded webinar, which will encourage interested parties to submit their feedback on the submitted recommendations in writing by email before maintenance updates are formally proposed in rulemaking.

As with the CY 2023 PFS final rule (87 FR 70210 through 70211), we acknowledge that there is administrative burden associated with the monitoring and review of the candidate MVPs. We are uncertain on the number of interested parties and members of the general public that will submit their recommendations for potential revisions to established MVPs for an applicable performance period. We are also uncertain if we will host a public webinar, webinar alternative, or other communications based on the review of the recommendations. In summary, we are unable to quantify the impact associated with these finalized changes.

(e) Reweighting Performance Categories When Data Is Not Submitted Due to Reasons Outside the Clinician's Control

As detailed in section IV.A.4.i.(2) of this final rule, we are finalizing our proposal to adopt a new reweighting performance category(ies) policy at

§ 414.1380(c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*) for occurrences where we determine that a third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. For more details on this proposal and the considerations when determining whether to apply reweighting to the affected performance category(ies), please see section IV.A.4.i.(2) of this final rule.

Because this is a new policy and we believe these occurrences will be rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may apply for reweighting based on this policy. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we did not make any changes to our currently approved burden estimates as a result of this policy.

(f) Advanced Primary Care Management

Advanced Primary Care Management (APCM) payment finalized in section II.G.2 of this final rule incorporates several specific, existing care management and communication technology-based services into a bundle and includes performance measurement requirements that, for MIPS eligible clinicians, could be met by reporting the Value in Primary Care MVP beginning in the CY 2025 performance period/2027 MIPS payment year. Billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) will not have to report the MVP in order to furnish and bill for APCM services. Billing practitioners who are not MIPS eligible clinicians (as defined at § 414.1305) will not have to report the MVP in order to furnish and bill for APCM services. For details on this policy, we refer readers to section II.G.2. of this final rule.

Absent data on these codes, we are unable to estimate the effect of this policy on MVP submissions and registrations for the CY 2025 performance period/2027 MIPS payment year. As outlined in section V.B.6.c.5.(a) of this final rule, we are unable to determine how many additional clinicians or practices will submit the Value in Primary Care MVP measures for the CY 2025 performance period/2027 MIPS payment year above our current estimates. Similarly, we cannot assess what participation levels clinicians or practices who might use these APCM codes have reported MIPS in the past (for example, eligibility requirements and special statuses, participation at the individual, group, virtual group, or Alternative Payment Model (APM) Entity level, or reporting via traditional MIPS, the APM Performance Pathway (APP), or MVPs), or if they will be MIPS eligible clinicians in future years. For MIPS eligible clinicians who move from reporting traditional MIPS to MVPs, we expect a decrease in overall program burden due to the reduced number of measures required for reporting the quality performance category. We will update these assumptions for MVP quality performance category reporting and MVP registration as more information is available.

(g) Mandatory Subgroup Registration

As summarized in section IV.A.3. of this final rule, we previously established a voluntary subgroup participation option for clinicians choosing to report an MVP beginning in the CY 2023 performance period/2025 MIPS payment year. We finalized a mandatory subgroup reporting requirement for multispecialty groups choosing to report as an MVP Participant beginning in the CY 2026 performance period/2028 MIPS payment year (§ 414.1305; 86 FR 65394 through 65397). The CY 2025 PFS proposed rule (89 FR 62016) included a Request for Information (RFI) to obtain feedback on what guidance/parameters are needed for multispecialty groups to place clinicians into subgroups for reporting an MVP relevant to the scope of care provided. Absent available submission data on MVP and subgroup reporting as outlined in section V.B.6.c.(5)(a)(ii), we are unable to estimate the effect of this established policy on reporting for the CY 2026 performance period/2028 MIPS payment year.

(h) APM Performance Pathway Plus Quality Measure Set

In section IV.A.4.c.(2) of this final rule, we are finalizing, with modification, the proposal to establish the quality measures included in APP Plus quality measure set beginning in the CY 2025 performance period/2027 MIPS payment year. MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set will report via one of the available collection types per measure: six quality measures for the CY 2025 performance period/2027 MIPS payment year; eight quality measures for the CY 2026 performance period/2028 MIPS payment year; and nine quality measures for the CY 2027 performance period/2029 MIPS payment year. Two additional measures will be added for the CY 2028 performance period/2030 MIPS payment year or the next performance period following the availability of the eCQM specifications, whichever is later. For the available collection types per measure, please see section IV.A.4.c.(3)(f) of this final rule.

In section V.B.6.a.(4) of this final rule, we compared the quality performance category burden for MIPS eligible clinicians who elect to report the APP Plus quality measure set compared to the APP quality measure set, traditional MIPS, and MVPs. We focused these analyses on quality measures required for MIPS eligible clinicians, groups, and APM Entities under the eCQM, MIPS CQMQCDR, and Medicare Part B claims collection types, as available for each participation option. We note these assumptions for actively submitting to assess clinician burden may differ from MIPS scoring policy. In this comparison, we assumed MIPS eligible clinicians incur no burden for administrative claims quality measures, specifically the two administrative claims quality measures required under the APP quality measure set (Quality #479 and #484), and that will be incrementally added to the APP Plus quality measure set (Quality #479 in CY 2025 performance period/2027 MIPS payment year and Quality #484 in CY 2026 performance period/2028 MIPS payment year). Additionally, burden estimates for the CAHPS for MIPS registration and patient reporting are provided in the CAHPS for MIPS PRA package under OMB control number 0938–1222 (CMS–10450); we do not assume that MIPS eligible clinicians, groups, and APM Entities incur additional reporting burden for reporting the CAHPS for MIPS quality measure under the APP quality measure set or as required under the APP Plus quality measure set beginning in the CY 2025 performance period/2027 MIPS payment year. Therefore, MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set, beginning in the CY 2025 performance period/2027 MIPS payment year, will need to actively submit performance data for more MIPS quality measures than MIPS eligible clinicians, groups, and APM Entities reporting via the APP quality measure set. Compared to MVP reporting, MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set will need to actively submit performance data for the same number of quality measures for the CY 2025 performance period/2027 MIPS payment year, and more quality measures beginning with the CY 2026 performance period/2028 MIPS

payment year. Compared to traditional MIPS reporting, MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus quality measure set will need to actively submit performance data for fewer quality measures for the CY 2025 and the 2026 performance periods/2027 and 2028 MIPS payment years, and the same number of quality measures for the CY 2027 performance period/2029 MIPS payment year. Once the final two quality measures are added to the APP Plus, for the CY 2028 performance period/2030 MIPS payment year or the next performance period following the availability of the eCQM specifications, whichever is later, MIPS eligible clinicians, groups, and APM Entities reporting the APP Plus will actively submit performance data for more quality measures than MIPS eligible clinicians, groups, and APM Entities reporting traditional MIPS.

As noted in the CY 2021 PFS final rule, one goal of the APP quality measure set was to reduce the burden of reporting quality measures twice: once to MIPS and once to their APMs. Therefore, clinicians reporting the APP quality measure set and APP Plus quality measure set who are required by their APMs to submit the same measure sets incur limited additional burden (88 FR 84862). We assume that all Shared Savings Program ACOs will report the APP via the APP Plus measure set for the CY 2025 performance period/2027 MIPS payment year. Per section 1899(e) of the Act, submissions received from eligible clinicians in ACOs are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. As the APP Plus is a new and optional quality measure set for MIPS eligible clinicians, groups, and APM Entities (excluding Shared Savings Program ACOs) with greater reporting burden than the APP quality measure set and APM specific requirements may vary, we are unable to estimate how many individual MIPS eligible clinicians, groups, or APM Entities will submit quality measures via the APP Plus at this time. Our burden estimates currently assume MIPS eligible clinicians in APM Entities (excluding Shared Savings Program ACOs) will participate through traditional MIPS or MVPs, submitting as an individual or group rather than as an APM Entity. We will update these estimates and assumptions as additional data are available.

i. Assumptions & Limitations

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in for the CY 2022 Quality Payment Program and submitted data will continue to elect to opt-in for the CY 2025 performance period/2027 MIPS payment year.

As discussed in section V.B.8. of this final rule, we are unable to predict which specific MIPS eligible clinicians will receive reweighting for one or more performance categories under policies at § 414.1380(c)(2) in the CY 2025 performance period/2027 MIPS payment rear. On this basis, we assumed that those MIPS eligible clinicians for whom we approved reweighting of one or more performance categories under our policies are representative of the number and attributes of MIPS eligible clinicians who will receive reweighting under these policies in the future.

In addition to the limitations described throughout the methodology sections, to the extent that there are year-to-year changes in the data submission, volume, and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 120.

F. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented above the estimated impact on total allowed charges by specialty.

1. Alternatives Considered Related to Strategies for Improving Global Surgery Payment Accuracy

As discussed previously and in section II.L. of this final rule, beginning for services furnished in 2025, we are finalizing our proposal to broaden the applicability of transfer of care modifier -54 for 90-day global packages as proposed. Beginning with services furnished in CY 2025, modifier -54 is required for all 90-day global surgical packages in any case when a practitioner plans to furnish only the surgical procedure portion of the global package (including both formal and other transfers of care). We are not finalizing any changes regarding the use of modifier -55 and modifier -56 for CY 2025. Modifiers -55 and -56 will continue to be billed exclusively in cases where there is a documented formal transfer of care.

Practitioners billing for a global package procedure code with modifier -54 and other practitioners in the same group practice as that practitioner will still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. Additionally, we are finalizing a global surgical add-on code, HCPCS code G0559, which we expect will be billed during the post-operative period of 90 days following the procedure. We expect that this code will be billed once during that timeframe when the patient is seen for an office/outpatient (O/O) evaluation and management (E/M) visit that is related to the recent surgical procedure. We believe that this code will be billed by a physician or practitioner who is seeing the patient for a visit during the post-operative period and did not furnish the surgical procedure.

As we were developing this proposal, we analyzed a few different policy options to best achieve our goal of improving the payment accuracy of the global packages. We considered whether to propose to revalue the 10 and 90-day global packages on the PFS utilizing our findings and data under the MACRA requirement to improve payment accuracy on the fee schedule, however we are precluded from doing so under MACRA. We also considered revaluing services specifically included in the RAND study,[941] which looked at claims for which reporting of follow up visits was requested. We also considered proposing requiring separate billing, which would result in separate payments for the procedures and post operative visits in global packages, based on our current research and analysis of how practitioners may be furnishing care described by global packages. We considered this alternative policy as an initial step towards more accurately paying for global packages, specifically for services including high utilization global packages discussed in the RAND study. We also considered proposing revisions to all global surgical packages in a phased approach starting with the subset of packages described above and gradually revising other global packages over time, to manage

[941] Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods; Updated Results Using Calendar Year 2019 Data.

payment predictability and stability within the PFS, rec.

2. Alternatives Considered Related to the Supervision of Outpatient Therapy Services in Private Practices

As discussed in section II.H of this final rule, we proposed to allow for the general supervision of occupational therapy assistants (OTAs) and physical therapist assistants (PTAs), by OT's and PT's in private practice (OTPPs and PTPPs, respectively) who are enrolled as suppliers in Medicare. Currently, and since 2005, OTPPs and PTPPs are required to provide direct supervision of their OTAs and PTAs which requires the OTPP/PTPP to be immediately available to furnish assistance and direction throughout the performance of the procedure in the office suite or in the patient's home when Medicare patients are treated in order to bill for therapy services furnished by their supervised OTAs and PTAs.

In developing our proposal to allow for general supervision in these private practice settings, we considered the possibility of allowing for virtual direct supervision by the OTPP/PTPP instead, as we have included OTPPs/PTPPs as ''supervising practitioners'' in the application of our virtual direct supervision policy since October 6, 2021, which is now extended through CY 2024. Due to the private practice direct supervision regulatory requirement, when using virtual direct supervision, this means (per our clarification in the CY 2021 PFS final rule (85 FR 84539)) that the OTPP or PTPP could meet the virtual direct supervision requirement by being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the service.

However, if this alternative policy were selected, it will leave the direct supervision requirement in place for OTPPs and PTPPs and they will still have to be immediately available to engage via audio/video technology and ensure their availability to do so. On the other hand, with general supervision, the OTPP's/PTPP's physical or virtual presence is not required when the OTA/PTA furnishes services, although the services continue to be furnished under their overall direction and control allowing the OTPP/PTPP, for example, to provide an evaluative service in the office while the OTA/PTA is off-site furnishing therapy services in a patient's home.

3. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. In section IV.A.4.g.(2)(c) of this final rule, we propose to set the performance threshold to 75 points for the CY 2025 MIPS performance period/CY 2027 MIPS payment year. Eighty-six (86) is a possible alternative value (mean of the CY 2019 performance period/2021 MIPS payment year) which we did not propose. To assess this alternative value, we ran a separate RIA model with a performance threshold of 86. This model has the same mean and median final score as our policies RIA model since the alternative performance threshold which we are assessing in this model does not change the final score. In our analysis of the alternative performance threshold of 86, which we considered but did not propose, 55.98 percent of MIPS eligible clinicians who submitted data will receive a negative payment adjustment in the baseline and 45.08 percent of MIPS eligible clinicians who submit data will receive a negative adjustment in the policies model.

We also reported the findings for the baseline RIA model which describes the impact for the CY 2025 performance period/2027 MIPS payment year if this proposal is not finalized. The baseline RIA model has a median final score of 82.20. We estimated that $517 million will be redistributed based on the budget neutrality requirement in the baseline model. The baseline includes a maximum payment adjustment of 2.98 percent and 22.84 percent of MIPS eligible clinicians will receive a negative payment adjustment.

G. Impact on Beneficiaries

1. Medicare Shared Savings Program Provisions

As noted previously in this final rule, the HEBA will mainly provide upwards adjustments to benchmarks for—and likely draw increased participation from—new ACOs with particular focus on coordinating care for beneficiaries in underserved communities. New ACOs of this type are therefore projected to ultimately increase assignment to the Shared Savings Program by roughly 500,000 beneficiaries per year, ranging from 50,000 to 1.0 million at the low and high ends of this projection range.

ACOs have been found to perform better on certain patient-experience and performance measures than physician groups participating in the MIPS. In performance year 2023, ACOs scored better than comparable MIPS groups on all 3 eCQMs, and the difference was statistically significant for the Controlling High Blood Pressure measure ($p < .001$). ACOs also performed better than comparable MIPS groups on 8 of 10 patient experience survey measures that contribute to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS measure, and for 3 measures the difference was statistically significant ($p < .05$): Getting Timely Care, Appointments, and Information; How Well Providers Communicate; and Patient's Rating of Provider. ACOs showed statistically significant improvement relative to PY 2022 for 7 of 10 CMS Web Interface measures. We anticipate that ACOs will continue to improve the quality of care for their Medicare fee-for-service beneficiaries through the reporting of Medicare CQMs, and that ACOs will continue to improve the quality of care for their all payer/all patient population through the reporting of eCQMs.

Increased participation in the Shared Savings Program will extend ACO care coordination and quality improvement to segments of the beneficiary population that potentially have more to benefit from care management.

2. Quality Payment Program

There are several changes in this final rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, if finalized, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate the policies in this final rule will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which would not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors

frequently of interest to patients when making decisions about treatment.

H. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rulemaking, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's rule will be the number of reviewers of this year's proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing this rulemaking. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the final rule. For these reasons, we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's final rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rulemaking.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rulemaking is $129.28, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this final rule. For each facility that reviews the rule, the estimated cost is $1,034.24 (8.0 hours × $129.28). Therefore, we estimated that the total cost of reviewing this regulation is $7,218,995 ($1,034.24 × 6,980 reviewers on this year's final rule).

As for the Medicare Diabetes Prevention Program, given that we tried to align this rulemaking as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rulemaking impacts only enrolled MDPP suppliers and eligible beneficiaries who have started MDPP or are interested in enrolling in MDPP.

I. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Tables 129 through 131 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2024 to CY 2025 based on the FY 2025 President's Budget baseline.

TABLE 129: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2025 Annualized Monetized Transfers	Estimated decrease in expenditures of $1.8 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 130: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2025 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.4 billion
From Whom to Whom?	Beneficiaries to Federal Government.

TABLE 131: Accounting Statement for Provisions for Medicare Shared Savings Program (CYs 2025-2034) ($ Millions)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 2%	-$17.3 million	-$200.4 million	$127.7 million	Tables 115 through 117; summarized in total in Table 118

Notes: Negative values reflect reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2024.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, 1395w–5, and 1395kk–2.

■ 2. Section 401.305 is amended by revising paragraphs (a)(2), (b)(1) introductory text and (b)(2) introductory text and adding paragraph (b)(3) to read as follows:

§ 401.305 Requirements for reporting and returning of overpayments.

(a) * * *

(2) A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

(b) * * *

(1) Except as provided in paragraphs (b)(2) and (3) of this section, a person who has received an overpayment must report and return the overpayment by the later of either of the following:

* * * * *

(2) The deadline for returning overpayments will be suspended (or will continue to be suspended following the completion of a timely, good faith investigation in accordance with paragraph (b)(3) of this section) when any of the following occurs:

* * * * *

(3)(i) The deadline for reporting and returning overpayments will be suspended when both of the following occurs:

(A) A person has identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason as the initially identified overpayment; and

(B) The person conducts a timely, good-faith investigation to determine whether related overpayments exist.

(ii) If the conditions of paragraph (b)(3)(i) of this section are satisfied, the deadline for reporting and returning the initially identified overpayment and related overpayments that arise from the same or similar cause or reason as the initially identified overpayment will remain suspended until the earlier of:

(A) The date that the investigation of related overpayments has concluded and the aggregate amount of the initially identified overpayments and related overpayments is calculated; or

(B) The date that is 180 days after the date on which the initial identified overpayment was identified.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 4. Section 405.2410 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(c) * * *

(1) For RHCs, the coinsurance amount is determined as described in paragraph (b)(1) of this section; or

(2) For FQHCs, the coinsurance amount is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The payment determined under § 405.2462(j)(2).

■ 5. Section 405.2462 is amended by—

■ a. In paragraphs (f) heading, (f)(1) introductory text, (f)(2), and (g)(1)(ii), removing ''grandfathered'' and adding in its place ''historically excepted''; and

■ b. Revising and republishing paragraph (j).

The revisions and republications read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(j) *Payment amount for intensive outpatient services.* (1) An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(i) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under this paragraph (j)(1).

(ii) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under this paragraph (j)(1); or

(iii) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under this paragraph (j)(1).

(2) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate, except that historically excepted tribal FQHCs are paid pursuant to paragraph (j)(2)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(1)(ii) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a historically excepted tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

■ 6. Section 405.2463 is amended by revising paragraphs (b)(3) introductory text and paragraph (c)(4) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(b) * * *

(3) *Visit-Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2026, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

* * * * *

(c) * * *

(4) For FQHCs billing under PPS, and historically excepted tribal FQHCs that are authorized to bill as a FQHC at the outpatient per visit rate for Medicare as set annually by the Indian Health Service—

* * * * *

■ 7. Section 405.2464 is amended by revising paragraphs (c) and (d) and adding paragraphs (g) and (h) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(c) *Payment for care coordination services.* RHCs and FQHCs are paid for the non-face-to-face care management work involved in coordinating care.

(1) For Chronic Care Management (CCM) services furnished between January 1, 2016, and December 31, 2017, payment to RHCs and FQHCs is based on the physician fee schedule national non-facility payment rate.

(2) For psychiatric collaborative care model (CoCM) services furnished on or after January 1, 2018, payment is based on the average of the national non-facility PFS payment rate set for each psychiatric CoCM service and updated annually based on the PFS amounts.

(3) For CCM and general Behavioral Health Integration (BHI) services furnished between January 1, 2018, and December 31, 2020, payment is based on the average of the national non-facility PFS payment rate set for each CCM and general BHI service and updated annually based on the PFS amounts.

(4) For CCM, general BHI, and Principal Care Management (PCM) services furnished between January 1, 2021, and December 31, 2022, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, and PCM service and updated annually based on the PFS amounts.

(5) For CCM, general BHI, PCM, Chronic Pain Management (CPM) services furnished between January 1, 2023, and December 31, 2023, payment is based on the average of the national non-facility PFS payment rate set for each CCM, general BHI, PCM and CPM service and updated annually based on the PFS amounts.

(6) For CCM, general BHI, PCM, CPM, Remote Physiologic Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Community Health Integration (CHI), Principal Illness Navigation (PIN), and PIN—Peer Support services furnished between January 1, 2024, and December 31, 2024, the payment amount is based on a weighted average of each CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, and PIN—Peer Support service using the most recently available PFS utilization data.

(7) For CCM, general BHI, PCM, CPM, RPM, RTM, CHI, PIN, PIN—Peer Support, and Advance Primary Care Management services furnished on or after January 1, 2025, payment is based on the PFS national non-facility payment rate.

(d) *Payment for FQHCs that are authorized to bill as historically excepted tribal FQHCs.* Historically excepted tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

* * * * *

(g) *Payment for non-behavioral health telecommunication technology services.* For an encounter furnished using interactive, real-time, audio and video telecommunications technology or for certain audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology services that are not described in § 405.2463(b)(3), payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the physician fee schedule (PFS) and costs associated with these services shall not be used in determining payments under the RHC all-inclusive rate or the FQHC prospective payment system.

(h) *Payment for drugs covered as additional preventive services (DCAPS).* For drugs covered as additional preventive services, as defined at § 410.64 of this subchapter, and for the administration and supplying fees for those drugs, payment to RHCs or FQHCs is 100 percent of the Medicare payment amount per § 405.2410(b) and § 410.152(l)(11) of this chapter, subject to the payment limitations described at § 410.152(o) of this chapter.

■ 8. Section 405.2466 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, hepatitis B

and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

§ 405.2469 [Amended]

■ 9. Section 405.2469 is amended in paragraph (a)(2) by removing ''grandfathered'' and adding in its place ''historically excepted''.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 10. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 11. Section 410.26 is amended by revising paragraph (a)(2) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(2) *Direct supervision* means, except as provided in paragraphs (a)(2)(i) and (ii) of this section, the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii). For the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision may include virtual presence through audio/video real-time communications technology (excluding audio-only):

(i) Services furnished incident to the services of a physician or other practitioner when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision and for which the underlying Healthcare Common Procedure Coding System (HCPCS) code has been assigned a PC/TC indicator of '5'.

(ii) Office or other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care practitioner.

* * * * *

■ 12. Section 410.30 is amended by revising paragraph (a) to read as follows:

§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that meet one of the following conditions:

(1) The drug has been approved for marketing by the FDA and—

(i) The approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue; or

(ii) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(2) The drug has been approved for marketing by FDA and determined by a Medicare Administrative Contractor (MAC) (in accordance with part 421, subpart C, of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the MACs may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(3) The drug is a compounded formulation with active ingredients derived only from a drug described in paragraph (a)(1) or (2) of this section and is orally or enterally administered.

* * * * *

■ 13. Section 410.32 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(3) * * *

(ii) *Direct supervision* in the office setting means that the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service. It does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. Through December 31, 2025, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 14. Section 410.37 is amended by—

■ a. In paragraph (a)(1)(iv), removing the text ''barium enemas'' and adding in its place ''computed tomography colonography'';

■ b. Revising paragraph (a)(4);

■ c. In paragraph (e)(2), removing the text ''barium enema'' and adding in its place ''computed tomography colonography'';

■ d. In paragraph (g)(2), removing the text ''barium enema'' and adding in its place ''computed tomography colonography'';

■ e. Revising paragraphs (h), (i), and (k).

The revisions read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(a) * * *

(4) *Screening computed tomography colonography* means a test that uses X-rays and computers to produce images of the entire colon (including image processing and a physician's interpretation of the results of the procedure).

* * * * *

(h) *Conditions for coverage of screening computed tomography colonography.* Medicare Part B pays for a screening computed tomography colonography if it is ordered in writing by the beneficiary's attending physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act).

(i) *Limitations on coverage of screening computed tomography colonography.* (1) In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 59 months have passed following the month in which the last screening computed tomography colonography was performed or 47 months have passed following the month in which the last screening flexible sigmoidoscopy or screening colonoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening computed tomography colonography performed after at least 23 months have passed following the month in which the last screening computed tomography colonography or the last screening colonoscopy was performed.

* * * * *

(k) *A complete colorectal cancer screening.* Effective January 1, 2025, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test or blood-based biomarker colorectal cancer screening test returns a positive result. A follow-on screening colonoscopy in the context of a complete colorectal

cancer screening is not subject to the frequency limitations for colorectal cancer screening in paragraphs (g)(2) or (3) of this section.

■ 15. Section 410.59 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(3) * * *

(ii) By, or under the general supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph (c)(2), occupational therapy services are performed by, or under the general supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, generally supervised by the therapist, and included in the fee for the therapist's services. Occupational therapy services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

* * * * *

■ 16. Section 410.60 is amended by revising paragraphs (a)(3)(ii) and (c)(2) to read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(3) * * *

(ii) By, or under the general supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

* * * * *

(c) * * *

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph (c)(2), physical therapy services are performed by, or under the general supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, generally supervised by the therapist, and included in the fee for the therapist's services. Physical therapy services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

* * * * *

■ 17. Section 410.63 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing the word ''and'' at the end of paragraph (a)(2)(ii);

■ c. Removing the period at the end of paragraph (a)(2)(iii) and adding in its place ''; and'';

■ d. Adding paragraph (a)(2)(iv); and

■ e. Revising paragraphs (b) and (c)(1).

The revisions and addition read as follows:

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

* * * * *

(a) *Hepatitis B vaccine: Conditions.* Effective January 1, 2025, hepatitis B vaccinations are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed in paragraphs (a)(1) through (3) of this section:

* * * * *

(2) * * *

(iv) Individuals who have not previously received a completed hepatitis B vaccination series or whose previous vaccination history is unknown.

* * * * *

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors that are self-administered and control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. Therapies that enable the body to produce clotting factor and do not directly integrate into the coagulation cascade are not themselves clotting factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) * * *

(1) Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors, as described in paragraph (b) of this section, unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay, or practitioners that furnish clotting factor to patients in an outpatient setting and are paid for under the Physician Fee Schedule.

* * * * *

■ 18. Section 410.67 is amended by—

■ a. In paragraph (b), in the definition of ''Opioid use disorder treatment service,'' by:

■ (i) Revising paragraphs (vi) and (vii); and

■ (ii) Adding paragraphs (x) and (xi);

■ b. Adding paragraphs (d)(4)(i)(G) and (H); and

■ c. Revising paragraphs (d)(4)(ii) and (iii).

The revisions and additions read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service

* * *

(vi) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title.

(A) For intake activities furnished via communications technology, the following flexibilities apply:

(*1*) Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(*2*) Services to initiate treatment with methadone may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, if the OTP practitioner determines that an adequate evaluation of the patient can be accomplished through audio-video communication technology.

(B) [Reserved]

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all

applicable requirements. In cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

(x) Coordinated care and/or referral services, provided by an OTP to link a beneficiary with community resources to address unmet health-related social needs or the need and interest for harm reduction interventions and recovery support services that significantly limit the ability to diagnose or treat a patient's opioid use disorder.

(xi) Patient navigational services and/or peer recovery support services, when provided directly by an OTP or through referral, in order to assist patients with an OUD in navigating the health system and accessing supportive services, and/or to provide support in meeting patient-driven OUD treatment and recovery goals.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(G) Coordinated care and/or referral services described in paragraph (x) of the definition of opioid use disorder treatment service in paragraph (b) of this section, an adjustment will be made when each additional 30 minutes of these services are furnished.

(H) Patient navigational services and/or peer recovery support services described in paragraph (xi) of the definition of opioid use disorder treatment service in paragraph (b) of this section, an adjustment will be made when each additional 30 minutes of these services are furnished.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, OTP intensive outpatient services, coordinated care and/or referral services, patient navigational services and/or peer recovery support services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, OTP intensive outpatient services, coordinated care and/or referral services, patient navigational services and/or peer recovery support services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this subchapter.

* * * * *

■ 19. Section 410.78 is amended by revising paragraph (a)(3) read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph (a)(3), multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. The following modifiers must be appended to a claim for telehealth services furnished using two-way, real-time audio-only communication technology to verify that the conditions set forth in the prior sentence have been met:

(i) Current Procedural Terminology (CPT) modifier ''93''; and

(ii) For rural health clinics (RHCs) and federally qualified health centers (FQHCs), Medicare modifier ''FQ''.

* * * * *

■ 20. Section 410.79 is amended by—

■ a. In paragraph (b):

■ i. Removing the definition of ''Combination delivery'';

■ ii. Adding the definitions of ''Combination with an online component,'' ''In-person with a distance learning component,'' and ''Online'' in alphabetical order;

■ iii. Removing the definition of ''Online delivery''; and

■ iv. Revising the definition of ''Set of MDPP services''; and

■ b. Revising paragraphs (d)(1) introductory text, (e)(3)(iii)(C), (e)(3)(iv)(F)(*3*), and (e)(3)(v)(F)(*2*).

The additions and revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(b) * * *

Combination with an online component refers to sessions that are delivered as a combination of online (non-live) with in-person or distance learning.

* * * * *

In-person with a distance learning component refers to DPP sessions that are delivered in person by trained Coaches where participants have the option of attending sessions via MDPP distance learning.

* * * * *

Online means sessions that are delivered 100 percent through the internet via phone, tablet, or laptop in an asynchronous (non-live) classroom where participants are experiencing the content on their own time without a live (including non-artificial intelligence (AI)) Coach teaching the content. These sessions must be furnished in a manner consistent with the DPRP Standards for online sessions. Live Coach interaction must be offered to each participant during weeks when the participant has engaged with content. Emails and text messages can count toward the requirement for live Coach interaction if there is bi-directional communication between the Coach and participant. Chat bots and AI forums do not count as live Coach interaction.

* * * * *

Set of MDPP services means the series of MDPP sessions, composed of core sessions and core maintenance sessions, and subject to paragraph (c)(3) of this section offered over the course of the MDPP services period.

* * * * *

(d) * * *

(1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. MDPP make-up sessions may only use in-person or distance learning delivery. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

* * * * *

(e) * * *

(3) * * *

(iii) * * *

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or

video conferencing, where in the MDPP Coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, or the MDPP supplier receives one (1) or two (2) date-stamped photo(s) or a video recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. Photo or video must clearly document the weight of the MDPP beneficiary as it appears on their digital scale on the date associated with the billable MDPP session. If choosing to submit one photo, this photo must show the beneficiary's weight on the scale with the beneficiary visible in their home. If choosing to submit 2 photos, one photo must show the beneficiary's weight on the digital scale, and a second photo must show the beneficiary visible in their home. All photos must be date-stamped.

* * * * *

(iv) * * *

(F) * * *

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24 for beneficiaries enrolled before January 1, 2022.

* * * * *

(v) * * *

(F) * * *

(*2*) For an MDPP beneficiary who began receiving the Set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

* * * * *

■ 21. Section 410.152 is amended by adding paragraph (o) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(o) *Amount of payment: Drugs covered as additional preventive services (DCAPS).* For a drug covered as an additional preventive service, as defined at § 410.64, payment must be made as follows:

(1) Payment for a drug covered as an additional preventive service, per section 1861(a)(1)(W)(ii) of the Act and paragraphs (l)(11) of this section and § 410.160(b)(13), is 100 percent of the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) The amount determined under the fee schedule as described in paragraph (o)(3) of this section.

(2) Payment for the supplying or administration of a drug covered as an additional preventive service per section 1861(a)(1)(W)(ii) of the Act and paragraphs (l)(11) of this section and § 410.160(b)(13), is 100 percent of the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) The amount determined under the fee schedule as described in paragraph (o)(4) of this section.

(3) The payment limit for a drug covered as an additional preventive service, as defined at § 410.64, appears on the DCAPS fee schedule and is determined as follows:

(i) If Average Sales Price (ASP) data is available for the drug, consistent with part 414, subpart J, of this chapter, then the payment limit is determined using the methodology set forth in section 1847A of the Act and according to the provisions in part 414, subpart K, of this chapter.

(ii) If ASP data is not available, then the payment limit is determined according to the most recently published National Average Drug Acquisition Cost (NADAC) prices for the drug and is the lesser of the median NADAC price of all generic forms of the drug or the lowest NADAC price brand name product.

(iii) If ASP data and NADAC prices are not available, then the payment limit is determined according to the most recently published pharmaceutical pricing data for the drug as included in the Federal Supply Schedule (FSS), as managed by the Department of Veterans Affairs per 48 CFR part 38, and is the lesser of the median FSS price of all generic forms of the drug or the lowest FSS price brand name product.

(iv) If ASP data, NADAC prices, and FSS pharmaceutical prices are not available, then the payment limit is the invoice price determined by the MAC.

(4) The payment limits for supplying and administering a drug covered as an additional preventive service, as defined at § 410.64, appear on the DCAPS fee schedule and are determined as follows:

(i) For a drug that is supplied by a pharmacy, the payment limit for a supplying fee is as follows:

(A) For the first prescription that the pharmacy provides to a beneficiary in a 30-day period for a drug covered as an additional preventive service, $24.

(B) For all subsequent prescriptions that the pharmacy provides to a beneficiary in a 30-day period for a drug covered as an additional preventive service, $16.

(ii) For a drug that is administered by a physician or a non-physician practitioner, the payment limit for administration is set in accordance with part 414, subpart B, of this chapter. This fee is not subject to the Part B deductible, per § 410.160(b)(13). This fee is equal to 100 percent of the Medicare payment amount established under the applicable payment methodology, per paragraph (l)(11) of this section.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 22. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 23. Section 411.15 is amended by adding paragraph (i)(3)(i)(F) to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(i) * * *

(3) * * *

(i) * * *

(F) Dental or oral examination performed as part of a comprehensive workup prior to, or contemporaneously with, Medicare-covered dialysis services when used in the treatment of end stage renal disease (ESRD); and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, Medicare-covered dialysis services when used in the treatment of ESRD.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 24. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 25. Section 414.84 is amended by—

■ a. In paragraph (a), removing the definition of ''Bridge payment'';

■ b. Revising paragraphs (b)(1) introductory text and (b)(2) introductory text;

■ c. Adding paragraph (c)(4);

■ d. Revising paragraph (d); and

■ e. Removing paragraph (e).

The revisions and addition read as follows:

§ 414.84 Payment for MDPP services.

* * * * *

(b) * * *

(1) *Performance Goal 1: Achieves the required minimum 5-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves the required minimum weight loss as measured in-person or during a distance learning session during a core session or

core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(2) *Performance Goal 2: Achieves 9-percent weight loss.* CMS makes a performance payment to an MDPP supplier for an MDPP beneficiary who achieves at least a 9-percent weight loss as measured in-person or in a distance learning session during a core session or core maintenance session furnished by that supplier. The amount of this performance payment is determined as follows:

* * * * *

(c) * * *

(4) Current Procedural Terminology (CPT) Modifier 76 (repeat services by same physician) must be appended to any claim for G9886 or G9887 to identify a MDPP make-up session that was held on the same day as a regularly scheduled MDPP session.

(d) *Updating performance payments and attendance payments.* The performance payments and attendance payments will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI–U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. The percent change update will be calculated based on the level of precision of the index as published by the Bureau of Labor Statistics (BLS) and applied based on one decimal place of precision. The annual MDPP services payment update will be published by CMS transmittal.

■ 26. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2026, through March 31, 2026, the data collection period is January 1, 2019, through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019, through June 30, 2019, the data reporting period is January 1, 2026, through March 31, 2026.

* * * * *

§ 414.504 [Amended]

■ 27. Section 414.504 is amended in paragraph (a)(1) by removing the reference ''January 1, 2024'' and adding in its place the reference ''January 1, 2026''.

■ 28. Section 414.507 is amended by revising paragraphs (d) introductory text and paragraphs (d)(7) and (8), and adding paragraphs (d)(10) and (11) to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2028, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(7) 2024—0.0 percent of the payment rate established in 2023.

(8) 2025—0.0 percent of the payment rate established in 2024.

* * * * *

(10) 2027—15 percent of the payment rate established in 2026.

(11) 2028—15 percent of the payment rate established in 2027.

* * * * *

■ 29. In § 414.605 amend the definition of ''Advanced life support, level 2 (ALS2)'' by adding paragraph (8) to read as follows:

§ 414.605 Definitions.

* * * * *

Advanced life support, level 2 (ALS2)

* * *

(8) Prehospital blood transfusion which includes:

(i) Administration of low titer O+ and O− whole blood (WBT);

(ii) Administration of packed red blood cells (PRBCs);

(iii) Administration of plasma; or

(iv) Administration of a combination of PRBCs and plasma.

* * * * *

■ 30. Section 414.902 is amended by revising the definition ''Refundable single-dose container or single-use package drug'' to read as follows:

§ 414.902 Definitions.

* * * * *

Refundable single-dose container or single-use package drug means:

(1) A single source drug or biological or a biosimilar biological product for which payment is made under this part and that is—

(i) Furnished from a single-dose container or single-use package based on FDA-approved labeling or product information; or

(ii) Furnished from an ampule for which product labeling does not have discard statement or language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container; or

(iii) Furnished from a container with a total labeled volume of 2 mL or less for which product labeling does not have language indicating if the container is single-dose container, single-use package, multiple-dose container, or single-patient-use container.

(2) Excludes—

(i) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(ii) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(iii) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

(iv) A drug approved or licensed by FDA on or after November 15, 2021 and for which the date the drug was first marketed (as reported to CMS) does not adequately approximate the date of first payment under Part B due to an applicable national coverage determination, until the last day of the sixth full quarter for which the drug has been covered and paid under Medicare Part B for the first National Drug Code assigned to the billing and payment code of such drug.

* * * * *

■ 31. Section 414.904 is amended by adding paragraph (e)(6) and revising paragraph (i) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(e) * * *

(6) *Radiopharmaceuticals furnished in settings other than the hospital outpatient department.* Medicare administrative contractors must determine payment limits for

radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

* * * * *

(i) *Manufacturer's average sales price (ASP) data not available prior to the publication deadline for quarterly payment limits.* For circumstances in which manufacturer's ASP data is not available prior to the publication deadline for quarterly payment limits as described in this section, payment limit must be determined as follows:

(1) For a multiple source drug (as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data, except in circumstances described in paragraph (i)(1)(iii) of this section.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated by carrying over all positive manufacturer's ASP data from the most recently available previous quarter with positive manufacturer's ASP data for at least one NDC until at least one NDC for the drug has positive manufacturer's ASP data for a quarter.

(iii) In circumstances in which manufacturer's ASP data is not available and the unavailability of the manufacturer's ASP data results in a significant change in the ASP payment limit compared to the previous quarter, the payment limit is calculated by carrying over the most recently available ASP data for the individual NDC(s), adjusted by the weighted average of the change in the manufacturer's ASP data for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(2) For a single source drug, excluding biosimilar biological products (both as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is calculated using only NDCs for that drug with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs associated with a billing and payment code for that drug for a given quarter, the payment limit for the given quarter is the lesser of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) 106 percent of the volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter in which at least one NDC for the drug has positive manufacturer's ASP data for the quarter. If the payment limit from such quarter was based on 106 percent of the wholesale acquisition cost because of the application of paragraph (d)(1) of this section, that payment limit is carried over; or

(B) 106 percent of the wholesale acquisition cost. If there is more than one WAC per billing unit for the drug, the payment limit is set using the lowest WAC per billing unit.

(3) For a biosimilar biological product (as defined in § 414.902)—

(i) In circumstances in which negative or zero manufacturer's ASP data is reported for one or more, but not all, NDCs for a given quarter, the payment limit for the given quarter is calculated using only NDCs with positive manufacturer's ASP data.

(ii) In circumstances in which negative or zero manufacturer's ASP data is reported for all NDCs for a given quarter, the payment limit for the given quarter is the sum of the following until at least one NDC for the drug has positive manufacturer's ASP data for a quarter:

(A) The volume-weighted average of the most recently available positive manufacturer's ASP data from a previous quarter; and

(B) Either:

(*1*) If the biosimilar is not a qualifying biosimilar (as both are defined at § 414.902), 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter; or

(*2*) If the biosimilar is a qualifying biosimilar (as both are defined at § 414.902), 8 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902) for the given quarter.

* * * * *

■ 32. Section 414.1001 is amended by—

■ a. Revising paragraph (a);

■ b. Removing paragraph (b);

■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively;

■ d. In newly redesignated paragraph (b)(2), removing ''(c)(1)'' and adding in its place ''(b)(1)''.

The revision reads as follows:

§ 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of $24 is paid to a pharmacy (no more often than once every 30 days) for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary, except as provided in paragraph (a)(2) of this section.

(2) A supplying fee of $50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(3) A supplying fee of $16 is paid to a pharmacy (no more often than once every 30 days) for each prescription following the first prescription (as specified in paragraphs (a)(1) and (2) of this section) of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary.

(4) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

* * * * *

■ 33. Section 414.1325 is amended by adding paragraphs (a)(1)(i) through (iii) and (f) to read as follows:

§ 414.1325 Data submission requirements.

(a) * * *

(1) * * *

(i) For the quality performance category, a data submission must include numerator and denominator data for at least one MIPS quality measure from the final list of MIPS quality measures.

(ii) For the improvement activities performance category, a data submission must include a response of ''yes'' for at least one activity in the MIPS improvement activities inventory.

(iii) For the Promoting Interoperability performance category, a data submission must include all of the following elements:

(A) Performance data, including any claim of an applicable exclusion, for the measures in each objective, as specified by CMS;

(B) Required attestation statements, as specified by CMS;

(C) CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL); and

(D) The start date and end date for the applicable performance period as set forth in § 414.1320.

* * * * *

(f) *Treatment of multiple data submissions.* (1) For multiple data submissions received in the quality and improvement activities performance categories in accordance with paragraphs (a)(1)(i) and (ii) of this section for an individual MIPS eligible clinician, group, subgroup, or virtual group from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. For multiple data submissions received for an individual MIPS eligible clinician, group, subgroup, or virtual group from one or multiple submitters in the same organization, CMS will score the most recent submission.

(2) For multiple data submissions received for the Promoting Interoperability performance category, CMS will calculate a score for each data submission received and assign the highest of the scores.

■ 34. Section 414.1330 is amended by adding paragraph (c) to read as follows.

§ 414.1330 Quality performance category.

* * * * *

(c)(1) CMS uses the following criteria to determine the removal of a quality measure:

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.

(ii) If a measure steward is no longer able to maintain the quality measure.

(iii) If the quality measure reached extremely topped out status.

(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.

(v) If the quality measure is duplicative.

(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.

(vii) If the quality measure is a process measure.

(viii) If the quality measure addresses a measurement gap.

(ix) If the quality measure is a patient-reported outcome.

(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.

(xi) The robustness of the quality measure.

(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

(2) A quality measure that otherwise meets the criteria for removal in paragraph (c)(1) of this section may nonetheless be retained based on the following considerations:

(i) Whether the removal of the process measure impacts the number of measures available for a specific specialty.

(ii) Whether the quality measure addresses a priority area.

(iii) Whether the quality measure promotes positive outcomes in patients.

(iv) Whether the quality measure is designated as high priority or not.

(v) Whether the quality measure has reached extremely topped out status.

(vi) Evaluation of the quality measure's performance data.

■ 35. Section 414.1335 is amended by revising paragraph (a) introductory text and adding paragraph (b) to read as follows.

§ 414.1335 Data submission criteria for the quality performance category.

(a) *Criteria.* Except as provided in paragraph (b) of this section, a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must submit data on MIPS quality measures in one of the following manners, as applicable:

* * * * *

(b) *Special rule for the APM Performance Pathway (APP) Plus measure set.* A MIPS eligible clinician, group, or APM Entity that reports the APP Plus measure set via the APP must report on all measures included in the APP Plus measure set, except for administrative claims-based quality measures as provided in § 414.1325(a)(2)(i).

■ 36. Section 414.1340 is amended by revising paragraphs (a)(4), (b)(4), (d) introductory text, and (d)(1) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(4) At least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

(b) * * *

(4) At least 75 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations that meet reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20 of this chapter, who meet the measure's denominator criteria for MIPS payment years 2026, 2027, 2028, 2029, and 2030.

* * * * *

■ 37. Section 414.1350 is amended by adding paragraph (e) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(e) *Cost measure removal criteria.* CMS may remove a cost measure from MIPS based on one or more of the following factors, provided however CMS may retain a cost measure that meets one or more of the following factors if CMS determines the benefit of retaining the measure outweighs the benefit of removing it.

(1) It is not feasible to implement the measure specifications.

(2) A measure steward is no longer able to maintain the cost measure.

(3) The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.

(4) The measure specifications do not reflect current clinical practice or guidelines.

(5) The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

■ 38. Section 414.1355 is amended by adding paragraph (d) to read as follows:

§ 414.1355 Improvement activities performance category.

* * * * *

(d) CMS may remove an improvement activity from MIPS based on one or more of the following factors, provided however CMS may retain an improvement activity that meets one or more of the following factors if CMS determines the benefit of retaining the activity outweighs the benefit of removing it:

(1) *Factor 1:* Activity is duplicative of another activity.

(2) *Factor 2:* There is an alternative activity with a stronger relationship to

quality care or improvements in clinical practice.

(3) *Factor 3:* Activity does not align with current clinical guidelines or practice.

(4) *Factor 4:* Activity does not align with at least one meaningful measures area.

(5) *Factor 5:* Activity does not align with the quality, cost, or Promoting Interoperability performance categories.

(6) *Factor 6:* There have been no attestations of the activity for 3 consecutive years.

(7) *Factor 7:* Activity is obsolete.

■ 39. Section 414.1365 is amended by revising paragraphs (b)(2)(i), (c)(3)(i) and (ii), (c)(4)(i)(A), (d)(3)(i)(A) introductory text, (d)(3)(i)(A)(*1*), (d)(3)(ii) introductory text, (d)(3)(ii)(A), and (d)(3)(iii) to read as follows:

§ 414.1365 MIPS Value Pathways.

* * * * *

(b) * * *

(2) * * *

(i) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each MVP Participant must select an MVP, one population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored. Beginning in the CY 2025 performance period/2027 MIPS payment year, each MVP Participant must select an MVP and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

* * * * *

(c) * * *

(3) * * *

(i) For the CY 2023 and 2024 performance periods/2025 through 2026 MIPS payment years:

(A) Two medium-weighted improvement activities.

(B) One high-weighted improvement activity.

(C) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(ii) Beginning in the CY 2025 performance period/2027 MIPS payment year:

(A) One improvement activity.

(B) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

* * * * *

(4) * * *

(i) * * *

(A) An MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, for the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points. Beginning in the CY 2025 performance period/2027 MIPS payment year, except as provided in paragraph (d)(3)(i)(A)(*1*) of this section, the highest score of all applicable and available population health measures will be used. If no population health measure has a benchmark or meets the case minimum requirement, each such measure is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) For the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, a subgroup is scored on each selected population health measure based on its affiliated group score, if available. Beginning in the CY 2025 performance period/2027 MIPS payment year, a subgroup is scored on the highest scoring of all available population health measures based on its affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

* * * * *

(ii) *Cost performance category.* The cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2) and the cost measures included in the MVP that they select and report.

(A) A subgroup is scored on each cost measure included in the MVP that it selects and reports based on its affiliated group score for each such measure, if available. If the subgroup's affiliated group score is not available for a measure, the measure is excluded from the subgroup's total measure achievement points and total available measure achievement points, as described under § 414.1380(b)(2).

* * * * *

(iii) *Improvement activities performance category.* In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Beginning in the CY 2025 performance period/2027 MIPS payment year, MVP Participants will receive 40 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized PCMH or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

* * * * *

■ 40. Section 414.1367 is amended by revising paragraph (c)(1) introductory text and adding paragraph (c)(1)(iii) to read as follows:

§ 414.1367 APM performance pathway.

* * * * *

(c) * * *

(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the quality measure set applicable to the MIPS eligible clinician, group, or APM Entity group under paragraph (c)(1)(iii) of this section and established by CMS through rulemaking for a MIPS payment year.

* * * * *

(iii)(A) For performance periods beginning prior to CY 2025 and MIPS payment years beginning prior to 2027, a MIPS eligible clinician, group, or APM Entity group must report the APM Performance Pathway quality measure set.

(B) Beginning with the CY 2025 performance period/2027 MIPS payment year, a MIPS eligible clinician, group, or APM Entity group may choose to report either the APM Performance Pathway quality measure set or the APP Plus quality measure set.

* * * * *

■ 41. Section 414.1380 is amended by—

■ a. Revising paragraph (b)(1)(ii) introductory text;

■ b. Adding paragraphs (b)(1)(ii)(E) and (F);
■ c. Revising paragraph (b)(1)(iv)(B);
■ d. Adding paragraph (b)(1)(iv)(C);
■ e. Revising paragraph (b)(1)(vii) introductory text;
■ f. Adding paragraph (b)(1)(vii)(C);
■ g. Revising paragraph (b)(2) introductory text;
■ h. Adding paragraphs (b)(2)(i)(A) and (B) and (b)(2)(v)(B);
■ i. Revising paragraph (b)(3) introductory text; and
■ j. Adding paragraphs (c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) through (F) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

* * * * *

(E) Beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

(F) Beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type use flat benchmarks for their first two performance periods in MIPS.

* * * * *

(iv) * * *

(B) Beginning with the 2021 MIPS payment year, except as provided for in paragraph (b)(1)(iv)(C) of this section, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(C) Beginning with the CY 2025 performance period/2027 MIPS payment year, measures impacted by limited measure choice as specified in paragraph (b)(1)(ii)(E) of this section are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B) of this section.

* * * * *

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section and Complex Organization Adjustment in paragraph (b)(1)(vii)(C) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

* * * * *

(C) Beginning in the CY 2025 performance period/2027 MIPS payment year, a Virtual Group and an APM Entity receives one measure achievement point for each eCQM submitted that meets the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340. Each measure may not exceed 10 measure achievement points. The total adjustment to the Virtual Group or APM Entity's quality performance category score under this paragraph (b)(1)(vii)(C) may not exceed 10 percent of the total available measure achievement points.

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark range the MIPS eligible clinician's performance on the measure is in. CMS assigns partial points based on where the MIPS eligible clinician's performance falls between the top and bottom of the benchmark ranges.

(i) * * *

(A) For the 2019 through 2025 MIPS payment years, CMS determines cost measure benchmark ranges based on linear percentile distributions.

(B) Beginning with the 2026 MIPS payment year, for each cost measure, CMS determines 10 benchmark ranges based on the median cost of all MIPS eligible clinicians attributed the measure, plus or minus standard deviations. CMS awards achievement points based on which benchmark range a MIPS eligible clinician's average cost for a cost measure corresponds. Additionally, CMS awards achievement points equivalent to 10 percent of the performance threshold for a MIPS eligible clinician whose average cost attributed under a cost measure is equal to the median cost for all MIPS eligible clinicians attributed the measure.

* * * * *

(v) * * *

(B) Beginning with the 2026 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(B), ''significant changes or errors'' are changes or errors external to the care provided, and that CMS determines may lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance. Significant changes or errors include, but are not limited to, rapid or unprecedented changes to service utilization, the inadvertent omission of codes or inclusion of codes, or changes to clinical guidelines or measure specifications. CMS will empirically assess the affected cost measure to determine the extent to which the changes or errors impact the calculation of a cost measure score such that calculating the cost measure score would lead to misleading or inaccurate results that negatively impact the measure's ability to reliably assess performance.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. In the CY 2023 through 2024 performance periods/2025 through 2026 MIPS payment years, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and

geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Beginning in the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 20 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 40 points for each improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*10*) Beginning with the 2026 MIPS payment year, for the quality and improvement activities performance categories, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the affected performance category(ies), CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

* * * * *

(C) * * *

(*12*) Beginning with the 2026 MIPS payment year, CMS determines, based on documentation provided to the agency on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the Promoting Interoperability performance category, CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category; whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category in accordance with applicable deadlines.

* * * * *

■ 42. Section 414.1405 is amended by adding paragraph (b)(10) and revising paragraph (g) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(10) Pursuant to the methodology established at paragraph (g)(2) of this section:

(i) The performance threshold for the 2027 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

(ii) [Reserved]

* * * * *

(g) *Performance threshold methodology.* (1) For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(9) of this section.

(2) For each of the 2027, 2028, and 2029 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b)(10) of this section.

■ 43. Section 414.1430 is amended by—

■ a. Revising paragraph (a)(1)(v);

■ b. Adding paragraph (a)(1)(vi);

■ c. Revising paragraph (a)(2)(v);

■ d. Adding paragraph (a)(2)(vi);

■ e. Revising paragraph (a)(3)(v);

■ f. Adding paragraph (a)(3)(vi);

■ g. Revising paragraph (a)(4)(v);

■ h. Adding paragraph (a)(4)(vi); and

■ i. Revising paragraphs (b)(1)(i)(A) and (B), (b)(2)(i)(A) and (B), (b)(3)(i)(A) and (B), and (b)(4)(i)(A) and (B).

The revisions and additions read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) * * *

(v) 2026: 50 percent.

(vi) 2027 and later: 75 percent.

(2) * * *

(v) 2026: 40 percent.

(vi) 2027 and later: 50 percent.

(3) * * *

(v) 2026: 35 percent.

(vi) 2027 and later: 50 percent.

(4) * * *

(v) 2026: 25 percent.

(vi) 2027 and later: 35 percent.

(b) * * *

(1) * * *

(i) * * *

(A) 2021 through 2026: 50 percent.

(B) 2027 and later: 75 percent.

* * * * *

(2) * * *

(i) * * *

(A) 2021 through 2026: 40 percent.

(B) 2027 and later: 50 percent.

* * * * *

(3) * * *

(i) * * *

(A) 2021 through 2026: 35 percent.

(B) 2027 and later: 50 percent.

* * * * *

(4) * * *

(i) * * *

(A) 2021 through 2026: 25 percent.

(B) 2027 and later: 35 percent.

* * * * *

■ 44. Section 414.1450 is amended by revising paragraph (a)(1)(i) and the first sentence of paragraph (b)(1) to read as follows:

§ 414.1450 APM incentive payment.

(a) * * *

(1) * * *

(i) For payment years 2019 through 2026, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section in the manner described in paragraphs (d) and (e) of this section.

* * * * *

(b) * * *

(1) For payment years 2019 through 2024, the amount of the APM Incentive Payment is equal to 5 percent, with respect to payment year 2025, 3.5 percent, or with respect to payment year 2026, 1.88 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. * * *

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 45. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 46. Section 422.326 is amended by revising paragraph (c) to read as follows:

§ 422.326 Reporting and returning of overpayments.

* * * * *

(c) *Identified overpayment.* The MA organization has identified an overpayment when the MA organization knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 47. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 48. Section 423.160 is amended by revising paragraph (a)(5) introductory text to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iii) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section, subject to the exemption in paragraph (a)(3)(iii) of this section. Prescriptions written for a beneficiary in a long-term care facility will not be included in determining compliance until January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a long-term care facility will commence on or after January 1, 2028. Compliance actions against prescribers who do not meet the compliance threshold based on other prescriptions will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

* * * * *

■ 49. Section 423.360 is amended by revising paragraph (c) to read as follows:

§ 423.360 Reporting and returning of overpayments.

* * * * *

(c) *Identified overpayment.* The Part D sponsor has identified an overpayment when the Part D sponsor knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 50. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 51. Section 424.24 is amended by revising paragraphs (c) heading, (c)(1)(i), and (c)(3)(ii) and adding paragraph (c)(5) to read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(c) *Outpatient physical therapy, occupational therapy, and speech-language pathology services*—

(1) * * *

(i) The individual needs, or needed, physical therapy, occupational therapy, or speech-language pathology services.

* * * * *

(3) * * *

(ii) If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case, except as specified in paragraph (c)(5) of this section.

* * * * *

(5) *Treatment plan.* If the plan of treatment is established by a physical therapist, occupational therapist, or speech-language pathologist, and there is a written order or referral from the individual's physician, nurse practitioner (NP), physician assistant (PA), or clinical nurse specialist (CNS) in the patient's record and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation, the certification does not need to be signed by a physician, NP, CNS, or PA who has knowledge of the case. If there is no written order or referral from the individual's physician, NP, CNS, or PA, in the patient's record, the therapist must obtain the signature of the physician, NP, PA, or CNS on the plan of treatment in accordance with paragraph (c)(3) of this section. No references to an order or referral in this subsection shall be construed to require an order or referral for outpatient physical therapy, occupational therapy, or speech-language pathology services.

* * * * *

■ 52. Section 424.205 is amended by revising paragraphs (c)(10), (f)(1)(ii), (f)(2)(i), and (f)(5) to read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(c) * * *

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person or distance learning core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which begins on the date of attendance at the first such core session.

(ii) 1 in-person or distance learning core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

* * * * *

(f) * * *

(1) * * *

(ii) Basic beneficiary information for each MDPP beneficiary in attendance, including but not limited to beneficiary name, Medicare Beneficiary Identifier (MBI), and age.

* * * * *

(2) * * *

(i) Documentation of the type of session (in-person or distance learning).

* * * * *

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has achieved the required minimum 5-percent weight loss as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(ii) Has achieved the required minimum 5-percent weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(1) of this chapter.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

(iv) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(2) of this chapter.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 53. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 54. Section 425.100 is amended by adding paragraph (e) to read as follows:

§ 425.100 General.

* * * * *

(e) An ACO is eligible to receive prepaid shared savings if it meets the criteria under § 425.640(b).

■ 55. Section 425.110 is amended by revising paragraph (b)(2) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) * * *

(2) For performance years starting before January 1, 2025, if the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a corrective action plan (CAP), CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

* * * * *

■ 56. Section 425.202 is amended by revising paragraph (a)(3) to read as follows:

§ 425.202 Application procedures.

(a) * * *

(3) An ACO that seeks to participate in the Shared Savings Program must agree that CMS can share a copy of their application with the Antitrust Agencies.

* * * * *

■ 57. Section 425.204 is amended by—

■ a. Revising paragraphs (f)(1) and (f)(3) introductory text;

■ b. In paragraphs (f)(3)(iv), (f)(4)(iv)(A), and (f)(6)(ii) introductory text, removing the phrase ''any shared losses incurred'' and adding in its place the phrase ''any shared losses incurred and prepaid shared savings determined to be owed'';

■ c. In paragraphs (f)(5) and (f)(6)(iv)(A), removing the phrase ''shared losses owed'' and adding in its place the phrase ''shared losses owed or prepaid shared savings determined to be owed'';

■ d. In paragraph (f)(6)(iii), removing the phrase ''shared losses'' and adding in its place the phrase ''shared losses or prepaid shared savings determined to be owed''; and

■ e. In paragraph (f)(6)(iv)(C), removing the phrase ''owe any shared losses'' and adding in its place the phrase ''owe any shared losses or prepaid shared savings''.

The revisions read as follows:

§ 425.204 Content of the application.

* * * * *

(f) * * *

(1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model and any prepaid shared savings determined to be owed.

* * * * *

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism. If the ACO will receive prepaid shared savings, the repayment mechanism must also support repayment of prepaid shared savings in accordance with § 425.640.

* * * * *

■ 58. Section 425.224 is amended by revising paragraph (a)(3) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

(a) * * *

(3) An ACO that seeks to enter a new participation agreement under the Shared Savings Program must agree that CMS can share a copy of its application with the Antitrust Agencies.

* * * * *

■ 59. Section 425.304 is amended by adding paragraph (d) to read as follows:

§ 425.304 Beneficiary incentives.

* * * * *

(d) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2) of this title) is available to protect remuneration furnished in the prepaid shared savings option of the Shared Savings Program in the form of direct beneficiary services that meets all safe harbor requirements set forth in § 1001.952(ii) of this title.

■ 60. Section 425.308 is amended by adding paragraph (b)(10) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(10) Information updated annually about the ACO's use of prepaid shared savings under § 425.640, for each performance year, including the following:

(i) Total amount of any prepaid shared savings received from CMS.

(ii) The ACO's spend plan.

(iii) An itemization of how prepaid shared savings were spent during the year, including expenditure categories, the dollar amounts spent on the various categories, information about which groups of beneficiaries received direct beneficiary services that were purchased with prepaid shared savings and investments that were made in the ACO with prepaid shared savings, how these direct beneficiary services were provided to beneficiaries and how the direct beneficiary services and investments supported the care of beneficiaries, any changes to the spend plan as submitted under § 425.640(d)(2) (if applicable), and such other information as may be specified by CMS.

* * * * *

■ 61. Section 425.312 is amended by revising paragraphs (a)(2)(iii) and (a)(2)(v)(A) to read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(iii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each beneficiary who received at least one primary care service during the assignment window or applicable expanded window for assignment (as defined in § 425.20) from a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in § 425.402(c), a FQHC or RHC that is part of the ACO, or an ACO professional in the ACO

whom the beneficiary designated as responsible for coordinating their overall care under § 425.402(e) with a standardized written notice at least once during an agreement period in the form and manner specified by CMS. The standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.

* * * * *

(v) * * *

(A) The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.

* * * * *

■ 62. Section 425.315 is amended by revising paragraph (a)(4) and adding paragraph (b) to read as follows:

§ 425.315 Reopening determinations of ACO shared savings or shared losses to correct financial reconciliation calculations.

(a) * * *

(4) CMS has the sole discretion to determine whether to reopen a payment determination under this section.

(b) *Reopening requests.* An ACO may request a reopening in a form and manner specified by CMS and consistent with the timeframes for a reopening specified in paragraphs (a)(1)(i) and (ii) of this section.

■ 63. Section 425.316 is amended by adding paragraph (f) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(f) *Monitoring ACO eligibility for and use of prepaid shared savings.* (1) CMS monitors an ACO that receives prepaid shared savings pursuant to § 425.640 to ensure ACO compliance with § 425.640(e) and to determine whether it would be appropriate to withhold or terminate an ACO's prepaid shared savings under § 425.640(h).

(2) If CMS determines that an ACO receiving prepaid shared savings is using the funds for a prohibited use under § 425.640(e)(2), fails to spend the funding in accordance with § 425.640(e)(1)(i) and (ii), or spends more than 50 percent of the estimated annual payment amount on staffing and healthcare infrastructure CMS:

(i) Will require the ACO to reallocate the funding as permitted by § 425.640(e) and submit an updated spend plan demonstrating the reallocation by a deadline specified by CMS.

(ii) May take compliance action as specified in §§ 425.216, 425.218, and 425.640(h)(1).

(3) If an ACO fails to reallocate prepaid shared savings it received as described in paragraph (f)(2)(i) of this section by a deadline specified by CMS, the ACO must repay all prepaid shared savings it received and may be subject to compliance action as specified in §§ 425.216 and 425.218. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

■ 64. Section 425.400 is amended by revising paragraph (c)(1)(viii) introductory text and adding paragraph (c)(1)(ix) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(viii) For the performance year starting on January 1, 2024, as follows:

* * * * *

(ix) For the performance year starting on January 1, 2025, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(ix)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for social determinants of health risk assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*14*) G0539 and G0540 (codes for individual behavior management/modification caregiver training services).

(*15*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*16*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*17*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*18*) G0560 (code for safety planning interventions).

(*19*) G2010 (code for the remote evaluation of patient video/images).

(*20*) G2012 and G2252 (codes for virtual check-in).

(*21*) G2058 (code for non-complex chronic care management).

(*22*) G2064 and G2065 (codes for principal care management services).

(*23*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*24*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*25*) G2214 (code for psychiatric collaborative care model).

(*26*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(ix)(A) of this section or a HCPCS code specified in paragraph (c)(1)(ix)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 65. Section 425.402 is amended by revising paragraph (e)(2)(ii) introductory text and adding paragraph (e)(2)(iii) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) * * *

(ii) For performance years starting on January 1, 2019, through 2024:

* * * * *

(iii) For performance year 2025 and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act that meets the following conditions—

(*1*) Claims-based assignment for the model is based solely on either—

(*i*) Claims for primary care and/or other services related to treatment of one or more specific diseases or conditions targeted by the model; or

(*ii*) Claims for services other than primary care services; and

(*2*) There has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

* * * * *

■ 66. Section 425.508 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

* * * * *

(b) *For performance years beginning in 2021–2024.* ACOs must submit the quality data via the APM Performance Pathway (APP) established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

(c) *For performance years beginning on or after January 1, 2025.* ACOs must submit the quality data via the APM Performance Pathway (APP) on the quality measures contained in the APP Plus quality measure set established under § 414.1367 of this chapter to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

■ 67. Section 425.510 is amended by revising the section heading and paragraph (b) to read as follows:

§ 425.510 Application of the APM Performance Pathway (APP) quality measure set or the APP Plus quality measure set (as applicable) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

* * * * *

(b) *Quality reporting.* (1) For performance years beginning in 2021–2024, ACOs must report quality data on the APP quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(2) For performance years beginning on or after January 1, 2025, ACOs must report quality data on the APP Plus quality measure set established under § 414.1367 of this chapter, according to the method of submission established by CMS.

* * * * *

■ 68. Section 425.512 is amended by—

■ a. Revising paragraph (a)(2)(iii);

■ b. Adding paragraph (a)(2)(iv);

■ c. Revising paragraphs (a)(5)(i) introductory text, (a)(5)(i)(A) introductory text, (a)(5)(i)(B);

■ d. Adding paragraph (a)(5)(i)(C);

■ e. Revising paragraphs (a)(5)(ii) and (a)(5)(iii)(B);

■ f. Adding paragraph (a)(5)(iii)(C);

■ g. Revising paragraph (a)(7);

■ h. Revising and republishing paragraph (b);

■ i. In paragraph (c)(3) introductory text, removing the phrase ''via the APP'' and adding in its place the phrase ''on the APP quality measure set or the APP Plus quality measure set (as applicable)'';

■ j. In paragraph (c)(3)(iii), removing the phrase ''and subsequent performance years'' after ''For performance year 2024''; and

■ k. Adding paragraph (c)(3)(iv).

The revisions, republication, and additions read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) * * *

(iii) For performance years 2025 and 2026. If the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter on all eCQMs/MIPS CQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, for the applicable performance year.

(iv) For performance year 2027 and subsequent performance years. If the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter on all eCQMs/Medicare CQMs, and the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this

subchapter, for the applicable performance year.

* * * * *

(5) * * *

(i) Except as specified in paragraphs (a)(2) and (7) of this section, CMS designates the quality performance standard as:

(A) For performance year 2024, the ACO reporting quality data on the APP quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—

* * * * *

(B) For performance years 2025 and 2026, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; or

(*2*) If the ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 of this subchapter for all eCQMs/MIPS CQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

(C) For performance year 2027 and subsequent performance years, the ACO reporting quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter, according to the method of submission established by CMS and—

(*1*) Achieving a health equity adjusted quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; or

(*2*) If the ACO reports all of the eCQMs in the APP Plus quality measure set applicable for a performance year, meeting the data completeness requirement at § 414.1340 of this subchapter for all eCQMs, and achieving a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

(ii) CMS designates an alternative quality performance standard for an ACO that does not meet the criteria described in paragraph (a)(2) or (a)(5)(i) of this section as the following:

(A) For performance year 2024, the ACO reports quality data on the APP quality measure set established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the four outcome measures in the APP quality measure set.

(B) For performance year 2025 and subsequent performance years, the ACO reports quality data on the APP Plus quality measure set established under § 414.1367 of this subchapter according to the method of submission established by CMS and achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set.

(iii) * * *

(B) For performance years 2025 and 2026, the ACO does not report any of the eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

(C) For performance year 2027 and subsequent performance years, the ACO does not report any of the eCQMs/Medicare CQMs in the APP Plus quality measure set and does not administer a CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter).

* * * * *

(7) CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when—

(i) For performance year 2024, if an ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP quality measure set and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(ii) For performance year 2025 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, for the relevant performance year, and the ACO meets either of the following:

(A) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(B) At least one of the required measures in the APP Plus quality measure set does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

(b) *Calculation of ACO's health equity adjusted quality performance score for performance year 2023 and subsequent performance years*—(1) *For performance year 2023.* For an ACO that reports the three eCQMs/MIPS CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs, and administers the CAHPS for MIPS survey, CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(2) *For performance year 2024.* For an ACO that reports the three eCQMs/MIPS CQMs/Medicare CQMs in the APP quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all three eCQMs/MIPS CQMs/Medicare CQMs, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this

subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(3) *For performance year 2025 and subsequent performance years.* For an ACO that reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for all of the required measures in the APP Plus quality measure set, and administers the CAHPS for MIPS survey (except as specified in § 414.1380(b)(1)(vii)(B) of this subchapter), CMS calculates the ACO's health equity adjusted quality performance score as the sum of the ACO's MIPS Quality performance category score for all measures in the APP Plus quality measure set and the ACO's health equity adjustment bonus points calculated in accordance with paragraph (b)(4) of this section. The sum of these values may not exceed 100 percent.

(4) *Calculation of ACO's health equity adjustment bonus points.* CMS calculates the ACO's health equity adjustment bonus points as follows:

(i) For each measure that an ACO is required to report for the applicable performance year, CMS groups an ACO's performance into the top, middle, or bottom third of ACO measure performers by reporting mechanism.

(ii) CMS assigns values to the ACO for its performance on each measure as follows:

(A) Values of four, two, or zero for each measure for which the ACO's performance places it in the top, middle, or bottom third of ACO measure performers, respectively.

(B) Values of zero for each measure that CMS does not evaluate because the measure is unscored or the ACO does not meet the case minimum or the minimum sample size for the measure.

(iii) CMS sums the values assigned to the ACO according to paragraph (b)(4)(ii) of this section, to calculate the ACO's measure performance scaler.

(iv) CMS calculates an underserved multiplier for the ACO.

(A)(*1*) CMS determines the proportion ranging from zero to one of the ACO's assigned beneficiary population for the performance year that is considered underserved based on the highest of either of the following:

(*i*) The proportion of the ACO's assigned beneficiaries residing in a census block group with an Area Deprivation Index (ADI) national percentile rank of at least 85. An ACO's assigned beneficiaries without an available numeric ADI national percentile rank are excluded from the calculation of the proportion of the ACO's assigned beneficiaries residing in a census block group with an ADI national percentile rank of at least 85.

(*ii*) The proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D low-income subsidy (LIS); or are dually eligible for Medicare and Medicaid.

(*2*) CMS calculates the proportions specified in paragraph (b)(4)(iv)(A)(*1*)(*ii*) of this section as follows:

(*i*) For performance year 2023, the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS or are dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries' person years.

(*ii*) For performance year 2024 and subsequent performance years, the proportion of the ACO's assigned beneficiaries with any months enrolled in LIS or dually eligible for Medicare and Medicaid divided by the total number of the ACO's assigned beneficiaries.

(B) If the proportion determined in accordance with paragraph (b)(4)(iv)(A) of this section is lower than 20 percent, the ACO is ineligible for health equity adjustment bonus points.

(v) Except as specified in paragraph (b)(4)(iv)(B) of this section, CMS calculates the ACO's health equity adjustment bonus points as the product of the measure performance scaler determined under paragraph (b)(4)(iii) of this section and the underserved multiplier determined under paragraph (b)(4)(iv) of this section. If the product of these values is greater than 10, the value of the ACO's health equity adjustment bonus points is set equal to 10.

(5) *Use of ACO's health equity adjusted quality performance score.* The ACO's health equity adjusted quality performance score, determined in accordance with paragraphs (b)(1) through (4) of this section, is used as follows:

(i) In determining whether the ACO meets the quality performance standard as specified under paragraphs (a)(4)(i)(A), (a)(5)(i)(A)(*1*), (a)(5)(i)(B), and (a)(7) of this section.

(ii) In determining the final sharing rate for calculating shared savings payments under the BASIC track in accordance with § 425.605(d), and under the ENHANCED track in accordance with § 425.610(d), for an ACO that meets the alternative quality performance standard by meeting the criteria specified in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iii) In determining the shared loss rate for calculating shared losses under the ENHANCED track in accordance with § 425.610(f), for an ACO that meets the quality performance standard established in paragraphs (a)(2), (a)(4)(i), and (a)(5)(i) of this section or the alternative quality performance standard established in paragraph (a)(4)(ii) or (a)(5)(ii) of this section.

(iv) In determining the quality performance score for an ACO affected by extreme and uncontrollable circumstances as described in paragraphs (c)(3)(ii) through (iv) of this section.

(c) * * *

(3) * * *

(iv) For performance year 2025 and subsequent performance years, if the ACO reports the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this subchapter and receives a MIPS Quality performance category score under § 414.1380(b)(1) of this subchapter, CMS will use the higher of the ACO's health equity adjusted quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

■ 69. Section 425.601 is amended by revising paragraph (a)(9) introductory text and adding paragraphs (a)(9)(iii) and (iv) to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on or after July 1, 2019, and before January 1, 2024.

(a) * * *

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for changes in values used in benchmark calculations as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the

performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

* * * * *

(iii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(iv) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

* * * * *

■ 70. Section 425.605 is amended by revising paragraph (a)(1)(ii)(C) to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) * * *

(1) * * *

(ii) * * *

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(1)(ii)(A) of this section and the aggregate growth in prospective hierarchical condition category (HCC) risk scores for purposes of paragraph (a)(1)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(2) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 71. Section 425.610 is amended by revising paragraph (a)(2)(ii)(C) to read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(2) * * *

(ii) * * *

(C) The aggregate growth in demographic risk scores for purposes of paragraph (a)(2)(ii)(A) of this section and the aggregate growth in prospective HCC risk scores for purposes of paragraph (a)(2)(ii)(B) of this section is calculated by taking a weighted average of the growth in demographic risk scores or prospective HCC risk scores, as applicable, across the populations described in paragraph (a)(3) of this section. When calculating the weighted average growth in demographic risk scores or prospective HCC risk scores, as applicable, the weight applied to the growth in risk scores (expressed as a ratio of the ACO's performance year risk score to the ACO's BY3 risk score) for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 72. Section 425.630 is amended by—

■ a. In paragraph (g)(3), removing the phrase ''paragraphs (g)(4) of this section'' and adding in its place the phrase ''paragraphs (g)(4) through (6) of this section'';

■ b. Redesignating paragraph (g)(5) as paragraph (g)(7);

■ c. Adding new paragraphs (g)(5) and (6);

■ d. In paragraph (h)(1)(ii), removing ''or'' at the end of the paragraph;

■ e. In paragraph (h)(1)(iii), removing the period at the end of paragraph and adding ''; or'' in its place; and

■ f. Adding paragraph (h)(1)(iv).

The additions read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(g) * * *

(5) If an ACO notifies CMS that it no longer wants to participate in the advance investment payment option but does want to continue its participation in the Shared Savings Program, the ACO must repay all outstanding advance investment payments it received. CMS will provide written notice to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

(6) If CMS terminates the participation agreement of an ACO that has an outstanding balance of advance investment payments owed to CMS, the ACO must repay any outstanding advance investment payments it received. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of such notification.

* * * * *

(h) * * *

(1) * * *

(iv) Voluntarily terminates payments of advance investment payments but continues its participation in the Shared Savings Program.

* * * * *

■ 73. Section 425.640 is added to read as follows:

§ 425.640 Option to receive prepaid shared savings.

(a) *Purpose.* Prepaid shared savings provide an additional cash flow option to ACOs with a history of earning shared savings that will encourage their investment in activities that reduce costs for the Medicare program and beneficiaries and improve the quality of care provided to their assigned beneficiaries.

(b) *Eligibility.* An ACO is eligible to receive prepaid shared savings in an agreement period as specified in this section if CMS determines that all of the following criteria are met:

(1) The ACO meets either of the following conditions:

(i) The ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026, or in subsequent years.

(ii) The ACO was a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2025, and applied to receive prepaid shared savings in accordance with paragraph (c)(2) of this section starting with the performance year beginning on January 1, 2026.

(2) The ACO must have received a shared savings payment for the most recent performance year that:

(i) Occurred prior to the agreement period for which the ACO has applied to receive prepaid shared savings; and

(ii) CMS has conducted financial reconciliation.

(3) The ACO must have a positive prior savings adjustment for the agreement period for which the ACO has applied to receive prepaid shared savings as calculated pursuant to § 425.658.

(4) The ACO does not have any outstanding shared losses or advance investment payments that have not yet been repaid to CMS after reconciliation for the most recent performance year for which CMS completed financial reconciliation.

(5) If the ACO received prepaid shared savings in the current agreement period or a prior agreement period, the ACO must have fully repaid the amount of prepaid shared savings received through the most recent performance year for which CMS has completed financial reconciliation.

(6) The ACO is participating in Levels C through E of the BASIC track or the ENHANCED track during the agreement period in which it would receive prepaid shared savings.

(7) The ACO has in place an adequate repayment mechanism in accordance with § 425.204(f) that can be used to recoup outstanding prepaid shared savings.

(8) During the agreement period immediately preceding the agreement period in which the ACO would receive prepaid shared savings, the ACO:

(i) Met the quality performance standard as specified under § 425.512; and

(ii) Has not been determined by CMS to have avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(c) *Application procedure.* (1) For an ACO renewing to enter an agreement period beginning on January 1, 2026, or in subsequent years, to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted pursuant to § 425.224) in the form and manner and by a deadline specified by CMS.

(2) For an ACO that renewed to enter an agreement period beginning on January 1, 2025, to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit to CMS a complete supplemental application for prepaid shared savings prior to the start of the performance year beginning on January 1, 2026, in the form and manner and by a deadline specified by CMS.

(d) *Application contents and review*—(1) *General.* An ACO must submit to CMS supplemental application information sufficient for CMS to determine whether the ACO is eligible to receive prepaid shared savings. In addition, the ACO must submit a proposed spend plan as part of the supplemental application information.

(2) *Spend plan.* The ACO's spend plan must:

(i) Describe how an ACO receiving prepaid shared savings will spend the payments during the first performance year in which it will receive prepaid shared savings. The spend plan must be updated annually for each performance year of the agreement period during which the ACO receives prepaid shared savings.

(ii) Identify the categories of items and services that will be purchased and investments that will be made in the ACO with prepaid shared savings (consistent with the allowable uses under paragraph (e) of this section), the dollar amounts to be spent on such categories, information about which groups of beneficiaries the ACO expects to receive direct beneficiary services that will be purchased with prepaid shared savings, how direct beneficiary services will be distributed to beneficiaries and how such services support the care of beneficiaries, descriptions of the investments that will be made in the ACO with prepaid shared savings, and such other information as may be specified by CMS.

(iii) Include an attestation that the ACO will not discriminate on the basis of race, color, religion, sex, national origin, disability, or age with respect to their use of prepaid shared savings.

(iv) Include the ACO's communication strategy for notifying CMS and any impacted beneficiaries if an ACO will no longer be providing any direct beneficiary services that had previously been provided by the ACO using prepaid shared savings.

(3) *CMS review.* CMS will review the supplemental application information to determine whether an ACO meets the eligibility criteria and other requirements necessary to receive prepaid shared savings and will approve or deny the ACO's prepaid shared savings application accordingly. CMS may review an ACO's spend plan at any time and require the ACO to modify its spend plan to comply with the requirements of this paragraph (d) and paragraph (e) of this section.

(e) *Use and management of prepaid shared savings*—(1) *Allowable uses.* An ACO must use prepaid shared savings to improve the quality and efficiency of items and services furnished to beneficiaries by investing in staffing, healthcare infrastructure, and direct beneficiary services. Expenditures of prepaid shared savings must comply with paragraph (e)(2) of this section, the beneficiary incentive provision at § 425.304(a), (b), and (d), and all other applicable laws and regulations.

(i) An ACO may spend up to 50 percent of its estimated annual prepaid shared savings on staffing and healthcare infrastructure in each performance year.

(ii) An ACO may spend up to 100 percent, but not less than 50 percent, of its estimated annual prepaid shared savings on direct beneficiary services in each performance year.

(2) *Prohibited uses.* An ACO may not use prepaid shared savings for any expense other than those allowed under paragraph (e)(1) of this section. Prohibited uses include the following—

(i) Management company or parent company profit;

(ii) Performance bonuses;

(iii) Provision of medical services covered by Medicare;

(iv) Cash or cash equivalent payments to patients;

(v) Items or activities unrelated to ACO operations or care of beneficiaries; and

(vi) In the case of an ACO participating in Levels C through E of the BASIC track or the ENHANCED track, the repayment of any shared losses incurred as specified in a written notice in accordance with § 425.605(e)(2) or § 425.610(h)(2), respectively.

(3) *Duration for spending payments.* An ACO must spend all prepaid shared savings in the agreement period in which they are received. An ACO must repay to CMS any unspent funds remaining at the end of each agreement period. Any unspent funds received for a performance year must be reallocated in the spend plan for the ACO's next performance year. When reallocated in the spend plan for the next performance year, the total unspent funds in each category must be reallocated within their originally indicated category specified in accordance with paragraph (d)(2) of this section. If an ACO fails to spend a majority of the prepaid shared savings they receive in a performance year, CMS may withhold future quarterly payments until the ACO spends the funding they have already received and reports this spending to CMS through an updated spend plan.

(f) *Payment & payment methodology.* An ACO determined eligible pursuant to paragraph (b) of this section receives quarterly prepaid shared savings payments equal to the maximum quarterly payment amount calculated pursuant to the methodology specified in paragraphs (f)(2) through (4) of this section unless the ACO elects to receive a lesser amount pursuant to paragraph (f)(6) of this section. CMS notifies in writing each ACO of its determination of the amount of prepaid shared savings and the notice will inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part. If CMS does not make any prepaid shared savings payment, the notice will specify the reason(s) why and inform the ACO of its right to request

reconsideration review in accordance with the procedures specified in subpart I.

(1) *Frequency of payments.* (i) An eligible ACO entering an agreement period beginning on January 1, 2026, or in subsequent years will receive quarterly prepaid shared savings payments for the entirety of the ACO's agreement period unless the payment is withheld or terminated pursuant to paragraph (h) of this section.

(ii) An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, and for the remainder of its agreement period, unless the payment is withheld or terminated pursuant to paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.

(iii) If an ACO's quarterly payment is withheld or terminated pursuant to paragraph (h) of this section, the ACO will not receive additional or catch-up payments if quarterly prepaid shared savings payments are later resumed.

(2) *Calculating the prepaid shared savings multiplier.* (i) Calculate total per capita savings or losses for each performance year that constitutes BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings. Per capita savings or losses will be set to zero for a performance year if the ACO was not reconciled for the performance year.

(ii) Take the simple average of the per capita savings or losses calculated in paragraph (f)(2)(i) of this section, including values of zero, if applicable.

(iii) Apply a proration factor to account for any upward growth in the ACO's assigned population in BY1 and BY2 of the agreement period in which the ACO receives prepaid shared savings as compared to the size of the assigned population when the ACO was reconciled for the corresponding performance years in its prior agreement period.

(iv) Adjust the pro-rated average per capita amount computed in paragraph (f)(2)(iii) of this section by multiplying by 50 percent.

(v) The prepaid shared savings multiplier is the lesser of the following:

(A) Two-thirds of the pro-rated, adjusted average per capita amount computed in paragraph (f)(2)(iv) of this section.

(B) 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY2 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY2 using data from the CMS Office of the Actuary and expressed as a single value by taking a person-year weighted average of the Medicare enrollment type-specific values.

(3) *Recalculation of the prepaid shared savings multiplier during an agreement period.* For the first performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for changes in per capita shared savings or losses for the performance years used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. For the second and each subsequent performance year during the term of the agreement period in which the ACO receives prepaid shared savings, the ACO's prepaid shared savings multiplier is recalculated for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, and for changes in per capita shared savings or losses for the performance years used in the calculation of the prepaid shared savings multiplier as a result of issuance of a revised initial determination under § 425.315. To recalculate the prepaid shared savings multiplier, CMS does the following:

(i) Takes into account changes to the ACO's savings or losses for a performance year for either of the 2 years that constitute BY1 and BY2 of the agreement period for which the ACO receives prepaid shared savings under paragraph (f)(2)(i) of this section, including values of zero, if applicable, as a result of issuance of a revised initial determination under § 425.315, when calculating the simple average of the per capita savings or losses calculated in paragraph (f)(2)(ii) of this section.

(ii) Redetermines the proration factor used in calculating the prepaid shared savings multiplier under paragraph (f)(2)(iii) of this section to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's agreement period in which the ACO receives prepaid shared savings due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology under subpart E of this part.

(4) *Calculating the maximum quarterly payment amount.* For each quarter for each performance year, the maximum quarterly prepaid shared savings amount is equal to the product of one-fourth of the prepaid shared savings multiplier calculated in paragraph (f)(2)(v) of this section or recalculated according to paragraph (f)(3) of this section and the ACO's performance year assigned beneficiary person years calculated from the ACO's most recent assignment list.

(5) *Estimated annual payment amount calculation methodology.* For the purposes of determining the amount of prepaid shared savings permitted to be allocated to the uses specified in paragraph (e) of this section during each performance year, the estimated annual prepaid shared savings amount can be calculated by multiplying the first quarterly payment amount the ACO receives in each performance year by four. If an ACO's maximum quarterly payments decrease over the performance year, the ACO will not be subject to compliance action solely because it spent more than 50 percent of the actual annual amount of prepaid shared savings it received during that PY on staffing and healthcare infrastructure, as long as it did not spend more than 50 percent of the originally estimated annual maximum prepaid shared savings amount on staffing and healthcare infrastructure.

(6) *ACO selection of quarterly payment amount.* An ACO may request a smaller quarterly payment amount from CMS in a form and manner and by a deadline specified by CMS.

(g) *Recoupment and recovery of prepaid shared savings; notice of bankruptcy.* (1) CMS will recoup prepaid shared savings made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of prepaid shared savings made to the ACO. CMS will carry forward any remaining balance owed to subsequent performance year(s) in which the ACO achieves shared savings.

(2) If the amount of shared savings earned by the ACO is revised upward by CMS for any reason, CMS will reduce the redetermined amount of shared savings by the amount of prepaid shared savings made to the ACO as of the date of the redetermination. If the amount of shared savings earned by the ACO is revised downward by CMS for any reason, the ACO will not receive a refund of any portion of the prepaid shared savings previously recouped or otherwise repaid, and any prepaid

shared savings that are now outstanding due to the revision in earned shared savings must be repaid to CMS upon request.

(3) If an ACO has an outstanding balance of prepaid shared savings after the calculation of shared savings or losses for the final performance year of an agreement period in which an ACO receives prepaid shared savings, the ACO must repay any outstanding amount of prepaid shared savings it received in full upon request from CMS. CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay any outstanding amount of prepaid shared savings within 90 days of that written notification, CMS will recoup any outstanding balance of prepaid shared savings from the ACO's repayment mechanism established under § 425.204(f). CMS may also recover any outstanding amount of prepaid shared savings owed by recouping from any future shared savings the ACO may be eligible to receive in a subsequent agreement period.

(4) Except as provided in paragraph (g)(4)(ii) of this section, if an ACO or CMS terminates the ACOs participation agreement during the agreement period in which it received prepaid shared savings, the ACO must repay all outstanding prepaid shared savings it received in full upon request from CMS.

(i) CMS will provide written notification to the ACO of the amount due and the ACO must pay such amount no later than 90 days after the receipt of notification. If the ACO fails to repay within 90 days, CMS will recoup any outstanding balance from the ACO's repayment mechanism established under § 425.204(f).

(ii) If the ACO terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program, CMS may recover the amount owed by recouping from any future shared savings the ACO may be eligible to receive in subsequent agreement periods.

(5)(i) If an ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment for the agreement period has been made by either CMS or the ACO and all administrative or judicial review proceedings relating to any payments under the Shared Savings Program have been fully and finally resolved.

(ii) The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(h) *Withholding or termination of prepaid shared savings*—(1) *General.* Except as provided in paragraph (h)(2) of this section, CMS may withhold or terminate an ACO's prepaid shared savings during an agreement period if—

(i) The ACO fails to comply with the requirements of this section;

(ii) The ACO meets any of the grounds for ACO termination set forth in § 425.218(b);

(iii) The ACO fails to earn sufficient shared savings in a performance year to repay the prepaid shared savings they received during that performance year;

(iv) CMS determines that the ACO is not expected to earn shared savings in a performance year during the agreement period in which the ACO received prepaid shared savings based on a rolling 12-month window of beneficiary claims data or year to date beneficiary claims data;

(v) The ACO falls below 5,000 assigned beneficiaries;

(vi) The ACO fails to spend the majority of prepaid shared savings they receive in a performance year; or

(vii) The ACO requests that CMS withhold a future quarterly prepaid shared savings payment.

(2) *Eligibility sanction.* CMS must terminate an ACO's prepaid shared savings if—

(i) The ACO fails to maintain an adequate repayment mechanism in accordance with § 425.204(f); or

(ii) The ACO fails to meet the quality performance standard as specified under § 425.512 or is subject to a pre-termination action after CMS determined the ACO avoided at-risk beneficiaries as specified under § 425.316(b)(2).

(3) *No additional payments.* If CMS withholds or terminates a quarterly payment pursuant to this paragraph (h), the ACO will not receive additional or catch-up payments if quarterly payments of prepaid shared savings are later resumed.

(4) *No pre-termination actions.* CMS may immediately terminate an ACO's prepaid shared savings under paragraphs (h)(1) and (2) of this section without taking any of the pre-termination actions set forth in § 425.216.

(i) *Reporting information on prepaid shared savings.* The ACO must report information on its receipt of and use of prepaid shared savings, as follows:

(1) The ACO must publicly report information about the ACO's use of prepaid shared savings for each performance year, in accordance with § 425.308(b)(10).

(2) In a form and manner and by a deadline specified by CMS, the ACO must report to CMS the same information it is required to publicly report under § 425.308(b)(10).

§ 425.650 [Amended]

■ 74. Section 425.650 is amended in paragraph (a) by removing the reference ''425.660'' and adding in its place the reference ''425.662''.

■ 75. Section 425.652 is amended by revising paragraph (a)(8) and revising and republishing paragraph (a)(9) to read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(8) Adjusts the historical benchmark, if applicable:

(i) For agreement periods beginning on January 1, 2024, except as provided in paragraph (a)(8)(i)(C) of this section, CMS adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), or for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656 and the prior savings adjustment in accordance with § 425.658.

(B) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(D) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is positive, the ACO will receive an adjustment to its benchmark equal to the higher of the following:

(*1*) The positive regional adjustment amount. The adjustment will be calculated as described in § 425.656(c) and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) The prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(E) If an ACO is eligible to receive a prior savings adjustment and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will receive an adjustment to its benchmark equal to the prior savings adjustment. The adjustment will be calculated as described in § 425.658(c) and applied as a flat dollar amount to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) For agreement periods beginning on January 1, 2025, and in subsequent years, except as provided in paragraph (a)(8)(ii)(B)(*2*) of this section, CMS adjusts the historical benchmark based on the ACO's regional service area expenditures (as specified under § 425.656), for savings generated by the ACO, if any, in the 3 most recent years prior to the start of the agreement period (as specified under § 425.658), or to account for the ACO serving higher proportions of underserved beneficiaries (as specified in § 425.662). CMS does all of the following to determine the adjustment, if any, applied to the historical benchmark:

(A) Computes the regional adjustment in accordance with § 425.656, the prior savings adjustment in accordance with § 425.658, and the health equity benchmark adjustment (HEBA) in accordance with § 425.662.

(B) Compares the regional adjustment, expressed as a single value as described in § 425.656(d), the per capita prior savings adjustment determined in § 425.658(c), if any, and the HEBA determined in § 425.662(b), if any, to determine the adjustment applied to the historical benchmark.

(*1*) The ACO will receive the highest of the positive adjustments for which it is eligible. The adjustment will be calculated as described in § 425.656(c), § 425.658(c), or § 425.662(b), respectively, and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(*2*) If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i) or the HEBA under § 425.662(b)(3), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO will not receive an adjustment to its benchmark.

(9) For the first performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), for a change to the beneficiary assignment methodology specified in subpart E of this part, for a change in the CMS–HCC risk adjustment methodology used to calculate prospective HCC risk scores under § 425.659, for changes in values used in benchmark calculations in accordance with § 425.316(b)(2)(ii)(B) or (C) due to compliance action to address avoidance of at-risk beneficiaries or as a result of issuance of a revised initial determination under § 425.315, and for changes in values used in benchmark calculations as a result of the performance year being affected by significant, anomalous, and highly suspect billing under § 425.672. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under § 425.656 according to the ACO's assigned beneficiaries for BY3, and based on the assignable population of beneficiaries identified for BY3 using the assignment window or expanded window for assignment that is consistent with the beneficiary assignment methodology selected by the ACO for the performance year according to § 425.400(a)(4)(ii).

(iii) Redetermines the offset factor used in determining the negative regional adjustment amount under § 425.656(c)(4) and (5).

(iv) Redetermines the proration factor used in calculating the prior savings adjustment under § 425.658(b)(3)(ii) to account for changes in the ACO's assigned beneficiary population in the benchmark years of the ACO's current agreement period due to the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or changes to the beneficiary assignment methodology under subpart E of this part.

(v) Redetermines the HEBA scaler used in calculating the HEBA under § 425.662(b)(2) to account for changes in the ACO's regional adjustment or prior savings adjustment in accordance with paragraphs (a)(9)(ii) through (iv) of this section.

(vi) In accordance with paragraph (a)(8) of this section, CMS redetermines the adjustment to the historical benchmark based on the redetermined regional adjustment (as specified under § 425.656), the prior savings adjustment (as specified under § 425.658), or the HEBA (as specified under § 425.662) if applicable.

(vii) Redetermines factors based on prospective HCC risk scores calculated for benchmark years by calculating the prospective HCC risk scores using the CMS–HCC risk adjustment methodology that applies for the calendar year corresponding to the applicable performance year in accordance with § 425.659(b)(1).

(viii) Recalculates benchmark year expenditures to account for the impact of improper payments, for the benchmark year corresponding to a

performance year for which CMS issued a revised initial determination under § 425.315. In recalculating expenditures for the benchmark year, CMS applies the calculation methodology applied in recalculating expenditures for the corresponding performance year in accordance with § 425.674.

(ix) Recalculates expenditures used in Shared Savings Program benchmark calculations under this section, and as applicable under §§ 425.654 through 425.662, to exclude the same HCPCS or CPT codes identified as displaying significant, anomalous, and highly suspect billing patterns in calculation of performance year expenditures, in accordance with § 425.672.

* * * * *

■ 76. Section 425.655 is amended by revising paragraph (d)(2) to read as follows:

§ 425.655 Calculating the regional risk score growth cap adjustment factor.

* * * * *

(d) * * *

(2) Determines the aggregate growth in regional risk scores by calculating a weighted average of the growth in regional prospective HCC risk scores or demographic risk scores, as applicable, across the populations described in paragraph (d)(1) of this section. When calculating the weighted average growth in prospective HCC risk scores or demographic risk scores, as applicable, the weight applied to the growth in risk scores for each Medicare enrollment type is equal to the product of the ACO's historical benchmark expenditures, adjusted in accordance with § 425.652(a)(8), for that enrollment type and the ACO's performance year assigned beneficiary person years for that enrollment type.

* * * * *

■ 77. Section 425.658 is amended by revising paragraph (d) to read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(d) *Applicability of the prior savings adjustment.* CMS compares the per capita prior savings adjustment determined in paragraph (c)(1) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the HEBA as determined in § 425.662(b), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8).

* * * * *

■ 78. Section 425.662 is added to read as follows:

§ 425.662 Calculating the health equity adjustment to the historical benchmark.

(a) *General.* For agreement periods beginning on January 1, 2025, and in subsequent years, CMS calculates a health equity adjustment to the historical benchmark (HEBA) to account for ACOs serving higher proportions of underserved beneficiaries.

(b) *Calculation of the health equity benchmark adjustment.* To calculate the adjustment described in paragraph (a) of this section, CMS does all of the following:

(1) Calculates the weighted average of the ACO's third benchmark year (BY3) national per capita expenditure amounts across the following populations of beneficiaries, where the weights are the ACO's BY3 proportion of assigned beneficiaries for that enrollment type:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates the HEBA scaler as the difference between 5 percent of the national per capita expenditure amount, expressed as single value as calculated in paragraph (b)(1) of this section, and the higher of: the regional adjustment, expressed as a single value as described in § 425.656(d); the per capita prior savings adjustment determined in § 425.658(c); or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

(3) Determines the ACO's eligibility for the HEBA based on the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D low-income subsidy (LIS) or dually eligible for Medicare and Medicaid. An ACO is only eligible for the HEBA if this proportion is greater than or equal to 15 percent. An ACO with a proportion less than 15 percent is ineligible to receive a HEBA.

(4) Calculates the HEBA. If the ACO is eligible for the HEBA as determined in paragraph (b)(3) of this section, the HEBA is equal to the product of the HEBA scaler calculated in paragraph (b)(2) of this section and the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid.

(c) *Applicability of the HEBA.* CMS compares the HEBA determined in paragraph (b)(4) of this section with the regional adjustment, expressed as a single value as described in § 425.656(d), and the per capita prior savings adjustment determined in § 425.658(c), if any, to determine the adjustment, if any, that will be applied to the ACO's benchmark in accordance with § 425.652(a)(8)(ii).

■ 79. Section 425.672 is added to read as follows:

§ 425.672 Adjustments to mitigate the impact of significant, anomalous, and highly suspect billing activity on Shared Savings Program financial calculations involving calendar year 2024 or subsequent calendar years.

(a) *General.* This section describes adjustments CMS may make to Shared Savings Program calculations to mitigate the impact of significant, anomalous, and highly suspect billing activity occurring in calendar year 2024 or subsequent calendar years.

(b) *Significant, anomalous, and highly suspect billing activity for a HCPCS or CPT code impacting Shared Savings Program calculations.* CMS, at its sole discretion, may determine that the billing of one or more specified HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants adjustment to calculations made under this part.

(c) *Applicability of adjustments to performance year and benchmark year calculations.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations, as applicable, to exclude all Medicare Parts A and B fee-for-service payment amounts on claims for the specified claim types associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for the periods identified in paragraph (d) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.654(a) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4) and 425.652(a)(4), and performance year expenditures under §§ 425.605(a)(3) and 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.654(a)(3).

(C) Truncating expenditures for assignable beneficiaries for purposes of determining truncated national per capita fee-for service expenditures for purposes of calculating the ACPT according to § 425.660(b)(3).

(iii) Determining truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for purposes of calculating the ACPT according to § 425.660(b)(3).

(iv) Determining national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to §§ 425.601(a)(8)(ii)(C) and 425.656(c)(3), capping the prior savings adjustment according to § 425.658(c)(1)(ii), capping the prepaid shared savings multiplier according to § 425.640(f)(2)(v), and calculating the HEBA scaler according to § 425.662(b)(2).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to §§ 425.601(a)(5)(ii) and 425.652(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to §§ 425.601(b)(2) and 425.652(b)(2)(i).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, determining an ACO's eligibility to receive advance investment payments according to § 425.630, and determining whether an ACO qualifies for a shared savings payment under § 425.605(h).

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

(d) *Periods of adjustment.* CMS adjusts the Shared Savings Program calculations identified in paragraph (c) of this section for significant, anomalous, and highly suspect billing activity identified for calendar year 2024 or subsequent calendar years as follows:

(1) The calendar year for which the significant, anomalous, and highly suspect billing activity was identified pursuant to paragraph (b) of this section, when it is either a performance year or a benchmark year.

(2) The 3 most recent years prior to the start of the ACO's agreement period used in establishing the historical benchmark, when such a benchmark is used to reconcile the ACO for a performance year adjusted in accordance with paragraph (d)(1) of this section.

(e) *Adjustments for growth rates used in calculating the ACPT.* In addition to adjustments described in paragraph (c) of this section, CMS makes adjustments for payments associated with a HCPCS or CPT code identified pursuant to paragraph (b) of this section for any calendar year corresponding to BY3 in projecting per capita growth in Parts A and B fee-for-service expenditures, according to § 425.660(b)(1), for purposes of calculating the ACPT for agreement periods beginning on January 1, 2024, and in subsequent years.

■ 80. Section 425.674 is added to read as follows:

§ 425.674 Accounting for the impact of improper payments on Shared Savings Program financial calculations.

(a) *General rule.* Upon the reopening of an initial determination pursuant to § 425.315(a)(4), CMS will use the methodology specified in this section to account for the impact of improper payments when:

(1) Determining savings or losses for the relevant performance year in accordance with § 425.315 in order to issue a revised initial determination.

(2) Adjusting the benchmark by recalculating benchmark year expenditures under §§ 425.601(a)(9)(iii) and 425.652(a)(9)(viii) in the event that CMS recalculates a payment determination and issues a revised initial determination for the corresponding performance year in a prior agreement period, in accordance with paragraph (a)(1) of this section.

(b) *Improper payment.* For the purpose of this section, improper payment includes:

(1) An amount associated with a demanded overpayment determination.

(2) An amount identified in a settlement agreement or judgment, pursuant to conduct by individuals or entities performing functions or services related to an ACO's activities, less any penalties or damages.

(c) *Accounting for improper payments.* To adjust Medicare Parts A and B fee-for-service expenditures for improper payments CMS does the following:

(1) Identify each Shared Savings Program expenditure calculation for a performance year or benchmark year, as calculated according to the standard methodology described in this subpart and expressed as a per capita dollar amount, that will be adjusted for the impact of improper payments.

(2) Determine each specific population of Medicare fee-for-service beneficiaries used to calculate the expenditure amount identified in paragraph (c)(1) of this section. The populations relevant for a specific expenditure calculation may include:

(i) The population of beneficiaries assigned to the ACO for calculating the ACO's performance year or benchmark year expenditures.

(ii) The population of assignable beneficiaries in each county in the ACO's regional service area for calculating county-level expenditures.

(iii) The national population of assignable beneficiaries for calculating national assignable expenditures.

(iv) The national population of Medicare fee-for-service beneficiaries for calculating national expenditures.

(3) Determine the per capita amount of improper payments for the performance year or benchmark year included in the per capita Medicare Parts A and B fee-for-service expenditure amount for a population identified in paragraph (c)(2) of this section in accordance with paragraph (d) of this section for all providers or suppliers with identified improper payments.

(4) Subtract the per capita amount determined in paragraph (c)(3) of this section from the expenditure calculation identified in paragraph (c)(1) of this section for the population identified in paragraph (c)(2) of this section for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(5) If applicable, CMS will do the following to adjust regional expenditures for improper payments:

(i) Adjust county-level fee-for-service expenditures determined under paragraph (c)(4) of this section, for each county in the ACO's regional service area, for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. This calculation is made for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(ii) Weight the risk adjusted county-level fee-for-service expenditures determined under paragraph (c)(5)(i) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined in accordance with § 425.601(d)(1), § 425.603(f)(1), or § 425.654(b)(1), as applicable, for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section.

(iii) Aggregate the values determined in paragraph (c)(5)(ii) of this section for each of the populations of beneficiaries identified in paragraphs (c)(4)(i) through (iv) of this section across all counties within the ACO's regional service area.

(d) *Determining the per capita amount of improper payments.* CMS may use one or more of the following approaches to determine the per capita amount that will be used to adjust expenditure calculations identified in paragraph (c)(1) of this section:

(1) Calculate aggregate improper payments attributable to a population identified in paragraph (c)(2) of this section for each provider or supplier that had improper payments.

(i) For improper payments associated with specific claims, CMS will do the following:

(A) For improper payments to a provider or supplier that correspond to payment amounts on claims or line items that were used in a Shared Savings Program calculation identified in paragraph (c)(1) of this section, and subsequently adjusted after the 3-month claims run out period, CMS will sum the improper payment amounts across all such claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures for the population identified in paragraph (c)(2) of this section.

(B) In the event CMS determines it is necessary to account for the impact of improper payments on Shared Savings Program financial calculations by adjusting the payment amounts for a specific HCPCS or CPT code billed by the provider or supplier for the population identified in paragraph (c)(2) of this section, CMS will do the following—

(*1*) Identify the applicable claims or line items with dates of service during the period used to calculate performance year or benchmark year expenditures processed before the end of the applicable 3-month claims run out period;

(*2*) Sum the claim or line item payment amounts, on the claims or line items identified in paragraph (d)(1)(i)(B)(*1*) of this section; and

(*3*) If applicable, multiply the sum calculated in paragraph (d)(1)(i)(B)(*2*) of this section by a scaling factor to compute the payment differential between the HCPCS or CPT code that was improperly billed and a CMS-identified alternate code.

(ii) For aggregate improper payment amounts that are not linked to specific claims or line items, CMS will calculate the amount attributable to the population identified in paragraph (c)(2) of this section by applying a proration factor to the aggregate improper payment amount identified for that provider or supplier. CMS calculates the proration factor as follows:

(A) The denominator of the proration factor is total Medicare Parts A and B claim or line item payment amounts to the provider or supplier for all fee-for-service beneficiaries on claims of specified claim types for the time period associated with the aggregate improper payment amount identified for the provider or supplier that were made before the end of the applicable 3-month claims run out period.

(B) The numerator of the proration factor is the portion of the total from the denominator, in paragraph (d)(1)(ii)(A) of this section, that CMS determines is attributable to the population identified in paragraph (c)(2) of this section with dates of service during the period used to calculate expenditures for the applicable performance year or benchmark year.

(2) Sum the amounts calculated pursuant to paragraph (d)(1) of this section attributable to a population identified in paragraph (c)(2) of this section across all providers or suppliers that had identified improper payments.

(3) Take the lesser of the following two values—

(i) The sum from paragraph (d)(2) of this section; or

(ii) Total Medicare Parts A and B claim or line item payment amounts to all providers or suppliers that had improper payments for the population identified in paragraph (c)(2) of this section on claims of specified claim types with dates of service within the performance year or benchmark year made before the end of the applicable 3-month claims run out period.

(4) Express the lesser-of amount from paragraph (d)(3) of this section as a per capita value by dividing by the total beneficiary person years in the population identified in paragraph (c)(2) of this section for the applicable performance year or the benchmark year.

■ 81. Part 427 is added to read as follows:

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

Sec.

Subpart G—Enforcement of Manufacturer Payment of Rebate Amounts 427.600 Civil money penalty notice and appeals procedures.

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

Subpart A—General Provisions

§ 427.10 Basis and scope.

(a) *Basis.* This part implements section 1847A(i) of the Social Security Act (''the Act'').

(b) *Scope.* This part sets forth the requirements of the Medicare Part B Drug Inflation Rebate Program, which requires, for each calendar quarter, manufacturers to pay rebates for certain single source drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 427.20 Definitions.

As used in this part, the following definitions apply:

Allowed charges means the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service.

Applicable calendar quarter means a calendar quarter (January 1 to March 31, April 1 to June 30, July 1 to September 30, or October 1 to December 31), starting with January 1, 2023.

Applicable threshold means the amount determined under § 427.101(c)(2).

Average sales price (ASP) means the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) determined under § 414.804 of this chapter.

Benchmark period Consumer Price Index for All Urban Consumers (CPI–U) means the CPI–U as set forth in § 427.302(e).

Billing and payment code means the specific code used to classify and report a drug or biological for purposes of Medicare Part B payment. A Healthcare Common Procedure Coding System (HCPCS) code, as established by CMS, is an example of a billing and payment code used to describe a drug or biological and for which CMS may publish a payment amount.

Billing and payment code FDA approval or licensure date means the earliest approval or licensure date for any FDA application number associated with any NDC ever assigned to the billing and payment code.

Billing unit means the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a HCPCS code), as established by CMS.

Biosimilar biological product has the meaning set forth in section 1847A(c)(6)(H) of the Act.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

Food and Drug Administration (FDA) application means, for the purposes of calculating the Part B rebate amount, a New Drug Application (NDA) or Biologics License Application (BLA) approved by the FDA.

Final action claim means a non-rejected claim for which a Medicare payment has been made, and for which all disputes and adjustments have been resolved.

First marketed date means the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. The first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available.

Grouped billing and payment code, for the purposes of Part B rebate calculations, means a billing and payment code, such as a HCPCS code, other than a Not Otherwise Classified (NOC) code, that typically contains multiple drug products approved under multiple NDAs or BLAs and may be inclusive of, but are not limited to, multiple source billing codes.

Inflation-adjusted payment amount means the amount determined under § 427.302(g).

Manufacturer has the meaning set forth in section 1847A(c)(6)(A) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product and package size and type.

Not Otherwise Classified (NOC) code means a billing and payment code, including an unclassified, unspecified, or unlisted code, for drugs and biological products for which no specific billing and payment code is assigned.

Part B rebatable drug means, subject to the exclusions set forth in § 427.101(b), a single source drug or biological product, including a biosimilar biological product but excluding a qualifying biosimilar biological product, for which payment is made under Part B.

Payment amount benchmark quarter means the calendar quarter set forth in § 427.302(c).

Payment amount in the payment amount benchmark quarter means the amount set forth in § 427.302(d).

Rebate period CPI–U means the CPI–U set forth in § 427.302(f).

Single source drug or biological product has the meaning set forth in section 1847A(c)(6)(D) of the Act.

Sold or marketed means, with respect to an NDC, that the NDC has either a date of first sale identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, or an NDC Directory start marketing date prior to or during the applicable calendar quarter and meets any of the following criteria:

(1) The NDC has units reported for the rebate quarter;

(2) The end marketing date is during the rebate quarter;

(3) The end marketing date is after the rebate quarter; or

(4) The end marketing date is missing.

Specified amount means the amount set forth in § 427.302(b).

Subsequently approved drug means a drug first approved or licensed by the FDA after December 1, 2020.

Unit means, with respect to a Part B rebatable drug, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids as reported under section 1847A(b)(2)(B) of the Act.

Subpart B—Determination of Part B Rebatable Drugs

§ 427.100 Definitions.

As used in this subpart, the following definitions apply:

EUA Declaration means the March 27, 2020, Emergency Use Authorization (EUA) Declaration for Drugs and Biological Products under section 564 of the Food, Drug, and Cosmetic (FD&C) Act.

Individual who uses such a drug or biological means a unique Medicare Part B beneficiary who was furnished the

Part B drug or biological that was covered under Part B during the applicable calendar quarter, identified using final action claims data with dates of service during the calendar year set forth in § 427.101(b)(6) and with allowed charges greater than zero.

§ 427.101 Identification of Part B rebatable drugs.

(a) *Determination of Part B rebatable drugs.* (1) For each applicable calendar quarter, CMS will:

(i) Identify single source drugs or biological products, including biosimilar biological products, covered under Part B; and

(ii) Identify the applicable billing and payment code for each drug or biological product set forth in paragraph (a)(1)(i) of this section.

(2) For a drug or biological product identified under paragraph (a)(1) of this section, CMS will determine whether the drug or biological product meets the exclusion criteria set forth in paragraph (b) or (c) of this section as of the first day of the applicable calendar quarter.

(3) To determine whether a drug or biological product is a Part B rebatable drug under this section, CMS will use the most recent available data submitted to CMS by manufacturers pursuant to section 1927(b)(3)(A)(iii) of the Act or section 1847A(f)(2), as applicable, and other available data, including but not limited to information available at FDA.gov and information in drug pricing compendia, as applicable.

(b) *Excluded product categories.* The following categories of products are not considered Part B rebatable drugs:

(1) *Qualifying biosimilar biological products.* Biological products as defined under section 1847A(b)(8)(B)(iii) of the Act.

(2) *Products with historically excepted grouped billing and payment codes.* Single source drugs or biological products that were within the same billing and payment code as of October 1, 2003, and which, as required under section 1847A(c)(6)(C)(ii) of the Act, are treated as multiple source drugs.

(3) *Products billed under a NOC code.* A drug or biological product billed under a NOC code.

(4) *Radiopharmaceutical drugs and biological products.* A separately payable radiopharmaceutical drug or biological product not paid under section 1847A of the Act.

(5) *Skin substitutes.* A product included within the suite of cellular- and tissue-based products that aid wound healing.

(6) *Drugs with average total allowed charges under the applicable threshold.* Drugs and biological products for which the Medicare Part B average total allowed charges for a year per individual that uses such drug or biological are below the applicable threshold, as set forth in paragraph (c) of this section.

(7) *Certain vaccines and other products.* The following products:

(i) The vaccines as set forth in section 1861(s)(10) of the Act, which includes the influenza, pneumococcal, hepatitis B, and COVID–19 vaccines.

(ii) Monoclonal antibodies used for treatment or post-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable quarters until the end of the calendar year in which the EUA Declaration ends.

(iii) Monoclonal antibodies that are used for pre-exposure prophylaxis of COVID–19 that are covered and paid for under section 1861(s)(10) of the Act. This exclusion will apply to applicable calendar quarters even after the year in which the EUA Declaration ends, as long as after the EUA Declaration is terminated, these products have an FDA-approved application or license.

(8) *Generic drugs.* Part B drugs approved under an Abbreviated New Drug Application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

(c) *Drugs and biological products with average total allowed charges below the applicable threshold.* For each applicable calendar quarter, CMS will identify drugs and biological products with Part B average total allowed charges for a year per individual that uses such a drug or biological product that are below the applicable threshold determined under the calculations set forth in this section. Such drugs and biological products are not considered Part B rebatable drugs and will be excluded from the identification of Part B rebatable drugs in paragraph (a) of this section.

(1) *Average total allowed charges for a year per individual.* For each drug or biological that is identified as set forth in paragraph (a) of this section, CMS will calculate average total allowed charges for a year per individual as follows:

(i) For single source drugs and biological products assigned to only one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 and divide the summed amount by the number of individuals who use such a drug or biological with allowed charges for this billing and payment code.

(ii) For single source drugs and biological products assigned to more than one billing and payment code, CMS will sum the allowed charges from final action claims greater than $0 for all billing and payment codes and divide the summed amount by the number of individuals who use such a drug or biological with allowed charges for these billing and payment codes.

(iii) For single source drugs and biological products previously crosswalked to a grouped billing and payment code:

(A) If crosswalked to a grouped billing and payment code during the full year, CMS will calculate the average total allowed charges per individual per year for the drug using allowed charges and the number of individuals who used the drug or biological product based on claims for the previously grouped billing and payment code during the year.

(B) If crosswalked to a grouped billing and payment code and later assigned to a unique billing and payment code for part of the year, CMS will calculate average total allowed charges per individual per year by:

(*1*) Summing the total allowed charges billed under the unique billing and payment code for the drug with dates of service on or after the Medicare effective date for this unique billing and payment code and identifying the individuals on those claims.

(*2*) Summing the total allowed charges on claims billed under the previously grouped billing and payment code and identifying individuals with claims prior to the unique billing and payment code's effective date.

(*3*) Summing the total allowed charges as determined in paragraphs (c)(1)(iii)(B)(*1*) and (*2*) of this section and dividing by the total number of individuals, de-duplicated for individuals determined under paragraphs (c)(1)(iii)(B)(*1*) and (*2*).

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable calendar quarter as follows:

(i) For applicable calendar quarters in 2023, the applicable threshold is equal to $100.

(ii) For applicable calendar quarters in 2024, the applicable threshold is equal to $100 increased by the percentage increase in the CPI–U for the 12-month period ending with June of 2023.

(iii) For applicable calendar quarters in each subsequent calendar year, the applicable threshold is equal to the unrounded applicable threshold calculated for the prior calendar year increased by the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

(iv) If the resulting amount under paragraphs (c)(2)(i) through (iii) of this

section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

(3) *Application of the* applicable *threshold at the billing and payment code level.* For each applicable calendar quarter, CMS will apply the exclusion of drugs and biological products identified in paragraph (c)(1) of this section, with average total allowed charges for a year per individual less than the applicable threshold set forth in paragraph (c)(2) of this section, to applicable billing and payment codes as follows:

(i) For single source drugs or biological products assigned to a unique billing and payment code, CMS will exclude the assigned billing and payment code for an applicable calendar quarter if the average total allowed charges for a year per individual are less than the applicable threshold.

(ii) For a single source drug or biological product that is assigned to more than one billing and payment code during a year, CMS will exclude all such assigned billing and payment codes for an applicable calendar quarter.

(4) *Definition of year.* For purposes of the calculations set forth in this section, a year is defined as the 4 consecutive calendar quarters beginning 6 calendar quarters before the applicable calendar quarter. CMS will use final action claims from the Medicare fee-for-service claims repository where separate payment was allowed for the applicable billing and payment code for dates of service within a year to calculate Part B average total allowed charges for that year.

Subpart C—Coinsurance Adjustment and Adjusted Medicare Payment for Part B Rebatable Drugs With Price Increases Faster Than Inflation

§ 427.200 Definitions.

As used in this subpart, *inflation-adjusted beneficiary coinsurance* means the coinsurance adjustment as determined under this subpart.

§ 427.201 Computation of beneficiary coinsurance and adjusted Medicare payment for Part B rebatable drugs with price increases faster than inflation.

(a) *Methodology.* CMS must use the methodology set forth in this section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6) of this chapter.

(b) *Calculation of inflation-adjusted beneficiary coinsurance.* To calculate the inflation-adjusted beneficiary coinsurance for Part B rebatable drugs with respect to a calendar quarter, CMS compares the payment amount, as set forth in paragraph (b)(3) of this section, to the inflation-adjusted payment amount for the applicable calendar quarter.

(1) If the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20.

(2) If the inflation-adjusted payment amount does not exceed the payment amount, the adjustment to the beneficiary coinsurance set forth in paragraph (b)(1) of this section is not applied.

(3) CMS will use the published payment amount in quarterly pricing files published by CMS as the payment amount in this determination.

(c) *Exclusions.* Any drug that is excluded from Part B rebatable drugs as set forth in § 427.101(b) is not subject to inflation-adjusted beneficiary coinsurance.

Subpart D—Determination of the Rebate Amount for Part B Rebatable Drugs

§ 427.300 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the Public Health Service (PHS) Act.

Refundable single-dose container or *single-use package drug* has the meaning set forth in § 414.902 of this chapter.

§ 427.301 Calculation of the total Part B rebate amount to be paid by manufacturers.

(a) *Total rebate.* Subject to paragraph (b) of this section, the total rebate amount to be paid for a Part B rebatable drug, as identified under § 427.101, for an applicable calendar quarter is equal to the product of the per unit Part B rebate amount of such drug, as determined under § 427.302, and the billing units of the Part B rebatable drug furnished during the applicable calendar quarter, as identified as set forth in § 427.303. The rebate amount may be reduced as set forth in subpart E of this part or adjusted as set forth in subpart F of this part.

(b) *Apportionment of the Part B rebate amount.* CMS will identify billing and payment codes for which multiple manufacturers report ASP, as set forth in sections 1927(b)(3) and 1847A(f) of the Act, for NDCs assigned to the billing and payment code. CMS will calculate the rebate amount owed by each manufacturer by:

(1) Determining the total billing units sold for each NDC assigned to the billing and payment code, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(2) Summing the individual manufacturer's total billing units sold during the applicable calendar quarter (for all NDCs of the manufacturer assigned to the billing and payment code).

(3) Summing all manufacturers' total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code.

(4) Dividing the resulting amount from paragraph (b)(2) of this section by the resulting amount from paragraph (b)(3) of this section.

(5) Multiplying the resulting amount from paragraph (b)(4) of this section by the total rebate amount as determined under paragraph (a) of this section.

(c) *Apportionment of the Part B rebate amount when reported units for NDCs within a billing and payment code are missing, negative, or equal to zero.*

(1) When there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for all NDCs are either missing, negative, or equal to zero but there is a positive rebate amount calculated under § 427.302(a), CMS will:

(i) With respect to NDCs that were sold or marketed during the applicable calendar quarter and for which all NDCs assigned to the grouped billing and payment code lack manufacturer-reported ASP data for the applicable calendar quarter, equally apportion a positive rebate amount to NDCs with missing ASP units that were sold or marketed during the applicable calendar quarter by dividing the total rebate amount for the grouped billing and payment code by the total number of NDCs sold or marketed during the applicable calendar quarter within the billing and payment code; and

(ii) With respect to NDCs that were not sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, NDCs with negative manufacturer-reported ASP units for the applicable calendar quarter, and NDCs with manufacturer-reported ASP units equal to zero for the applicable calendar quarter, apportion a $0 rebate amount to each respective NDC. If all NDCs assigned to the grouped billing and payment code are determined under this subparagraph, no rebate will be assessed for that billing and payment code.

(2) When there are multiple NDCs in a grouped billing and payment code and the manufacturer-reported ASP units for some but not all NDCs assigned to the grouped billing and payment code are either missing, negative, or equal to zero but there is a positive rebate amount calculated under § 427.302(a), CMS will:

(i) With respect to NDCs that were not sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, NDCs with negative manufacturer-reported ASP units for the applicable calendar quarter, and NDCs with manufacturer-reported ASP units equal to zero for the applicable calendar quarter, apportion a $0 rebate amount to each respective NDC;

(ii) With respect to NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter, and NDCs that were sold or marketed during the applicable calendar quarter and for which respective NDCs have positive manufacturer-reported units by, apportion rebate amounts as follows:

(A) Solely for purposes of the calculation determined under this paragraph (c)(2)(ii) of this section, assign to NDCs that were sold or marketed during the applicable calendar quarter and lack manufacturer-reported ASP units for the applicable calendar quarter the number of ASP units that is equal to the lowest positive number of manufacturer reported ASP units for any NDC in the grouped billing and payment code;

(B) Determine the total billing units sold for each NDC assigned to the billing and payment code, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit;

(C) With respect to all NDCs of each individual manufacturer assigned to the billing and payment code, sum the total billing units for such NDCs sold during the applicable calendar quarter;

(D) Sum the total billing units sold during the applicable calendar quarter for all NDCs of the Part B rebatable drug assigned to the billing and payment code, including those assigned a ASP unit value as set forth in paragraph (c)(2)(ii)(A) of this section;

(E) Divide the resulting amount from paragraph (c)(2)(ii)(C) of this section by the resulting amount from paragraph (c)(2)(ii)(D) of this section; and

(F) Multiply the resulting amount from paragraph (c)(2)(ii)(E) of this section by the total rebate amount as determined under paragraph (a) of this section.

§ 427.302 Calculation of the per unit Part B drug rebate amount.

(a) *Formula for calculating the per unit Part B rebate amount.* CMS will calculate the per unit Part B rebate amount for a Part B rebatable drug and applicable calendar quarter by determining the amount by which the specified amount, as determined under paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as determined under paragraph (g) of this section.

(b) *Identification of the specified amount for the applicable calendar quarter.* For each applicable calendar quarter, subject to paragraph (b)(3) of this section, the specified amount is equal to the amount determined under section 1847A(i)(3)(A)(ii)(I)(aa) or (bb) of the Act, as applicable, for the calendar quarter.

(1) Subject to paragraph (b)(2) of this section, the first applicable calendar quarter for a Part B rebatable drug shall be no earlier than the calendar quarter beginning January 1, 2023 and shall be the later of one of the following:

(i) The first full calendar quarter that is at least the third calendar quarter after the payment amount benchmark quarter identified in paragraphs (c)(1) through (5) of this section.

(ii) The calendar quarter beginning January 1, 2023.

(2) Notwithstanding paragraph (b)(1) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after the effective date of the drug's assigned billing and payment code other than a NOC code, whichever is later, the first applicable calendar quarter is the first full calendar quarter that follows the payment amount benchmark quarter identified in paragraphs (c)(1) through (5) of this section.

(3) If all NDCs in the billing and payment code have neither manufacturer-reported ASP nor Wholesale Acquisition Cost (WAC) price data available for the applicable calendar quarter, CMS will use WAC price data from other public sources, if available, to calculate 106 percent of WAC, which will serve as the specified amount.

(c) *Identification of the payment amount benchmark quarter.* For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) and (5) of this section, using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment as of the applicable calendar quarter have been marketed:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the payment amount benchmark quarter is the calendar quarter beginning July 1, 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(3) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, but with a first marketed date after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (c)(3) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the payment amount benchmark quarter is the third full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) For a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, for each applicable quarter beginning after the price applicability period with respect to such drug, the payment amount benchmark quarter is the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug.

(d) *Identification of the payment amount in the payment amount benchmark quarter.* CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter identified as set forth in paragraph (c) of this section.

(1) For a Part B rebatable drug, subject to paragraphs (d)(1)(i) and (ii) of this section and except as provided in paragraph (d)(2) of this section, CMS will identify the payment amount in the payment amount benchmark quarter using the published payment limit for the billing and payment code for the applicable payment amount benchmark quarter determined under section 1847A of the Act.

(i) If a published payment limit is not available for the applicable payment amount benchmark quarter, CMS will use the lower of 106 percent of manufacturer-reported ASP or 106 percent of manufacturer-reported WAC.

(ii) If neither a published payment limit nor manufacturer-reported ASP or WAC data are available, CMS will use WAC data from other public sources to calculate 106 percent of WAC, which, solely for the purposes of this section, CMS will consider to be the payment amount for the payment amount benchmark quarter.

(2) For a Part B rebatable drug previously billed under a grouped billing and payment code during the payment amount benchmark quarter and later billed under a unique billing and payment code, CMS will use the grouped billing and payment code payment limit as the payment amount in the payment amount benchmark quarter.

(e) *Identification of the benchmark period CPI–U.* For each Part B rebatable drug, CMS will identify the applicable benchmark period CPI–U at the billing and payment code level as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a Part B rebatable drug first approved or licensed by the FDA after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(2) of this section, for a Part B rebatable drug first approved or licensed by FDA on or before December 1, 2020, and with a first marketed date after December 1, 2020, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date.

(4) Notwithstanding paragraph (e)(3) of this section, for a Part B rebatable drug that was billed under a NOC code during the calendar quarter beginning July 1, 2021, or the third full calendar quarter after such drug's first marketed date, whichever is later, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after the Part B rebatable drug is assigned a billing and payment code other than a NOC code.

(5) Notwithstanding paragraph (e)(4) of this section, for a Part B rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part B rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for the July of the year preceding the last year during such price applicability period.

(f) *Identification of the rebate period CPI–U.* For each Part B rebatable drug by billing and payment code, CMS will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is two calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished.

(g) *Determination of inflation-adjusted payment amount.* For each applicable calendar quarter and for each Part B rebatable drug by billing and payment code, CMS will calculate the inflation-adjusted payment amount by dividing the rebate period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the payment amount in the payment amount benchmark quarter, determined under paragraph (d) of this section.

§ 427.303 Determination of total number of billing units.

(a) *General.* For each Part B rebatable drug, CMS will determine the total number of billing units of the billing and payment code subject to a rebate in the applicable calendar quarter using final action Medicare fee-for-service claims for which Medicare payment was allowed and greater than zero.

(b) *Total billing units.* Using final action claims in the Medicare fee-for-service claims repository, at least 3 months after the end of the applicable calendar quarter, CMS will determine the total number of billing units for a Part B rebatable drug in an applicable calendar quarter by identifying separately payable claim lines for the billing and payment code for dates of service in that applicable calendar quarter and excluding the following billing units in claim lines as applicable:

(1) *Billing units of drugs acquired through the 340B Program.* CMS will exclude billing units acquired under the 340B Program as identified through—

(i) Separately payable units in all professional claim lines for dates of service during 2023 and 2024 that were billed with the ''JG'' or ''TB'' modifiers and separately payable billing units in claim lines for professional claims with dates of service during 2023 and 2024 from suppliers that are associated with covered entities listed by the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) as participating in the 340B Program. CMS will use National Provider Identifiers (NPI) and/or Medicare Provider Numbers (MPN), or other fields in the OPAIS database (such as name and address) if NPI or MPN is not available, to identify these suppliers and the claims submitted with such identifiers;

(ii) Separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers and units in institutional claims from covered entities that are critical access hospitals and Maryland waiver hospitals with dates of service from January 1, 2023 through December 31, 2023. CMS will use NPIs and MPNs, or other fields in the OPAIS database (such as name and address) if NPI or MPN are not available, to identify these suppliers and the claims submitted with such identifiers;

(iii) Separately payable billing units in claim lines for institutional claims that are billed with the ''JG'' or ''TB'' modifiers for claims with dates of service from January 1, 2024 through December 31, 2024; and

(iv) Separately payable billing units in claim lines billed with the ''TB'' modifier for claims with dates of service on or after January 1, 2025.

(2) *Billing units with a rebate under section 1927 of the Social Security Act.* Subject to paragraph (b)(2)(i) of this section, CMS will exclude billing units from claims with dates of service during a month within an applicable calendar quarter if the units are furnished to a dually eligible Medicare beneficiary who has Medicaid coverage that may provide cost-sharing assistance.

(i) CMS will not exclude billing units from claims when the Medicare beneficiary has Medicaid coverage that does not include cost-sharing assistance, including Specified Low-Income Medicare Beneficiaries (SLMB), Qualified Disabled and Working Individuals (QDWI), and Qualifying Individuals (QI) beneficiaries.

(ii) [Reserved]

(3) *Billing units that are packaged into the payment amount for an item or service and are not separately payable.* CMS will exclude billing units that are packaged into the payment amount for an item or service and are not separately payable.

(4) *Billing units when a drug is no longer a Part B rebatable drug.* In situations where a Part B rebatable drug that is a single source drug becomes a multiple source drug during an applicable calendar quarter, CMS will:

(i) Determine if such drug has become a multiple source drug by reviewing FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) for a drug that is that is rated as therapeutically equivalent to such drug; and,

(ii) If a therapeutically equivalent drug is identified as set forth in paragraph (b)(4)(i) of this section, determine if the therapeutically equivalent drug was sold or marketed during the applicable calendar quarter; and

(iii) Exclude billing units of such drug furnished on and after the first day of the calendar month in which the therapeutically equivalent drug was first sold or marketed during the applicable calendar quarter.

(5) *Billing units subject to discarded drug refunds.* CMS will exclude billing units of discarded refundable single-dose container or single-use package drugs for which a refund is owed as set forth in § 414.940 of this chapter from the calculation of rebate amounts. For applicable calendar quarters beginning on or after January 1, 2024, these billing units will be excluded as part of the reconciliation process described at § 427.501(d).

§ 427.304 Adjustments for changes to billing and payment codes.

(a) *Changes in billing unit dose description.* If there has been a change to the dose description for a Part B rebatable drug (causing a new billing and payment code to be assigned), CMS will calculate a conversion factor based on the ratio of the billing unit dose description for the current billing and payment code to the billing unit dose description for the prior billing and payment code. CMS will apply the conversion factor to the payment amount in the payment amount benchmark quarter, as set forth in § 427.302(d), before applying the percentage by which the rebate period CPI–U for the calendar quarter exceeds the benchmark period CPI–U.

(b) *Instances when a new billing and payment code is assigned.* If a new billing and payment code is assigned for a Part B rebatable drug, CMS will use the payment amount in the payment amount benchmark quarter, the payment amount benchmark quarter, and the benchmark quarter CPI–U of the prior billing and payment code to calculate the per unit Part B rebate amount under § 427.302.

(c) *Documentation.* CMS will maintain a crosswalk reflecting the changes in billing and payment codes and dose descriptions as applicable.

Subpart E—Reducing the Rebate Amount for Part B Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption

§ 427.400 Definitions.

As used in this subpart, the following definitions apply:

Currently in shortage means that at least one NDC–10 assigned to the billing and payment code of a Part B rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a Part B rebatable biosimilar biological product by a manufacturer and significantly affects the ability of the manufacturer of the biosimilar biological product to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 427.401 Reducing the rebate amount for Part B rebatable drugs currently in shortage.

(a) *General.* As required under section 1847A(i)(3)(G)(i) of the Act, CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable drug that is currently in shortage, as set forth in § 427.400, at any point during the applicable calendar quarter.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable calendar quarter beginning on or after January 1, 2023, the reduced total rebate amount for a Part B rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced Total Rebate Amount = the total rebate amount multiplied by (1 *minus* applicable percent reduction) multiplied by (percentage of time drug was currently in shortage during the applicable calendar quarter) added to the total rebate amount multiplied by (1 *minus* percentage of time drug was currently in shortage during the applicable calendar quarter)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part B rebatable drug that is a plasma-derived product:

(A) 75 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 50 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 25 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(ii) For a Part B rebatable drug that is not a plasma-derived product:

(A) 25 percent for the first 4 consecutive applicable calendar quarters such drug is currently in shortage.

(B) 10 percent for the second 4 consecutive applicable calendar quarters such drug is currently in shortage.

(C) 2 percent for each subsequent applicable calendar quarter such drug is currently in shortage.

(iii) Except as provided in paragraph (b)(iv) of this section, CMS will apply the greatest applicable percent reduction as set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section

starting with the first applicable calendar quarter that a Part B drug or biological product is described as currently in shortage regardless of whether the drug or biological product meets the definition of a Part B rebatable drug or whether a rebate amount is owed for that calendar quarter, starting with the calendar quarter that begins January 1, 2023.

(iv) If any applicable calendar quarter for which a rebate reduction determined under § 427.402 has been granted would be the first of the four consecutive applicable calendar quarters set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section and the Part B rebatable drug or biological product continues to be currently in shortage after the rebate reduction period set forth in § 427.402, CMS will treat the quarter following the final quarter in which the rebate reduction determined under § 427.402 applies as the first of the four consecutive applicable calendar quarters so described.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable calendar quarter is equal to the number of days such drug is currently in shortage in an applicable calendar quarter, divided by the total number of days in the applicable calendar quarter.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to all the NDCs under the relevant billing and payment code.

§ 427.402 Reducing the rebate amount for certain Part B rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1847A(i)(3)(G)(ii) of the Act, CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable calendar quarter such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product by 75 percent for the applicable calendar quarter in which the event occurred or began, or the following applicable calendar quarter if the request is submitted less than 60 calendar days before the end of an applicable calendar quarter, and the 3 subsequent applicable calendar quarters.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a fifth applicable calendar quarter as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount determined under § 427.301(a), if any is owed, for a Part B rebatable biosimilar biological product by 75 percent for that fifth applicable calendar quarter and an additional 3 consecutive applicable calendar quarters.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11 assigned to a billing and payment code, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to all the NDCs under the relevant billing and payment code.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part B rebatable drug and applicable calendar quarter.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same 4 applicable calendar quarters for the same Part B rebatable biosimilar biological product and submits multiple rebate reduction requests for the same product, CMS will grant no more than 1 rebate reduction determined under paragraph (b)(1) or (2) of this section for that product for those consecutive applicable calendar quarters.

(ii) If CMS grants a rebate reduction request under this section, and the Part B rebatable biosimilar biological product subject to the reduction appears as currently in shortage during any of the 4 applicable calendar quarters as the ones for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction determined under § 427.401 during those applicable calendar quarters.

(iii) If a Part B rebatable biosimilar biological product that is currently in shortage experiences a severe supply chain disruption, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction determined under § 427.401 during those applicable calendar quarters.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to Part B rebatable biosimilar biological products for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024, that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began in order to receive consideration for a reduction in the rebate amount owed as set forth in paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the Part B rebatable biosimilar biological product(s), such as a change in the production or distribution of the Part B rebatable biosimilar biological product(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the Part B rebatable biosimilar biological product(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the Part B rebatable biosimilar biological product(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the Part B rebatable biosimilar biological product(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster

or other unique or unexpected event that affects the manufacturer's Part B rebatable biosimilar biological product(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the Part B rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount determined under § 427.301(a), if any is owed, if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable calendar quarter;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a Part B rebatable biosimilar biological product that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by a severe supply chain disruption, CMS will grant a single extension of the reduction for 4 additional consecutive applicable calendar quarters and reduce the rebate amount calculated at § 427.301(a), if any is owed as determined under paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the Part B rebatable biosimilar biological product continues to be affected by the severe supply chain disruption during the fifth through eighth applicable calendar quarters.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the fifth applicable calendar quarter to receive consideration for a reduction in the rebate amount owed, if any, as determined under paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable calendar quarter that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5), or if a reduction determined under paragraph (b)(1) of this section was not granted for such biosimilar biological product.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemptions 3 and/or 4 in 5 U.S.C. 552.

Subpart F—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 427.500 Definitions.

As used in this subpart, *date of receipt* is the calendar day following the day on which a report of a rebate amount (as set forth in §§ 427.501(b) through (d) and 427.502(b) and (c) is made available to the manufacturer of a Part B rebatable drug by CMS.

§ 427.501 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part B rebatable drugs for all applicable calendar quarters except as otherwise set forth in § 427.502 regarding the applicable calendar quarters in calendar years 2023 and 2024.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part B rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable calendar quarter.

(1) The Preliminary Rebate Report for each Part B rebatable drug will include the following information:

(i) The NDC(s) and billing and payment codes identified for the Part B rebatable drug set forth in § 427.20.

(ii) Total number of billing units as determined under § 427.303.

(iii) Payment amount benchmark quarter and payment amount in the payment amount benchmark quarter as determined under § 427.302(c) and (d).

(iv) Applicable calendar quarter specified amount as determined under § 427.302(b).

(v) Applicable benchmark period and rebate period CPI–Us as set forth in § 427.302(e) and (f).

(vi) Inflation-adjusted payment amount as determined under § 427.302(g).

(vii) The amount, if any, by which the specified amount as determined under § 427.302(b) exceeds the inflation-adjusted payment amount as determined under § 427.302(g) for the Part B rebatable drug for the applicable calendar quarter as set forth in § 427.302.

(viii) Any applied reductions as determined under §§ 427.401 and 427.402.

(ix) Rebate amount due as determined under § 427.301(a).

(2) [Reserved]

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each applicable calendar quarter.

(1) The Rebate Report will include the information specified in paragraph (b)(1) of this section, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as determined under § 427.301, if any, for a Part B rebatable drug for an applicable calendar quarter.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of a rebate amount provided in a Rebate Report specified in paragraph (c) of this section for an applicable calendar quarter in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise set forth in § 427.502, CMS will perform one regular reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for each applicable calendar

quarter to include revisions to the information used to calculate the rebate amount set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount determined under paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of a rebate amount for an applicable calendar quarter determined under paragraph (d)(3) of this section based on the information set forth in this paragraph (b)(1)(i) and paragraphs (d)(1)(ii) through (ix) of this section and provide the information specified in this paragraph (b)(1)(i) and paragraphs (d)(1)(ii) through (ix) to the manufacturer of a Part B rebatable drug for the applicable calendar quarter, if applicable:

(A) Updated total number of rebatable units, as determined under § 427.303.

(B) Updated payment amount benchmark quarter and payment amount in the payment amount benchmark quarter, as determined under § 427.302(c) and (d) if any inputs are restated within the reconciliation run-out period.

(C) Applicable calendar quarter specified amount as determined under § 427.302(b), if any inputs are restated within the reconciliation run-out period.

(D) The excess amount by which the specified amount exceeds the inflation-adjusted payment amount as determined under § 427.302, if any inputs are restated within the reconciliation run-out period.

(E) Reconciled total rebate amount as determined under § 427.301(a).

(F) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 427.503, if applicable, a report with the reconciled rebate amount will be provided to each manufacturer of a Part B rebatable drug within 12 months after the issuance of the Rebate Report described in paragraph (c) of this section.

(2) *CMS identification of error and manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part B rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an agency error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 3 years from the date of receipt by a manufacturer of a reconciled rebate amount for the applicable calendar quarter; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in this paragraph (d) could result in an increase, decrease, or no change to the rebate amount, as determined under § 427.301, owed by a manufacturer for the applicable calendar quarter for the Part B rebatable drug compared to the amount described in the Rebate Report described in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as determined under § 427.301 for a Part B rebatable drug for an applicable calendar quarter.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part B that does not meet the requirements of a rebatable drug specified in subpart B for an applicable calendar quarter will not be included in a reconciliation under this paragraph (d).

§ 427.502 Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024.

(a) *Transition rule for reporting.* Section 1847A(i)(1)(C) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount described in § 427.501(c) for applicable calendar quarters in calendar years 2023 and 2024 until not later than September 30, 2025.

(b) *Rebate Report information for applicable calendar quarters in calendar years 2023 and 2024.* The Rebate Reports for applicable calendar quarters in calendar years 2023 and 2024 will include the information set forth in § 427.501(b)(1).

(c) *Rebate Report procedures for applicable calendar quarters in calendar years 2023 and 2024.* Rebate amounts for the applicable calendar quarters in calendar year 2023 and 2024 will be reported as follows:

(1) The 4 applicable calendar quarters in calendar year 2023 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) Discarded drug units for which a refund is owed will be removed from the total number of billing units in the single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023.

(ii) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2023, the Suggestion of Error period as set forth in § 427.503 will be 30 calendar days.

(iii) No regular reconciliation of the rebate amount as set forth in § 427.501(d)(1) will be conducted for the rebate amount in the single Rebate Report for the applicable calendar quarters in calendar year 2023.

(2) The four applicable calendar quarters in calendar year 2024 will be consolidated into a single report and manufacturers will receive a single Preliminary Rebate Report followed by a single Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable calendar quarters in calendar year 2024, the Suggestion of Error period as set forth in § 427.503 will be 30 calendar days.

(ii) Nine months after issuance of the single Rebate Report, CMS will perform one regular reconciliation for the applicable calendar quarters in calendar year 2024 in order to include revisions to the information used, determined under § 427.501(b)(1), to calculate the rebate amount. Such reconciliation will be as determined under § 427.501(d) inclusive of a preliminary reconciliation and a report with the reconciled rebate amount.

(iii) The Suggestion of Error period for the preliminary reconciliation for the applicable calendar quarters in calendar year 2024 will be 10 calendar days.

§ 427.503 Suggestion of Error.

(a) *General.* The manufacturer of a Part B rebatable drug may submit a Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation of the rebate amount, as applicable, is finalized.

(1) Section 1847A(i)(8) of the Act precludes administrative or judicial review on the determination of units as set forth in § 427.303, the determination of whether a drug is a Part B rebatable drug as set forth in § 427.101, and the calculation of the rebate amount as set

forth in § 427.301, inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as set forth in § 427.502 for applicable calendar quarters in calendar year 2023 and 2024, a manufacturer must submit its Suggestion of Error for the applicable calendar quarter within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 427.501(c) or § 427.502(c) as well as any report of reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 427.504 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part B rebatable drug to:

(1) Access the manufacturer's Rebate Report as set forth in §§ 427.501 and 427.502, including any report of reconciled rebate amount as set forth in §§ 427.501(d) and 427.502(c)(2)(ii);

(2) Submit a Suggestion of Error as set forth in §§ 427.502(c)(1)(ii) and (c)(2)(i) and 427.503; and

(3) Pay a rebate amount as set forth in § 427.505.

(b) [Reserved]

§ 427.505 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For a rebate amount owed by a manufacturer, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30th calendar day after the date of receipt of information regarding the rebate amount on—

(1) A Rebate Report as set forth in § 427.501(c) or § 427.502(c)(1) or (2); or

(2) A report of a reconciled rebate amount as set forth in § 427.501(d) or § 427.502(c)(2)(ii).

(b) *Failure to pay a rebate amount.* Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart G of this part.

(c) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable calendar quarter as set forth in § 427.501(d) or § 427.502(c)(2)(ii) is less than what the manufacturer paid for that applicable calendar quarter, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart G—Enforcement of Manufacturer Payment of Rebate Amounts

§ 427.600 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount determined in § 427.301(a) on a Part B rebatable drug as set forth in § 427.101, by the payment deadline as set forth in § 427.505(a) for such drug for such applicable calendar quarter.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to provide an inflation rebate for an applicable calendar quarter equal to 125 percent of the rebate amount determined in § 427.301(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as determined in § 427.501(d) or § 427.502(c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable quarter for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty described in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as set forth in paragraph (e)(3) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS under paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as set forth in § 427.505.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with notice pursuant to the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the Government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

■ 82. Part 428 is added to read as follows:

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

Subpart A—General Provisions

Sec.

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

Subpart A—General Provisions

§ 428.10 Basis and scope.

(a) *Basis.* This part implements section 1860D–14B of the Social Security Act (''the Act'').

(b) *Scope.* This part sets forth the requirements of the Medicare Part D Drug Inflation Rebate Program, which requires, for each 12-month applicable period, manufacturers to pay rebates for certain drugs and biological products with prices that increase faster than the rate of inflation.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 428.20 Definitions.

As used in this part, the following definitions apply:

Annual manufacturer price (AnMP) means the amount determined under § 428.202(b).

Applicable period means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

Applicable period Consumer Price Index for All Urban Consumers (CPI–U) means, with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October).

Applicable threshold means the amount determined under § 428.101(b)(2).

Average manufacturer price (AMP) means the average price paid to the manufacturer for the drug by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer, determined under § 447.504 of this chapter.

Benchmark period CPI–U means the CPI–U identified as set forth in § 428.202(e).

Benchmark period manufacturer price means the amount determined under § 428.202(d).

Covered Part D Drug has the meaning set forth in section 1860D–2(e) of the Act and § 423.100 of this chapter.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

First marketed date means the date that a manufacturer is required to report for a Part D rebatable drug as its ''market date'' under section 1927(b)(3)(A)(v) of the Act.

Inflation-adjusted payment amount means the amount determined under § 428.202(f).

Manufacturer has the meaning set forth in section 1927(k)(5) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with FDA identifying the product.

Part D rebatable drug means, subject to the exclusion set forth in § 428.101(b), a drug or biological that is a covered Part D drug that, as of the first day of the applicable period, is:

(1) A drug approved under a New Drug Application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act;

(2) A generic drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act (''section 505(j) ANDA''), in the case where:

(i) The reference listed drug approved under an NDA under section 505(c) of the FD&C Act, including any authorized generic drug as defined in section 505(t)(3) of the FD&C Act, is not being marketed, as identified in the Food and Drug Administration's (FDA) NDC Directory;

(ii) There is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent in FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book), and that is being marketed, as identified in FDA's NDC Directory;

(iii) The manufacturer is not a ''first applicant'' during the ''180-day exclusivity period,'' as those terms are defined in section 505(j)(5)(B)(iv) of the FD&C Act; and

(iv) The manufacturer is not a ''first approved applicant'' for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the FD&C Act; or

(3) A biological licensed under section 351 of the Public Health Service (PHS) Act, including a biosimilar.

Payment amount benchmark period means the period identified as set forth in § 428.202(c).

Subsequently approved drug means a Part D rebatable drug first approved or licensed by the FDA after October 1, 2021.

Unit means, with respect to a Part D rebatable drug, the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams) of the Part D rebatable drug, as reported under section 1927 of the Act.

Subpart B—Determination of Part D Rebatable Drugs

§ 428.100 Definitions.

As used in this subpart, the following definitions apply:

Individual who uses such a drug or biological means a unique Medicare Part D beneficiary who was dispensed the Part D drug or biological that was covered by their Part D plan sponsor during the applicable period, identified using Prescription Drug Event (PDE) data with dates of service during the applicable period and with gross covered prescription drug costs greater than zero.

Gross covered prescription drug costs has the meaning set forth in § 423.308 of this chapter.

§ 428.101 Identification of Part D rebatable drugs.

(a) *Determination of Part D rebatable drugs.* (1) For each applicable period, CMS will use PDE data to identify all covered Part D drugs.

(2) CMS will match the covered Part D drugs identified in the PDE data with application numbers using FDA sources to determine whether each covered Part D drug is a drug or biological approved under an NDA under section 505(c) of the FD&C Act, approved under an ANDA under section 505(j) of the FD&C Act, or licensed under a Biologics License Application (BLA) under section 351 of the PHS Act, as of the first day of the applicable period.

(3) For a covered Part D drug identified in the PDE that is approved under an ANDA under section 505(j) of the FD&C Act, CMS will determine whether such drug meets the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act as of the first day of the applicable period as follows:

(i) To determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(I) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(ii) To determine whether another drug has been approved under an ANDA that is therapeutically equivalent to the Part D rebatable drug identified as set forth in this paragraph (a)(3), CMS will use FDA's Orange Book. To determine if this therapeutically equivalent drug is being marketed, as required under section 1860D–14B(g)(1)(C)(ii)(II) of the Act, CMS will use FDA's NDC Directory, including historical information from NDC Directory files, such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website.

(iii) To determine whether the manufacturer of the drug identified as set forth in this paragraph (a)(3) is a first applicant during the 180-day exclusivity period, or whether the manufacturer of this drug is a first approved applicant for a competitive generic drug therapy, CMS will refer to publicly available FDA sources such as the Orange Book and may consult with FDA for technical assistance as needed.

(b) *Drugs and biologicals with average annual total cost below the applicable threshold.* For each applicable period, CMS will identify drugs and biologicals with average annual total costs under Part D for such applicable period, per individual who uses such drug or biological, that are below the applicable threshold in accordance with the steps described in this paragraph (b). Such drugs and biologicals are not considered Part D rebatable drugs and will be excluded from the identification of Part D rebatable drugs set forth in paragraph (a) of this section.

(1) *Average annual total cost.* For each drug or biological that is identified as set forth in paragraph (a) of this section, CMS will calculate average annual total costs under Part D per individual who uses such drug or biological by dividing the gross covered prescription drug costs for the drug or biological by the number of individuals who use such drug or biological in the applicable period. When calculating the gross covered prescription drug costs for the drug or biological, CMS will exclude PDE records indicating the drug or biological was billed as a compound.

(2) *Applicable threshold.* CMS will calculate the applicable threshold for an applicable period as follows:

(i) For the applicable period beginning October 1, 2022, the applicable threshold is equal to $100.

(ii) For the applicable period beginning October 1, 2023, the applicable threshold is equal to $100 increased by the percentage increase in CPI–U for the 12-month period beginning October 1, 2023.

(iii) For subsequent applicable periods, the applicable threshold is equal to the applicable threshold for the prior applicable period increased by the percentage increase in the CPI–U for the 12-month period beginning with October of the previous period.

(iv) If the resulting amount determined under paragraph (b)(2)(ii) or (iii) of this section is not a multiple of $10, CMS will round that amount to the nearest multiple of $10.

Subpart C—Determination of the Rebate Amount for Part D Rebatable Drugs

§ 428.200 Definitions.

As used in this subpart, the following definitions apply:

340B Program is the program under section 340B of the PHS Act.

Line extension has the meaning set forth in § 447.502 of this chapter.

New formulation has the meaning set forth in § 447.502 of this chapter.

Oral solid dosage form has the meaning set forth in § 447.502 of this chapter.

§ 428.201 Calculation of the total rebate amount to be paid by manufacturers.

(a) *Total rebate.* (1) Subject to paragraph (b) of this section, the total rebate amount to be paid by a manufacturer for a Part D rebatable drug, identified as set forth in § 428.101, for an applicable period is equal to:

(i) The product of the per unit Part D rebate amount of such drug, as determined under § 428.202(a), and the total number of units dispensed of such drug under Part D, as determined under § 428.203; or

(ii) In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the amount determined under § 428.204.

(2) The rebate amount may be reduced in accordance with subpart D of this part or adjusted in accordance with subpart E of this part.

(b) *Drugs and biologicals excluded from Part D rebate calculations.* CMS will exclude from the Part D drug inflation rebate calculations described in this subpart—

(1) Drugs and biologicals that meet the definition of a Part D rebatable drug but whose manufacturers do not have an agreement in effect with the HHS Secretary under section 1927 of the Act at any point during the applicable period, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

(2) Drugs and biologicals that meet the definition of a Part D rebatable drug but, for the entire duration of the applicable period, are excluded from the definition of covered outpatient drugs as defined in section 1927(k)(2)–(4) of the Act and § 447.502 of this chapter, as determined by CMS through consultation with Medicaid Drug Rebate Program staff and review of the Medicaid Drug Programs system.

§ 428.202 Calculation of the per unit Part D drug rebate amount.

(a) *Formula for calculating the per unit Part D rebate amount.* CMS will calculate the per unit Part D drug inflation rebate amount for a Part D rebatable drug and applicable period by determining the amount by which the AnMP for the Part D rebatable drug, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as calculated in accordance with paragraph (f) of this section.

(b) *Calculation of the AnMP for the applicable period.* Subject to paragraph

(g) of this section, CMS will calculate the AnMP for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for each calendar quarter of the applicable period and units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act for each month of the applicable period.

(1) CMS will calculate the AnMP for a Part D rebatable drug as the sum of the following:

(i) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning October of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(ii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning January of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iii) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning April of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(iv) The product of—

(A) The AMP for the Part D rebatable drug reported for the calendar quarter beginning July of the applicable period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the applicable period divided by the sum of the monthly units reported for the 4 calendar quarters in the applicable period.

(2) The first applicable period for a Part D rebatable drug will be the earliest applicable period that follows the payment amount benchmark period identified as set forth in paragraphs (c)(1) through (4) of this section.

(c) *Identification of the payment amount benchmark period.* As applicable under this paragraph, CMS will use information reported by a manufacturer under section 1927(b)(3) of the Act, including without limitation the date of FDA approval or licensure and the first marketed date, to identify the payment amount benchmark period as set forth in paragraphs (c)(1) and (2) of this section, subject to paragraphs (c)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the payment amount benchmark period is the period beginning on January 1, 2021, and ending on September 30, 2021;

(2) For a subsequently approved drug, the payment amount benchmark period is the first calendar year beginning after the drug's first marketed date;

(3) Notwithstanding paragraph (c)(1) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3), the payment amount benchmark period is the first calendar year no earlier than calendar year 2021 in which such NDC–9 has at least 1 quarter of AMP reported;

(4) Notwithstanding paragraph (c)(2) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the payment amount benchmark period is the first calendar year in which such NDC–9 has at least 1 quarter of AMP reported; and

(5) Notwithstanding paragraphs (c)(1) through (4) of this section, for a Part D rebatable drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, for each applicable period beginning after the price applicability period with respect to such drug, the payment amount benchmark period is the last calendar year of such price applicability period with respect to such selected drug.

(d) *Calculation of benchmark period manufacturer price.* Subject to paragraphs (d)(3) and (g) of this section, CMS will calculate the benchmark period manufacturer price for a Part D rebatable drug using the AMP reported by a manufacturer under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for each calendar quarter of the payment amount benchmark period and the monthly units reported by a manufacturer under section 1927(b)(3)(A)(iv) of the Act during the payment amount benchmark period.

(1) For a Part D rebatable drug with a payment amount benchmark period identified as set forth in paragraph (c)(1) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning January 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning April 2021 divided by the sum of the monthly units reported for the 3 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July 2021; and

(B) The sum of the monthly units reported for the calendar quarter beginning July 2021 divided by the sum of the units reported for the 3 quarters of the payment amount benchmark period.

(2) For a Part D rebatable drug with a payment amount benchmark period identified under paragraphs (c)(2) through (5) of this section, CMS will calculate the benchmark period manufacturer price as the sum of the following:

(i) The product of—

(A) The AMP reported for the calendar quarter beginning January of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning January of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(ii) The product of—

(A) The AMP reported for the calendar quarter beginning April of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning April of the payment amount

benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iii) The product of—

(A) The AMP reported for the calendar quarter beginning July of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning July of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(iv) The product of—

(A) The AMP reported for the calendar quarter beginning in October of the payment amount benchmark period; and

(B) The sum of the monthly units reported for the calendar quarter beginning October of the payment amount benchmark period divided by the sum of the monthly units reported for the 4 quarters of the payment amount benchmark period.

(3) To the extent that a new NDC–9 of a Part D rebatable drug is reported under section 1927 of the Act and AMP has not been reported for such NDC–9 under section 1927(b)(3)(A)(i)(I) or (ii) of the Act during the period set forth in paragraph (c)(1) or (2) of this section, as applicable, CMS will identify the payment amount benchmark period and calculate the benchmark period manufacturer price for such NDC–9 using other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug, as available, such as the base date AMP if such base date AMP is reported for a calendar quarter that overlaps with the period set forth in paragraph (c)(1) or (2) of this section. Base date AMP has the meaning set forth in § 447.509(a)(7)(ii)(B) of this title.

(e) *Identification of the benchmark period CPI–U.* For each Part D rebatable drug, CMS will identify the benchmark period CPI–U as set forth in paragraphs (e)(1) and (2) of this section, subject to paragraphs (e)(3) through (5) of this section:

(1) For a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the benchmark period CPI–U is the CPI–U for January 2021.

(2) For a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date.

(3) Notwithstanding paragraph (e)(1) of this section, for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, for which there are no quarters during the period beginning on January 1, 2021, and ending on September 30, 2021, for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period identified under paragraph (c)(3) of this section.

(4) Notwithstanding paragraph (e)(2) of this section, for a subsequently approved drug for which there are no quarters during the first calendar year beginning after the drug's first marketed date for which AMP has been reported under section 1927(b)(3) of the Act for the NDC–9, including information as set forth in paragraph (d)(3) of this section, the benchmark period CPI–U is the CPI–U for January of the payment amount benchmark period identified as set forth in paragraph (c)(4) of this section.

(5) Notwithstanding paragraphs (e)(1) through (4) of this section, for a drug that is a selected drug (as defined in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), in the case such Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period.

(f) *Calculation of inflation-adjusted payment amount.* For an applicable period for each Part D rebatable drug, CMS will calculate the inflation-adjusted payment amount by dividing the applicable period CPI–U by the benchmark period CPI–U and then multiplying the quotient by the benchmark period manufacturer price.

(g) *Situations in which manufacturers do not report units under section 1927(b)(3)(A)(iv) of the Act.* For the purpose of calculating the AnMP as determined under paragraph (b) of this section and the benchmark period manufacturer price as determined under paragraph (d) of this section—

(1) If there is 1 or more quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act but has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act, CMS will calculate the benchmark period manufacturer price or AnMP, as applicable, using data only from quarter(s) with units. Quarter(s) in the payment amount benchmark period or applicable period for which a manufacturer has not reported units under section 1927(b)(3)(A)(iv) of the Act will be excluded from the calculation.

(2) If there are no quarters of the payment amount benchmark period or applicable period for which a manufacturer has reported units under section 1927(b)(3)(A)(iv) of the Act, but the manufacturer has reported AMP under sections 1927(b)(3)(A)(i)(I) and (ii) of the Act for at least 1 quarter of such period or, with respect to paragraph (d)(3), there exists other information reported by a manufacturer under section 1927(b)(3) of the Act for the Part D rebatable drug to identify the payment amount benchmark period, CMS will use the AMP or other information as applicable as set forth in paragraph (d)(3) reported for 1 quarter to calculate the benchmark period manufacturer price or AnMP, respectively. If AMP is reported for more than 1 quarter, CMS will use the average of the AMP over the calendar quarters of the payment amount benchmark period or applicable period for which AMP is reported to calculate the benchmark period manufacturer price or AnMP, respectively.

§ 428.203 Determination of the total number of units dispensed under Part D.

(a) *General.* For each Part D rebatable drug, CMS will determine the total number of units as follows:

(1) *Use of PDE data to determine total units dispensed.* To determine the total number of units of each Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during an applicable period, CMS will use the quantity dispensed reported on the PDE record for each Part D rebatable drug with gross covered prescription drug costs greater than zero.

(2) *Crosswalk to AMP units.* CMS will crosswalk the information from the PDE record to database(s) that includes the unit type (for example, each, capsule) for the Part D rebatable drug, matching on the NDC of the Part D rebatable drug. If the unit type obtained from such database does not match the AMP unit type reported by a manufacturer to the Medicaid Drug Programs system, CMS will convert the total units reported on the PDE to the AMP units reported.

(b) *Removal of certain units.* CMS will exclude certain units from the total number of units dispensed of a Part D rebatable drug, with respect to an applicable period, as follows:

(1) *Removal of units when a generic drug is no longer a Part D rebatable drug.* To determine whether a generic drug that meets the definition of a Part D rebatable drug on the first day of an applicable period ceases to meet such

definition later in the applicable period, CMS will—

(i) Review FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine whether the reference listed drug or an authorized generic of the reference listed drug is being marketed;

(ii) Review the most recent version of the downloadable FDA Orange Book to determine whether another drug has been approved under a section 505(j) ANDA that is therapeutically equivalent to such generic drug. If CMS determines that FDA has approved such a therapeutically equivalent drug under a section 505(j) ANDA, CMS will then: use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings provided by the FDA or published on the FDA website to determine the marketing status of such therapeutically equivalent drug and whether, during the applicable period, the therapeutically equivalent drug was marketed; and

(iii) Exclude from the total number of units determined under paragraph (a) of this section any units dispensed on or after the first day of the calendar month that a generic drug no longer meets the definition of a Part D rebatable drug.

(2) *Exclusion of units acquired through the 340B Program.* (i) For the applicable period beginning October 1, 2025, and subsequent applicable periods, CMS will exclude from the total number of units determined under paragraph (a) of this section units for which a manufacturer provided a discount under the 340B Program (''340B units'') as follows:

(A) For the applicable period beginning October 1, 2025, 340B units will be excluded from the total number of units dispensed for claims with a date of service on or after January 1, 2026.

(B) For the applicable period beginning October 1, 2026, and applicable periods thereafter, 340B units will be excluded from the total number of units dispensed.

(ii) To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, CMS will use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period.

(3) *Exclusion of compounded drug units.* CMS will exclude units from the total number of units dispensed of a Part D rebatable drug when those units are associated with a Part D rebatable drug that has been billed as compounded.

§ 428.204 Treatment of new formulations of Part D rebatable drugs.

In the case of a Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form, the rebate amount for an applicable period is equal to the amount determined under § 428.201(a) for such new drug or, if greater, the alternative total rebate amount. CMS will determine the alternative total rebate amount for such new formulations according to the following:

(a) *Identification* of the *initial drug.* The initial drug that CMS will use to calculate the inflation rebate amount ratio is the initial drug identified in accordance with § 447.509(a)(4)(iii)(B) of this chapter for the last quarter of the applicable period or, if an initial drug was not identified in the last quarter, the initial drug identified for a quarter most recently in that applicable period.

(b) *Calculation of the inflation rebate amount ratio.* The inflation rebate amount ratio is equal to the per unit Part D drug inflation rebate amount for the initial drug, as determined under § 428.202(a), divided by the AnMP for that initial drug for the applicable period.

(c) *Calculation of the alternative total rebate amount.* The alternative total rebate amount is equal to the product of all of the following:

(1) The AnMP for the applicable period, as determined under § 428.202(b), of the Part D rebatable drug that is a line extension of a Part D rebatable drug that is an oral solid dosage form.

(2) The inflation rebate amount ratio as determined under paragraph (b) of this section.

(3) The total number of units dispensed under Part D identified as set forth in § 428.203.

Subpart D—Reducing the Rebate Amount for Part D Rebatable Drugs in Shortage and When There Is a Severe Supply Chain Disruption or Likely Shortage

§ 428.300 Definitions.

As used in this subpart, the following definitions apply:

Biosimilar has the meaning set forth in section 351(i) of the PHS Act.

Currently in shortage means that at least one NDC–10 of a Part D rebatable drug with the status ''currently in shortage'' is on a shortage list maintained by the FDA under section 506E of the FD&C Act.

Drug shortage or *shortage* means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug (see section 506C(h)(2) of the FD&C Act).

Generic Part D rebatable drug means a generic drug approved under an ANDA under section 505(j) of the FD&C Act that meets the sole source criteria specified in § 428.101(a)(3).

Likely to be in shortage means that a generic Part D rebatable drug is likely to be described as currently in shortage during a subsequent applicable period without such rebate reduction.

Natural disaster means any natural catastrophe, including, but not limited to any of the following: hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought, or regardless of cause, any fire, flood, or explosion.

Other unique or unexpected event means any exogenous, unpredictable event outside of a manufacturer's control, including, but not limited to, a geopolitical disruption, pandemic, or act of terror.

Plasma-derived product means a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling.

Severe supply chain disruption means a change in production or distribution that is reasonably likely to lead to a significant reduction in the U.S. supply of a generic Part D rebatable drug or biosimilar by a manufacturer and significantly affects the ability of the manufacturer of the generic drug or biosimilar to fill orders or meet expected demand for its product in the United States for at least 90 days. This definition does not include interruptions in manufacturing due to matters such as routine maintenance, manufacturing quality issues, or insignificant changes made in the manufacturing process for the drug.

§ 428.301 Reducing the rebate amount for Part D rebatable drugs currently in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(i) of the Act, CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a Part D rebatable drug that is currently in shortage, as set forth in § 428.300, at any point during the applicable period.

(b) *Calculation of the reduced rebate amount.* (1) For each applicable period beginning on or after October 1, 2022, the reduced total rebate amount for a Part D rebatable drug currently in shortage will be calculated using the following formula:

Equation 1 to Paragraph (b)(1)

Reduced *Total* Rebate Amount = the total rebate amount *multiplied by* (1 *minus* applicable percent reduction) *multiplied by* (percentage of time drug was currently in shortage during the applicable period) *added to* the total rebate amount *multiplied by* (1 *minus* percentage of time drug was currently in shortage during the applicable period)

(2) For purposes of paragraph (b)(1) of this section, the applicable percent reduction is:

(i) For a Part D rebatable drug that is a generic drug or plasma-derived product:

(A) 75 percent for the first applicable period such drug is currently in shortage.

(B) 50 percent for the second applicable period such drug is currently in shortage.

(C) 25 percent for each subsequent period such drug is currently in shortage.

(ii) For a Part D rebatable drug that is not a generic drug or plasma-derived product:

(A) 25 percent for the first applicable period such drug is currently in shortage.

(B) 10 percent for the second applicable period such drug is currently in shortage.

(C) 2 percent for each subsequent applicable period such drug is currently in shortage.

(iii) Except as provided in paragraph (b)(iv) of this section, CMS will apply the greatest applicable percent reduction as set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section starting with the first applicable period that a Part D drug or biological is described as currently in shortage, regardless of whether the drug or biological meets the definition of a Part D rebatable drug or whether a rebate amount is owed for that applicable period, starting with the applicable period that begins October 1, 2022.

(iv) If an applicable period for which a rebate reduction determined under § 428.302 or 428.303 has been granted would be the first applicable period set forth in paragraph (b)(2)(i)(A) or (b)(2)(ii)(A) of this section and the Part D rebatable drug or biosimilar continues to be in shortage after the rebate reduction period set forth in § 428.302 or 428.303, as applicable, CMS will treat the applicable period following the applicable period in which the rebate reduction determined under § 428.302 or 428.303 applies as the first applicable period so described.

(3) For purposes of paragraph (b)(1) of this section, the percentage of time the drug is currently in shortage during the applicable period is equal to the number of days such drug is currently in shortage in an applicable period, divided by the total number of days in the applicable period.

(c) *Application of reduction.* CMS will apply a reduction of the rebate amount as determined under paragraph (b) of this section to the Part D rebatable drug at the NDC–9 level.

§ 428.302 Reducing the rebate amount for certain Part D rebatable drugs when there is a severe supply chain disruption.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(ii) of the Act, CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar when CMS determines there is a severe supply chain disruption during the applicable period such as that caused by a natural disaster or other unique or unexpected event.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar by 75 percent for the applicable period in which the event occurred or began or, the following applicable period if the request is submitted less than 60 calendar days before the end of an applicable period.

(2) *Extension of reduction.* If CMS determines a severe supply chain disruption continues into a second consecutive applicable period as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar by 75 percent for that second applicable period.

(3) *Application of reduction.* If CMS determines there is a severe supply chain disruption for an NDC–11, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to a Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* CMS will not apply multiple rebate reductions for the same Part D rebatable drug and applicable period.

(i) If a manufacturer believes there are multiple events causing severe supply chain disruptions during the same applicable period for the same generic Part D rebatable drug or biosimilar and submits multiple rebate reduction requests for the same drug or biosimilar, CMS will grant no more than 1 rebate reduction determined under paragraph (b)(1) or (2) of this section for that product for the applicable period.

(ii) If CMS grants a rebate reduction request under this section and the generic Part D rebatable drug or biosimilar subject to the reduction appears as currently in shortage during the same applicable period as the one for which the severe supply chain disruption reduction request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction as set forth in § 428.301 during that applicable period.

(iii) If a generic Part D rebatable drug or biosimilar that is currently in shortage experiences a severe supply chain disruption, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section, and will not grant a reduction as set forth in § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to generic Part D rebatable drugs and biosimilars for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* For a natural disaster or other unique or unexpected event occurring on or after August 2, 2024 that the manufacturer believes caused a severe supply chain disruption, the manufacturer must submit the rebate reduction request within 60 calendar days from the first day that the natural disaster or other unique or unexpected event occurred or began to receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed as determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that the severe supply chain disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, a contract manufacturer, or a method of shipping or distribution that the manufacturer uses to make or distribute the generic Part D rebatable drug(s) or biosimilar(s), such as a change in the production or distribution of the generic Part D

rebatable drug(s) or biosimilar(s) that is reasonably likely to lead to a significant reduction in the U.S. supply of product and significantly affects the manufacturer's ability to fill orders or meet expected demand for the generic Part D rebatable drug(s) or biosimilar(s) for at least 90 days;

(ii) Information about when the manufacturer expects supply of the generic Part D rebatable drug(s) or biosimilar(s) to meet expected demand;

(iii) Evidence that the natural disaster or other unique or unexpected event caused the severe supply chain disruption, including when the natural disaster or other unique or unexpected event occurred or began occurring, and the expected or actual duration of the severe supply chain disruption; and

(iv) Evidence of the manufacturer's physical presence related to manufacturing the generic Part D rebatable drug(s) or biosimilar(s) in a geographic area where a natural disaster or other unique or unexpected event occurred. If the manufacturer is not physically present in a geographic area where a natural disaster or other unique or unexpected event occurred, but believes there is a severe supply chain disruption caused by a natural disaster or other unique or unexpected event that affects the manufacturer's generic Part D rebatable drug(s) or biosimilar(s), the information and supporting documentation may include evidence of the impact of the natural disaster or other unique or unexpected event on the supply chain of the generic Part D rebatable drug or biosimilar, on a supplier of an ingredient or packaging, or method of shipping or distribution that the manufacturer uses.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the total rebate amount determined under § 428.201, if any is owed, if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) A severe supply chain disruption has occurred during the applicable period;

(ii) The severe supply chain disruption directly affects the manufacturer itself, a contract manufacturer, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the generic Part D rebatable drug or biosimilar; and

(iii) The severe supply chain disruption was caused by a natural disaster or other unique or unexpected event.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug or biosimilar that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by the severe supply chain disruption, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the total rebate amount determined under § 428.201, if any is owed, as set forth in paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug or biosimilar continues to be affected by the severe supply chain disruption during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period to receive consideration for a reduction in the rebate amount owed, if any, determined under paragraph (b)(2) of this section, except for when the initial request is made less than 60 calendar days before the end of an applicable period such that the initial rebate reduction is applied to the next applicable period rather than the applicable period in which the event that caused the severe supply chain disruption occurred or began. In these cases, the rebate reduction extension request must be submitted at least 60 calendar days prior to the end of the applicable period in which the initial reduction determined under paragraph (b)(1) of this section is applied.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5) of this section, or if a reduction determined under paragraph (b)(1) of this section was not granted for such generic Part D rebatable drug or biosimilar.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction request that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

§ 428.303 Reducing the rebate amount for generic Part D rebatable drugs likely to be in shortage.

(a) *General.* As required under section 1860D–14B(b)(1)(C)(iii) of the Act, CMS will reduce the total rebate amount determined under § 428.201, if any is owed, for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage, as set forth in § 428.300.

(b) *Calculation of the reduced rebate amount*—(1) *Initial reduction.* If CMS determines the criteria set forth in paragraph (c)(4) of this section are met, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for the applicable period in which the request was submitted or the following applicable period, depending on the timing of the submission of the request.

(2) *Extension of reduction.* If CMS determines the generic Part D rebatable drug is likely to be in shortage in a second applicable period as set forth in paragraph (c)(5) of this section, then CMS will reduce the total rebate amount owed by the manufacturer for a generic Part D rebatable drug by 75 percent for a second consecutive applicable period.

(3) *Application of reduction.* If CMS determines that an NDC–11 is likely to be in shortage, CMS will apply any reduction of the rebate amount as determined under paragraphs (b)(1) and (2) of this section to the generic Part D rebatable drug at the NDC–9 level.

(4) *Limitation on rebate reductions.* If CMS grants a rebate reduction request under this section, and the generic Part D rebatable drug subject to the reduction is currently in shortage during the same applicable period as the one for which the request was granted, CMS will reduce the rebate amount as determined under paragraph (b)(1) of this section and will not grant a reduction

determined under § 428.301 during that applicable period.

(c) *Eligibility for a rebate reduction*—(1) *Eligible drug.* Subject to paragraph (b)(3) of this section, eligibility for a rebate reduction under this section is limited to generic Part D rebatable drugs for which a manufacturer submits a rebate reduction request under this section.

(2) *Timing.* The manufacturer must submit the rebate reduction request before the start of the next applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section.

(3) *Required elements of a rebate reduction request.* To receive consideration for a reduction in the rebate amount owed determined under paragraph (b)(1) of this section, the manufacturer must submit to CMS information and supporting documentation to substantiate the evaluation criteria set forth in paragraph (c)(4) of this section. Such information and supporting documentation include the following:

(i) Evidence that demonstrates a generic Part D rebatable drug is likely to be in shortage, including anticipated cause(s) of the shortage and information about why the manufacturer believes the generic Part D rebatable drug is likely to be in shortage; and

(ii) Evidence of the anticipated start date and duration of the potential drug shortage, the actions the manufacturer is taking to avoid the potential drug shortage, and how the reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(4) *Evaluation criteria.* In accordance with paragraph (b)(1) of this section, CMS will grant a reduction in the rebate amount owed if a manufacturer submits to CMS a request in writing for an eligible drug, in accordance with the timing set forth in paragraph (c)(2) of this section, demonstrating that:

(i) The generic Part D rebatable drug is likely to be in shortage;

(ii) The manufacturer is taking actions to avoid the potential drug shortage; and

(iii) The reduction of the rebate amount would reduce the likelihood of the drug appearing on an FDA shortage list.

(5) *Rebate reduction extensions.* If CMS determines that a generic Part D rebatable drug that received a reduction of the rebate amount as determined under paragraph (b)(1) of this section continues to be affected by the potential drug shortage, CMS will grant a single extension of the reduction for 1 additional consecutive applicable period and reduce the total rebate amount determined under § 428.201, if any is owed, as determined under paragraph (b)(2) of this section.

(i) To receive consideration for a rebate reduction extension, a manufacturer must submit a request with updated or new information and supporting documentation on why the generic Part D rebatable drug continues to be affected by the potential drug shortage during the second applicable period.

(ii) A manufacturer must submit the rebate reduction extension request at least 60 calendar days before the start of the second consecutive applicable period in which the manufacturer believes the generic Part D rebatable drug is likely to be in shortage to receive consideration for a reduction in the rebate amount owed, if any, in accordance with paragraph (b)(2) of this section.

(6) *Decision to grant or deny a request.* CMS will review rebate reduction requests and rebate reduction extension requests within 60 calendar days of receipt of all documentation, if feasible, beginning with the applicable period that begins on October 1, 2024.

(i) CMS will deny a rebate reduction request that does not meet the criteria set forth in paragraph (c)(4) of this section or that is incomplete or untimely based on the requirements set forth in this paragraph (c).

(ii) CMS will deny a rebate reduction extension request that does not meet the criteria set forth in paragraph (c)(5) of this section, that is incomplete or untimely based on the requirements set forth in paragraph (c)(5) of this section, or if a reduction determined under paragraph (b)(1) of this section was not granted for such generic Part D rebatable drug.

(iii) CMS' decisions to deny a request are final and will not be subject to an appeals process.

(7) *Public disclosure of information.* CMS will keep confidential, to the extent allowable under law, any requests for a rebate reduction, including supporting documentation. Information provided as part of a request for a rebate reduction that the submitter indicates is a trade secret or confidential commercial or financial information will be protected from disclosure if CMS determines the information meets the requirements set forth under Exemption 3 or Exemption 4 in 5 U.S.C. 552.

Subpart E—Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

§ 428.400 Definitions.

For the purposes of this subpart, *date of receipt* is the calendar day following the day in which a report of a rebate amount (as set forth in §§ 428.401(b), (c), and (d) and 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS.

§ 428.401 Rebate Reports and reconciliation.

(a) *General.* This section applies to Part D rebatable drugs for all applicable periods except as otherwise set forth in § 428.402 for the applicable periods beginning October 1, 2022, and October 1, 2023.

(b) *Preliminary Rebate Report.* A Preliminary Rebate Report will be provided to each manufacturer of a Part D rebatable drug at least 1 month prior to the issuance of the Rebate Report as set forth in paragraph (c) of this section for an applicable period.

(1) The Preliminary Rebate Report for each Part D rebatable drug will include the following information:

(i) The NDC(s) identified for the Part D rebatable drug as set forth in § 428.20;

(ii) The total number of units dispensed under Part D for the Part D rebatable drug for the applicable period as determined under § 428.203;

(iii) The payment amount benchmark period and benchmark period manufacturer price as set forth in §§ 428.202(c) and (d);

(iv) The AnMP for the Part D rebatable drug for the applicable period as determined under § 428.202(b);

(v) The amount, if any, of the excess AnMP for the Part D rebatable drug for the applicable period as set forth in § 428.202(a);

(vi) The benchmark period and applicable period CPI-Us as set forth in §§ 428.202(e) and 428.20, respectively;

(vii) The inflation-adjusted payment amount as set forth in § 428.202(f);

(viii) Any applied reductions determined under §§ 428.301, 428.302, and 428.303; and

(ix) The rebate amount due as set forth in § 428.201(a).

(2) If the Part D rebatable drug is a line extension, the Preliminary Rebate Report will also include the following information as set forth in § 428.204:

(i) The NDC for the initial drug;

(ii) The inflation rebate amount ratio for the initial drug; and

(iii) The alternative total rebate amount.

(c) *Rebate Report.* A Rebate Report will be provided to each manufacturer

of a Part D rebatable drug no later than 9 months after the end of each applicable period.

(1) The Rebate Report will include the information described in paragraphs (b)(1) and (2) of this section, if applicable, with the inclusion of any revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, and any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The Rebate Report is the invoice of a manufacturer's rebate amount due as determined in § 428.201(a), if any, for a Part D rebatable drug for an applicable period.

(d) *Reconciliation of the rebate amount.* CMS will perform reconciliation of the rebate amount provided in a Rebate Report as determined in paragraph (c) of this section for an applicable period in the following circumstances:

(1) *Regular reconciliation.* Except as otherwise described in § 428.402, CMS will perform a reconciliation of the rebate amount within 12 months of the date of receipt of the Rebate Report for an applicable period and a second reconciliation approximately 24 months thereafter to include revisions to the information used to calculate the rebate amount as set forth in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable period as set forth in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable period based on the information specified in paragraphs (d)(1)(i)(A) through (G) of this section, and CMS will provide the information specified in paragraphs (d)(1)(i)(A) through (G) to the manufacturer of a Part D rebatable drug for the applicable period, if applicable:

(A) Updated total number of rebatable units, including updates submitted by a prescription drug plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan sponsor and updates to 340B units (as applicable to the dates of service and applicable periods set forth in § 428.203(b)(2)(i)(A) and (B)), or units otherwise excluded as determined under § 428.203(b);

(B) The inflation-adjusted payment amount as determined under § 428.202(f) if any inputs are restated or newly reported within the reconciliation run-out period;

(C) Updated payment amount benchmark period and benchmark period manufacturer price as set forth in § 428.202(c) and (d) if any inputs are restated or newly reported;

(D) The excess amount by which the AnMP exceeds the inflation-adjusted payment amount for the applicable period as determined under § 428.202(a), using the most recent AMP (if any inputs are restated or newly reported within the reconciliation run-out period);

(E) Updated data on line extension calculations, including the initial drug identified as set forth in § 447.509(a)(4)(iii)(B) of this chapter, the inflation rebate amount ratio, and the alternative total rebate amount as determined under § 428.204 if any inputs are restated or newly reported within the reconciliation run-out period;

(F) The reconciled rebate amount as determined under § 428.201(a); and

(G) The difference between the total rebate amount due as specified on the Rebate Report set forth in paragraph (c) of this section and the reconciled rebate amount as set forth in this paragraph (d)(1)(i).

(ii) *Report with a reconciled rebate amount.* With the inclusion of any additional revisions to such information resulting from CMS' review of a Suggestion of Error as set forth in § 428.403, if applicable, a report with the reconciled rebate amount will be provided to each manufacturer of a Part D rebatable drug within 12 months and 36 months after the issuance of the Rebate Report set forth in paragraph (c) of this section.

(2) *CMS identification of an error or manufacturer misreporting.* CMS may recalculate a rebate amount and provide the manufacturer of a Part D rebatable drug a report with a reconciled rebate amount when:

(i) CMS identifies an error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 5 years from the date of receipt by a manufacturer of a reconciled rebate amount for the applicable period; or

(ii) CMS determines at any time that the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as determined under this paragraph (d) could result in an increase, decrease, or no change to the rebate amount as determined under § 428.201(a) owed by a manufacturer for the applicable period for the Part D rebatable drug compared to the amount described in the Rebate Report set forth in paragraph (c) of this section or an amount described in a previous reconciliation.

(i) A report with a reconciled rebate amount that is an increase to the rebate amount is the invoice for such additional amount due on the manufacturer's rebate amount as set forth in § 428.201 for a Part D rebatable drug for an applicable period.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part D that does not meet the requirements of a rebatable drug set forth in § 428.101 for an applicable period will not be included in a reconciliation as determined under this paragraph (d).

§ 428.402 Rebate Reports for applicable periods beginning October 1, 2022, and October 1, 2023.

(a) *Transition rule for reporting.* Section 1860D–14B(a)(3) of the Act allows CMS to delay the timeframe for reporting the information and rebate amount set forth in § 428.401 for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

(b) *Rebate Report information for applicable periods beginning October 1, 2022, and October 1, 2023.* The Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023, will include the information set forth in § 428.401(b)(1).

(c) *Rebate Report procedures for applicable periods beginning October 1, 2022, and October 1, 2023.* Rebate amounts for the applicable periods beginning October 1, 2022, and October 1, 2023, will be reported as follows:

(1) The Rebate Report for the applicable period beginning October 1, 2022, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as set forth in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 21 months after the Rebate Report set forth in paragraph (c)(1) of this section is issued to include the information set forth in § 428.401(d)(1)(i)(A) through (G).

(iii) The Suggestion of Error period for the reconciliation set forth in paragraph (c)(1)(ii) of this section will be 10 calendar days.

(2) The Rebate Report for the applicable period beginning October 1, 2023, will be issued no later than December 31, 2025. The Preliminary Rebate Report for such applicable period will be issued at least 1 month prior to the Rebate Report.

(i) For this single Preliminary Rebate Report for the applicable period, the Suggestion of Error period as set forth in § 428.403 will be 30 calendar days.

(ii) The rebate amount will be reconciled 9 months after the Rebate Report and 33 months after the Rebate Report specified in paragraph (b)(2) of this section is issued to include the information determined under § 428.401(d)(1)(i)(A) through (G).

§ 428.403 Suggestion of Error.

(a) *General.* Manufacturers of Part D rebatable drugs may submit a Suggestion of Error about the information in their Preliminary Rebate Report and the report detailing the preliminary reconciliation of the rebate amount to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report or a subsequent reconciliation, as applicable, is finalized.

(1) Section 1860D–14B(f) of the Act precludes administrative or judicial review on the determination of units as set forth in § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth in § 428.101, and the calculation of the rebate amount as set forth in § 428.201(a) inclusive of any reconciled rebate amount.

(2) [Reserved]

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the Suggestion of Error and provide supporting documentation (if applicable).

(c) *Timing.* Except as set forth in § 428.402 for the applicable periods beginning on October 1, 2022, and October 1, 2023, a manufacturer must submit its Suggestion of Error for the applicable period within 10 calendar days from the date of receipt of a Preliminary Rebate Report or a preliminary reconciliation of a rebate amount using the method and process set forth by CMS in paragraph (b) of this section.

(d) *Notice.* (1) CMS will include any revisions to the calculation of the rebate amount, if determined necessary by CMS based on the Suggestion of Error submitted under this section prior to issuance of the Rebate Report as set forth in § 428.401(c) or § 428.402(c) as well as any report of a reconciled rebate amount as set forth in § 428.401(d) or § 428.402(c)(1)(ii) and (c)(2)(ii).

(2) CMS will notify the manufacturer whether CMS revised its calculation of the rebate amount based on the Suggestion of Error.

§ 428.404 Manufacturer access to Rebate Reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the Part D rebatable drug to:

(1) Access the Rebate Report as set forth in §§ 428.401 and 428.402, including any report of a reconciled rebate amount as set forth in §§ 428.401 and 428.402;

(2) Submit a Suggestion of Error as set forth in §§ 428.402(c) and 428.403; and

(3) Pay a rebate amount as set forth in § 428.405.

(b) [Reserved]

§ 428.405 Deadline and process for payment of rebate amount.

(a) *Rebate amounts owed by a manufacturer.* For payment of a rebate amount owed by a manufacturer:

(1) Upon receipt of a rebate amount, payment is due no later than 11:59 p.m. Pacific Time (PT) on the 30 calendar days after the date of receipt of information regarding the rebate amount on—

(i) A Rebate Report as set forth in § 428.401(c) or § 428.402; or

(ii) A report of a reconciled rebate amount as set forth in § 428.401(d) or § 428.402.

(2) Failure to pay a rebate amount due timely and in full may result in an enforcement action as described in subpart F of this part.

(b) *Refund to the manufacturer.* If a reconciled rebate amount for an applicable period as set forth in § 428.401(d) or § 428.402 is less than what the manufacturer paid for that applicable period, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 days of the date of receipt of the report with such reconciled rebate amount.

Subpart F—Enforcement of Manufacturer Payment of Rebate Amounts

§ 428.500 Civil money penalty notice and appeals procedures.

(a) *General.* CMS may impose a civil money penalty on a manufacturer that fails to pay the rebate amount set forth in § 428.201(a) on a Part D rebatable drug set forth in § 428.20, by the payment deadline as set forth in section § 428.405(a) for such drug for such applicable period.

(b) *Determination of the civil money penalty amount.* CMS may impose a civil money penalty for each failure by a manufacturer to provide an applicable inflation rebate equal to 125 percent of the rebate amount determined in § 428.201(a).

(1) The civil money penalty is in addition to the rebate amount due.

(2) If a reconciled rebate amount as determined in § 428.401(d) or § 428.402(c)(1)(ii) or (c)(2)(ii) results in an increase to the rebate amount due, a separate civil money penalty may be imposed for the failure by a manufacturer to provide an inflation rebate for the applicable period for the increase to the rebate amount due.

(c) *Notice of imposition of civil money penalties.* If CMS makes a determination to impose a civil money penalty set forth in paragraph (b) of this section, CMS will send a written notice of its decision to impose a civil money penalty that includes the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing as set forth in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(d) *Collection.* (1) A manufacturer must pay the civil money penalty in full within 60 calendar days after the date of the notice of imposition of a civil money penalty from CMS as set forth in paragraph (c) of this section.

(2) In the event a manufacturer requests a hearing, pursuant to 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil money penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Appeal procedures for civil money penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil money penalty until the affected party has had notice and the opportunity for a hearing.

(1) Manufacturers may appeal the following determinations:

(i) A CMS determination that the rebate amount was not paid by the applicable payment deadline as set forth in § 428.405.

(ii) The calculation of the amount of the civil money penalty.

(2) If CMS decides to impose a civil money penalty, CMS will provide the manufacturer with notice pursuant to the process set forth in paragraph (c) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil money penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(g) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the full rebate amount owed or the total sum of civil money penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil money penalties owed by the manufacturer.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 83. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

■ 84. Section 491.9 by—
■ a. Redesignating paragraph (a)(3) as paragraph (a)(4);
■ b. Adding new paragraph (a)(3);
■ c. Removing paragraphs (c)(2)(ii) and (iv);
■ d. Redesignating paragraphs (c)(2)(iii), (v), and (vi) as paragraphs (c)(2)(ii) through (iv); and
■ e. Revising newly designated paragraph (c)(2)(iv).

The additions and revisions read as follows:

§ 491.9 Provision of services.

(a) * * *

(3) The RHC must provide primary care services.

* * * * *

(c) * * *

(2) * * *

(iv) Collection of patient specimens for transmittal to a certified laboratory for culturing.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following Appendices will not appear in the Code of Federal Regulations.

Appendix 1: MIPS Quality Measures

Note: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the CY 2025 performance period/2027 MIPS payment year and future years. Previously finalized measures and specialty sets are in the CY 2017 through CY 2024 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, and 88 FR 79556 through 79964. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE #/eCQM CBE #.

Table Group A: New MIPS Quality Measures Finalized and Not Finalized for the CY 2025 Performance Period/ 2027 MIPS Payment Year and Future Years

Note: In the CY 2024 PFS final rule, measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level), was finalized with a 1-year delay to the CY 2025 performance period (88 FR 79556 through 79560) and does not have a new measure table in this final rule.

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A.1. Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	506
Description:	Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
Numerator:	Patients who had a positive PD-L1 biomarker expression test result prior to the initiation of first-line immune checkpoint inhibitor therapy.
Denominator:	Patients aged 18 years and older with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) and on first-line immune checkpoint inhibitors without chemotherapy.
Exclusions:	Patients with NSCLC with epidermal growth factor receptor (EGFR) mutations, ALK genomic tumor aberrations, or other targetable genomic abnormalities with approved first-line targeted therapy, such as NSCLC with ROS1 rearrangement, BRAF V600E mutation, NTRK 1/2/3 gene fusion, MET ex14 skipping mutation, and RET rearrangement.
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure.

Category	Description
Rationale:	We proposed this process measure because it addresses timely biomarker testing, which impacts treatment decisions for patients with a diagnosis of metastatic NSCLC cancer or squamous cell carcinoma of the head and neck. This measure aligns with CMS priorities of improving patient outcomes and safety and promotes improved efficacy through timely treatment. Appropriate intervention and timeliness of PD-L1 biomarker expression testing prior to initiation of first-line treatment for metastatic NSCLC cancer or squamous cell carcinoma of the head and neck can lead to improvements in mortality and morbidity rates.[942] Untimely biomarker testing could lead to negative clinical implications or outcomes, including delayed care and treatment and/or ineffective or incorrect prescribed therapies leading to chemotherapy toxicity, decreased quality of life, and unnecessary healthcare costs.[943] [944] Immunotherapy remains a new realm for oncology and health care clinicians; therefore, opportunities exist to improve care for patients receiving immune checkpoint inhibitor therapy. In 2017, a survey conducted by the Association of Community Cancer Centers (ACCC) indicated only 24 percent of respondents reported they had a deep familiarity with checkpoint inhibitors, 32 percent with monoclonal antibody therapy, and only 17 percent with combination treatment regimens.[945] This measure is predicated on two evidence-based clinical guidelines that address the measure's quality actions of a positive PD-L1 biomarker expression test prior to giving first-line immune checkpoint inhibitor therapy in the metastatic NSCLC cancer or squamous cell carcinoma of the head and neck population.[946] [947] The measure will enhance compliance with the clinical guidelines by incentivizing clinicians to address timely biomarker testing, therein positively influencing treatment decisions and improving patient outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee conditionally supported this measure and requested additional testing examining measure performance and feasibility. This measure has been fully developed and tested at the clinician level with high reliability based upon signal-to-noise scores, and adequate face validity. As a part of the MERIT submission, the measure developer reported adequate reliability testing of the individual data elements via Cohen's kappa coefficient, which substantiates the feasibility for implementation in MIPS. Testing of measure performance indicated a large gap in care for conducting timely biomarker testing, with an average performance rate of 19.6 percent, which allows significant room for improvement among clinicians treating this patient population and conducting the biomarker testing for this measure. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure aligns with the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines.[948] [949] We recognized that not all measures within MIPS are applicable or appropriate for all clinicians due to the nuances for each clinician specialization, scope of care, or regional location. However, this measure fills a gap in MIPS quality measures for treatment of patients with NSCLC cancer and squamous cell carcinoma of the head and neck. In addition, it will provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. Furthermore, this measure could be added to the Advancing Cancer Care MVP in the future and will fill a current quality measure inventory gap within the oncologic clinical topic. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[942] Lim, C., Tsao, M. S., Le, L. W., Shepherd, F. A., Feld, R., Burkes, R. L., Liu, G., Kamel-Reid, S., Hwang, D., Tanguay, J., da Cunha Santos, G., & Leighl, N. B. (2015). Biomarker Testing and Time to Treatment Decision in Patients with Advanced Nonsmall-cell Lung Cancer. *Annals of Oncology: Official Journal of the European Society for Medical Oncology*, *26*(7), 1415–1421. https://doi.org/10.1093/annonc/mdv208.

[943] Pai, S., Blaisdell, D., Brodie, R., Carlson, R., Finnes, H., Galioto, M., Jensen, R. E., Valuck, T., Sepulveda, A. R., & Kaufman, H. L. (2020). Defining Current Gaps in Quality Measures for Cancer Immunotherapy: Consensus Report from the Society for Immunotherapy of Cancer (SITC) 2019 Quality Summit. Journal for Immunotherapy of Cancer, 8(1), e000112. https://doi.org/10.1136/jitc-2019-000112.

[944] See footnote Lim et al., 2015.

[945] Association of Community Cancer Centers (ACCC). (2017-2018). Immuno-Oncology: Transforming the Delivery of Cancer Care in the Community [White paper]. http://www.informz.net/ACCC/data/images/Attachments/2017%20IO%20White%20Paper.pdf.

[946] Ettinger, D. S., Wood, D. E., Aisner, D. L., Akerley, W., Bauman, J. R., Bharat, A., Bruno, D. S., Chang, J. Y., Chirieac, L. R., D'Amico, T. A., DeCamp, M., Dilling, T. J., Dowell, J., Gettinger, S., Grotz, T. E., Gubens, M. A., Hegde, A., Lackner, R. P., Lanuti, M., Lin, J., … Hughes, M. (2022). Non-Small Cell Lung Cancer, Version 3.2022, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network: JNCCN, 20(5), 497–530. https://doi.org/10.6004/jnccn.2022.0025.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy measure. Two of these commenters indicated the measure is guideline-concordant and fills a gap in care that can significantly improve patient outcomes. Current evidence-based NCCN Clinical Practice Guidelines in Oncology: NSCLC and NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancer[950] address the measure's quality actions of a positive PD-L1 biomarker expression test prior to giving first-line immune checkpoint inhibitor therapy in the metastatic NSCLC or squamous cell carcinoma of head and neck populations. The measure is also in concordance with the FDA indications for these therapies and will help to ensure compliance when providing them to patients. Through the development and testing of this measure, it was shown there was a significant gap in patients receiving timely biomarker testing for this indication, and this measure will help to address this gap improving clinician decision making as well as patient outcomes. Another commenter stated this new measure will help better inform treatment decisions and outcomes for beneficiaries.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62251 through 62253), we are finalizing the *Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

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[947] Pfister, D. G., Spencer, S., Adelstein, D., Adkins, D., Anzai, Y., Brizel, D. M., Bruce, J. Y., Busse, P. M., Caudell, J. J., Cmelak, A. J., Colevas, A. D., Eisele, D. W., Fenton, M., Foote, R. L., Galloway, T., Gillison, M. L., Haddad, R. I., Hicks, W. L., Hitchcock, Y. J., Jimeno, A., … Darlow, S. D. (2020). Head and Neck Cancers, Version 2.2020, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network: JNCCN, 18(7), 873–898. https://doi.org/10.6004/jnccn.2020.0031.

[948] National Comprehensive Cancer Network (2021). NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancer. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.

[949] National Comprehensive Cancer Network (2021). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.

[950] Riely, G. J., Wood, D. E., Ettinger, D. S., Aisner, D. L., Akerley, W., Bauman, J. R., Bharat, A., Bruno, D. S., Chang, J. Y., Chirieac, L. R., DeCamp, M., Desai, A. P., Dilling, T. J., Dowell, J., Durm, G. A., Gettinger, S., Grotz, T. E., Gubens, M. A., Juloori, A., Lackner, R. P., … Hang, L. (2024). Non-Small Cell Lung Cancer, Version 4.2024, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network : JNCCN, 22(4), 249–274. https://doi.org/10.6004/jnccn.2204.0023.

A.2. Appropriate Germline Testing for Ovarian Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	507
Description:	Percentage of patients aged 18 and older diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.
Measure Steward:	American Society of Clinical Oncology
Numerator:	Patients who receive germline genetic testing for BRCA1 and BRCA2 (ideally within the context of a multigene panel) or who have genetic counseling completed within 6 months of diagnosis.
Denominator:	All patients, aged 18 and older, with epithelial ovarian, fallopian tube, or primary peritoneal cancer newly diagnosed between July 1st of the previous calendar year through June 30th of the current performance period with two encounters during the performance period.
Exclusions:	Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We proposed this process measure because it helps guide the most appropriate treatment for patients diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of their diagnosis. Additionally, this measure addresses the CMS priority of promoting more personalized diagnostic, predictive, prognostic, and therapeutic options for the patient. According to the American Cancer Society, estimates indicate that in the U.S in 2024 there will be about 19,680 new cases of ovarian cancer diagnoses and an estimated 12,740 women will die of the disease.[951] "Knowledge about underlying molecular alterations in ovarian cancer could allow for more personalized diagnostic, predictive, prognostic, and therapeutic strategies for the patient but also have clinical implications for her family members."[952] Despite current recommendations for all women diagnosed with ovarian cancer to receive genetic testing, only approximately 30 percent of those women undergo any genetic testing.[953] Germline mutations in BRCA1 and BRCA2 have been identified in 13 to 15 percent of women diagnosed with ovarian cancer, with somatic mutations found in an additional 7 percent of women. The high incidence of these mutations, in conjunction with the advent of therapy targeting BRCA mutations, warrants testing in all individuals diagnosed with ovarian cancer.[954] This testing serves multiple purposes, including determination of appropriate and best treatment recommendations, risk of other cancers, and need for cascade testing of family members. "Testing for germline mutations should be performed at the time of initial diagnosis. Presence of a germline mutation in a woman with advanced cancer designates her as eligible for maintenance therapy with a poly (ADP-ribose) polymerase (PARP) inhibitor (Olaparib) after response to initial chemotherapy."[955] Although the FDA recently approved frontline maintenance therapy for patients independent of mutation status following the publication of the ASCO evidence-based guidelines, emerging evidence is expected to indicate an overall survival benefit in ovarian cancer patients with germline mutations, based upon prognostic information from these patients. Germline mutations testing allows for more personalized therapeutic strategies, therefore ovarian cancer patients with germline mutations are expected to derive greater benefit from therapy, thereby increasing the survival rate in this patient population.[956] Additionally, germline testing informs potential clinical implications for the relatives of ovarian cancer patients with germline mutations who should be offered individualized genetic risk evaluation, counseling, and genetic testing as reflected in Recommendation 1.5 in the ASCO germline testing guidelines.[957] Furthermore, National Comprehensive Cancer Network (NCCN) evidence-based guidelines[958] indicate all patients with histologically confirmed ovarian, fallopian tube, or primary peritoneal cancer should undergo genetic risk evaluation as well as germline and somatic testing if not previously performed due to germline and/or somatic BRCA1 and BRCA2 statuses delineating future options for maintenance therapy. This measure could be added to the Advancing Cancer Care MVP in the future and will fill a current quality measure inventory gap within the oncologic clinical topic. Additionally, it will provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. The PRMR Clinician Recommendation Committee conditionally supported this measure for rulemaking pending endorsement of the measure by a CBE. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As mentioned above, this measure aligns with ASCO and NCCN evidence-based clinical guidelines.[959] [960] Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[951] American Cancer Society (ACS). (2024). Key Statistics for Ovarian Cancer. https://www.cancer.org/cancer/types/ovarian-cancer/about/key-statistics.html#:~:text=The%20American%20Cancer%20Society%20estimates%20for%20ovarian%20cancer,About%2012%2C740%20women%20will%20die%20from%20ovarian%20cancer.

[952] Konstantinopoulos, P. A., Norquist, B., Lacchetti, C., Armstrong, D., Grisham, R. N., Goodfellow, P. J., Kohn, E. C., Levine, D. A., Liu, J. F., Lu, K. H., Sparacio, D., & Annunziata, C. M. (2020). Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 38(11), 1222–1245.* https://doi.org/10.1200/JCO.19.02960.

[953] See footnote Konstantinopoulos et al., 2020.

[954] See footnote Konstantinopoulos et al., 2020.

[955] See footnote Konstantinopoulos et al., 2020.

[956] See footnote Konstantinopoulos et al., 2020.

[957] See footnote Konstantinopoulos et al., 2020.

[958] NCCN. (2024). NCCN Guidelines: Detection, Prevention, and Risk Reduction. https://www.nccn.org/guidelines/category_2.

[959] See footnote Konstantinopoulos et al., 2020.

[960] See footnote NCCN, 2024.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Appropriate Germline Testing for Ovarian Cancer Patients measure. One commenter stated that germline genetic testing can be used to identify patients with cancer predisposition syndromes, for whom targeted therapeutic interventions, additional screenings, and testing of family members may be indicated. Rates of germline testing in these patients remain suboptimal and the inclusion of this measure may improve utilization. Another commenter indicated it is important that patients who are diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer have genetic counseling services within 6 months of diagnosis and are assisted in an evaluation of available options, including germline genetic testing of BRCA1 and BRCA2, and a discussion of genetic predispositions. Another commenter stated this new measure would help inform treatment decisions and outcomes for beneficiaries.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: Two commenters supported this new measure and encouraged CMS to expand the measure in accordance with evidence-based guidelines to include germline genetic testing for additional cancers related to BRCA1 and BRCA2 genes, such as prostate, pancreatic, melanoma, gastric, colorectal, uterine and breast cancer. One commenter also recommended removing the genetic counseling numerator criteria as genetic counseling does not replace the need for germline testing and is not consistent with applicable guidelines that do not reference genetic counseling (for example, patients with a personal history of these cancers should have germline testing).

Response: We thank the commenters for these suggestions and encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62253 through 62254), we are finalizing the *Appropriate Germline Testing for Ovarian Cancer Patients* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

A.3. Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer

Category	Description
CBE # / eCQM CBE #:	CBE 3718 / N/A
Quality #:	N/A
Description:	The PRO-PM will assess pain interference following chemotherapy administered with curative intent to adult female patients with breast cancer.
Measure Steward:	Purchaser Business Group on Health
Numerator:	The mean of the patient-level PROMIS Pain Interference scores at the follow-up survey.
Denominator:	Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen.
Exclusions:	● Patients on a therapeutic clinical trial ● Patients with recurrence/disease progression ● Patients who leave the practice during the follow-up period ● Patients who died during the follow-up period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We proposed this measure because it addresses a CMS high priority as a PRO-PM and fills a gap in providing the patient's experience of care related to breakthrough pain after chemotherapy for breast cancer lending to performance improvement. Common persistent symptoms following chemotherapy include pain, fatigue, and detriments to health-related quality of life. Data from this measure will provide insight into the effectiveness of minimizing the persistent symptoms following treatment(s), thereby driving quality improvement leading to practice changes and better patient outcomes. This oncology PRO-PM's conceptual development is grounded in the evidence-based premise that medical oncologists who provide the highest quality care (including medical and non-medical support services) to patients receiving curative-intent cytotoxic therapy can reduce longer-term symptom burden, thus improving a patient's transition into the cancer survivorship period.[961] [962] [963] Additionally, research suggests collecting and using patient-reported symptoms during cancer care can improve patient outcomes, such as increased survival, reduced symptom burden and improved patient experience.[964] [965] Using a standardized symptom assessment process will facilitate appropriate follow-up to ensure patient needs are addressed, while supporting and improving patient-provider communication. This measure could be added to the Advancing Cancer Care MVP in the future and will fill a current quality measure inventory gap within the oncologic clinical topic. In addition, it will provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. This will be the first outcome specialty specific oncology measure to address the patient experience of care. There is potential consideration for adding broader cancer diagnoses, such as colon and lung cancer, to this measure in the future. The PRMR Clinician Recommendation Committee conditionally supported this measure for rulemaking with the condition of implementation at the group level. This measure was endorsed by the CBE as CBE 3718. We proposed this measure for implementation at the individual clinician level in addition to the group level. As part of the MERIT submission, testing was completed at the clinician level with a small sample size due to accessibility to data. However, the measure steward estimated that measure score reliability given an average sample size of 26 yielded a reliability of 0.7. The measure was found during the MERIT submission to be feasible at the clinician level and data element testing was completed showing exact agreement values between 71.63 and 100 percent, with the lowest sensitivity variable being 'recurrence,' which correlated to a small subset of the patient population. The requirements for quality measure scoring include a case minimum threshold. Therefore, we proposed to allow this measure for group and clinician level implementation as it is an important concept and meets all testing and development criteria for MIPS quality measures. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer measure. Another commenter supported this new measure and supported the use of patient-reported outcomes (PROs) in provider quality reporting and value-based purchasing programs. Additionally, this

[961] NCCN. (2024). Clinical Practice Guidelines in Oncology, Cancer-Related Fatigue, Version 2.2024. https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1424.

[962] Smith, T. G., Troeschel, A. N., Castro, K. M., Arora, N. K., Stein, K., Lipscomb, J., Brawley, O. W., McCabe, R. M., Clauser, S. B., & Ward, E. (2019). Perceptions of Patients With Breast and Colon Cancer of the Management of Cancer-Related Pain, Fatigue, and Emotional Distress in Community Oncology. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 37(19), 1666–1676. https://doi.org/10.1200/JCO.18.01579.

[963] Bubis, L. D., Davis, L., Mahar, A., Barbera, L., Li, Q., Moody, L., Karanicolas, P., Sutradhar, R., & Coburn, N. G. (2018). Symptom Burden in the First Year After Cancer Diagnosis: An Analysis of Patient-Reported Outcomes. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 36(11), 1103–1111. https://doi.org/10.1200/JCO.2017.76.0876.

[964] Basch, E., Deal, A. M., Kris, M. G., Scher, H. I., Hudis, C. A., Sabbatini, P., Rogak, L., Bennett, A. V., Dueck, A. C., Atkinson, T. M., Chou, J. F., Dulko, D., Sit, L., Barz, A., Novotny, P., Fruscione, M., Sloan, J. A., & Schrag, D. (2016). Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 34(6), 557–565. https://doi.org/10.1200/JCO.2015.63.0830.

[965] Papageorgiou, L., Le Provost, J. B., Di Palma, M., Langlois, M., Salma, I., Lopes, M., Minvielle, E., Abbas, M., & Scotté, F. (2024). Supportive Care Needs of Newly Diagnosed Cancer Patients in a Comprehensive Cancer Center: Identifying Care Profiles and Future Perspectives. Cancers, 16(5), 1017. https://doi.org/10.3390/cancers16051017.

measure could play an important role in improving quality of life for patients with cancer and ensuring symptoms and side effects are effectively managed. The commenter requested this measure receive CBE endorsement to ensure it can be feasibly implemented.

Response: We thank the commenters for supporting this new measure in MIPS. This measure received CBE endorsement in July 2023 as CBE 3718.

Comment: One commenter supported PRO measures as they provide a patient-centered approach to assessing healthcare quality. However, this measure and the Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer measure under Table A.4 of this Appendix are currently limited to one tool for data collection (PROMIS). The commenter recommended the measure steward broaden the measure numerator to include other validated screening tools so more clinicians can report on the measures.

Response: We thank the commenter for supporting this new measure in MIPS.

Comment: One commenter was generally supportive of PRO-PMs due to value in understanding the patient's clinical experience through their treatment regimen. However, the commenter stated it is difficult to control patient responses and is concerned with any required completion percentages of patient surveys. The commenter was particularly concerned with any required response rates for measures involving cancer patients as the survey response may be a low priority for patients who are navigating the challenges of chemotherapy. The commenter supported this measure and the measure under Table A.4 of this Appendix but strongly recommended CMS not install survey completion requirements due to the fragile nature of the population in question.

Response: We thank the commenter for supporting this new measure in MIPS. We acknowledge the patient is required to complete the surveys; however, the measure requires completion of an index and follow up survey for the clinician to be assessed for the numerator. Patients who do not complete both surveys for any reason are not included in the denominator. As there is no minimum threshold requirement for survey completion for this measure, the clinician will not be penalized if the patient refuses or is unable to complete both surveys. This measure will still be subject to MIPS reporting requirements including case minimum and data completeness.

We appreciate the public comments on this proposed new measure. However, because the measure steward is no longer able to maintain the quality measure, we are not finalizing the *Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

A.4. Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer

Category	Description
CBE # / eCQM CBE #:	CBE 3720 / N/A
Quality #:	N/A
Description:	The PRO-PM will assess fatigue following chemotherapy administered with curative intent to adult female patients with breast cancer.
Measure Steward:	Purchaser Business Group on Health
Numerator:	The mean of the patient-level PROMIS Fatigue scores at the follow-up survey.
Denominator:	Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen.
Exclusions:	● Patients on a therapeutic clinical trial ● Patients with recurrence/disease progression ● Patients who leave the practice during the follow-up period ● Patients who died during the follow-up period
Measure Type:	Patient-Reported Outcome-based Performance Measure (PRO-PM)
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We proposed this measure because it addresses a CMS high priority as a PRO-PM and fills a gap in providing the patient reported symptom of fatigue experienced following chemotherapy for breast cancer, lending to performance improvement. This measure is an important addition to MIPS for those patients diagnosed with and receiving treatment for breast cancer. Based on a recent study, interested parties generated recommendations for performance measures on how adults with cancer feel and function included depression/anxiety, pain, and fatigue as top priorities.[966] This oncology PRO-PM's conceptual development is grounded in the evidence-based premise that medical oncologists who provide the highest quality care (including medical and non-medical support services) to patients receiving curative-intent cytotoxic therapy can reduce longer-term symptom burden, thus improving a patient's transition into the cancer survivorship period.[967] [968] [969] Additionally, research suggests collecting and using patient-reported symptoms during cancer care can improve patient outcomes, such as increased survival, reduced symptom burden and improved patient experience.[970] Using a standardized symptom assessment process will facilitate appropriate follow-up to ensure patient needs are addressed, while supporting and improving patient-provider communication. Evidence from one study indicated 30 to 50 percent of breast cancer patients reported not discussing, nor receiving advice or desired help for three common symptoms, pain, fatigue, and emotional distress.[971] Fatigue was the most common symptom reported in the study (74 percent); of those patients who had fatigue as a symptom, many reported they discussed the symptom (78 percent).[972] However, patients who experienced fatigue were also least likely to report receiving the desired help for it (40 percent).[973] Appropriate use of patient-reported outcome measures (PROMs), which measure cancer symptoms and patients' perceptions of their care, can improve the collection of clinically actionable data, supporting clinical improvement in the treatment of common symptoms and the overall care of patients with cancer, ultimately improving their quality of life.[974] This measure could be added to the Advancing Cancer Care MVP in the future and will fill a current quality measure inventory gap within the oncologic clinical topic. In addition, it will provide a specialty specific measure for the MIPS Oncology/Hematology specialty set under Table B.27a of this Appendix. This measure will address the patient voice/experience of care for those with breast cancer with fatigue experienced following chemotherapy. There is potential consideration for adding broader cancer diagnoses, such as colon and lung cancer, to this measure in the future. The PRMR Clinician Recommendation Committee did not reach consensus for this measure. This measure was endorsed by the CBE as CBE 3720. While concerns were discussed regarding electronic health record implementation, patient survey fatigue and low response impact, this measure is an important clinical topic for oncology clinicians in conjunction with the pain PRO-PM. More specifically, the measure provides a means to capture the patient voice while driving quality of care and improving patient outcomes. We proposed this measure for implementation at the individual clinician level in addition to the group level. Testing was completed at the clinician level with a small sample size due to accessibility to data. The measure was found during the MERIT submission process to be feasible at the clinician level and data element testing was completed showing exact agreement values between 71.63 and 100 percent, with the lowest sensitivity variable being 'recurrence,' which correlated to a small subset of the patient population. The requirements for quality measure scoring include a case minimum threshold. Therefore, we proposed to allow this measure for group and clinician level implementation as it is an important concept and meets all testing and development criteria for MIPS quality measures. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer measure. As mentioned above under Table A.3, commenters supported PRO-PMs as there is value in understanding the patient's clinical experience through their treatment regimen, and these measures provide a patient-centered approach to assessing healthcare quality.

[966] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[967] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[968] See footnote NCCN, 2024 in Table A.3 of this Appendix.
[969] See footnote Bubis et al., 2018 in Table A.3 of this Appendix.
[970] See footnote Basch et al., 2016 in Table A.3 of this Appendix.
[971] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[972] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[973] See footnote Smith et al., 2019 in Table A.3 of this Appendix.
[974] See footnote Smith et al., 2019 in Table A.3 of this Appendix.

Response: We thank the commenters for supporting this new measure in MIPS.

We appreciate the public comments on this proposed new measure. However, because the measure steward is no longer able to maintain the quality measure, we are not finalizing the *Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

A.5. Adult COVID-19 Vaccination Status

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	508
Description:	Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients that are up to date on their COVID-19 vaccinations as defined by CDC recommendations on current vaccination as of the date of the encounter.
Denominator:	All patients aged 18 years and older seen for a visit during the performance period.
Exclusions:	Patient received hospice services any time during the performance period.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Rationale:	We proposed this process measure because it represents an important clinical topic following the recently ended Public Health Emergency (PHE) for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). Widespread vaccination to prevent a severe COVID-19 infection is critically important to stemming the morbidity and mortality caused by this virus. The CDC reports millions of cases and deaths caused by COVID-19.[975] In 2020 and 2021, COVID-19 was the third leading cause of death in the U.S., exceeded only by cancer and heart disease.[976] The percent of the population reporting receipt of the updated 2023-24 COVID-19 vaccine is 13.1 percent (95 percent confidence interval: 12.5-13.7) for children and 22.5 percent (21.7-22.7) for adults 18 years and older, including 41.5 percent (40.2-42.9) among adults age 65 years and older.[977] [978] This recent data suggests a considerable gap in care for patients in the measure population and allows clinicians the opportunity to positively affect vaccination rates. Additionally, during measure testing, the measure developer found even the 75th percentile of performance yielded only 58 percent of a clinician's patient load being vaccinated with one booster. The measure was initially submitted to the CY 2022 Call for Quality Measures and included on the Measures under Consideration (MUC) list for review. During the 2022 cycle, the Measure Applications Partnership (MAP) recommended not to support the measure and requested the measure be revised before resubmitting for consideration to, among other things, include the most recent CDC recommendations for the numerator and use the current CDC definition of "up to date" for assessment of the quality action for each denominator eligible patient. These requests were addressed, and the measure was resubmitted to the CY 2023 Call for Quality Measures. We acknowledged the recommendations for boosters have continued to evolve; however, the quality action in this measure is aligned with current and potential future recommendations. Since December 2020, there have been more than 19 ACIP recommendations relating to COVID-19 vaccination. On September 12, 2023, ACIP recommended all persons aged 6 months and older receive an updated COVID-19 vaccine.[979] Updated COVID-19 vaccines are considered the 2023-2024 formula developed by the pharmaceutical and biotechnology companies Moderna, Pfizer-BioNTech, and Novavax. Because this measure uses the CDC's definition of "up to date," please refer to the CDC's website[980] to confirm the current definition of "up to date." We note that this definition may change in the future as new updated versions of the vaccine are created and recommended. Based on clinical recommendations and systemic reviews, there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[981] [982] [983] While this measure does not meet the definition of a fully developed measure as outlined in the Measures Management System (MMS),[984] MIPS currently includes several quality measures that assess for vaccine administration, which have been implemented for multiple years.[985] We request interested parties consider whether the measure is "beyond the measure concept phase of development and [has] started testing, at a minimum, with strong encouragement and preference for measures that have completed or are near completion of reliability and validity testing" when submitting a quality measure for possible inclusion (83 FR 53636; 84 FR 62954). While we take under consideration whether a measure is fully tested, it is not the only relevant standard for MIPS. Nevertheless, this consideration reinforces the importance of all clinicians actively addressing vaccination against the COVID-19 virus. According to the World Health Organization (WHO), getting vaccinated is one of the most important steps an individual can take to not only to protect oneself, but to help end the pandemic and stop the emergence of new variants.[986] The PRMR Clinician Recommendation Committee did not reach consensus on this measure for rulemaking, expressing concerns about data collection for vaccines administered through off-site locations (for example, pharmacies), as well as vaccine hesitancy that may vary across geography, political affiliation, ethnicity, and income. The committee considered the measure's importance to patients, with emphasis on those at higher risk for complications from COVID-19. ACIP recommendations support the measure, all of which are evidence-based.[987] This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CDC COVID-19 Immunization Schedule, based on ACIP recommendations, can be referenced at the following webpage: *https://www.cdc.gov/vaccines/hcp/imz-schedules/index.html*. Clinical recommendations are in universal agreement that COVID-19 vaccines are safe, effective, and may prevent costly and harmful hospitalizations. The MIPS quality measure set includes several vaccine administration quality measures that have been implemented for several years; however, such measures do not include the COVID-19 vaccination.[988] This measure could also be considered for potential inclusion in the Primary Care MVP as it will fill a current quality measure inventory gap within the vaccination clinical topic for primary care settings. This measure, along with other activities, are a part of a larger Federal effort to promote and track vaccine uptake.[989] Since vaccine uptake is partially driven by patients requesting the vaccine followed by clinicians administering it to eligible patients, the patient/clinician relationship is a vital aspect for ensuring patients are vaccinated. This clinician-level measure will provide useful information regarding the success of vaccination efforts at the point of care, and, again, represents a priority topic to engage clinicians in quality improvements that drive positive health outcomes for their patients. We acknowledged this measure may not be selected by all clinicians, but this factor aligns with MIPS providing clinician choice in choosing quality measures that best represent their scope of care. Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination. As with all quality measures within MIPS, we continue to monitor all updates to the clinical recommendations and guidelines and address changes as needed utilizing the current annual revision cycle.

Category	Description
	Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Adult COVID-19 Vaccination Status measure. One commenter stated this measure will continue to build resilience for the next PHE. Data has proven to be critical for public health nurses and the entire nursing workforce when responding to rapidly evolving infectious diseases. The commenter was committed to utilizing vaccines to eliminate preventable diseases and urging all individuals to receive vaccines in accordance with the best and most current evidence. Another commenter agreed this measure fills a critical measurement gap in MIPS and can serve to support COVID-19 vaccination in all adult populations. An additional commenter supported CMS' efforts to increase adult vaccination rates while filling an important measurement gap in MIPS and including this measure in various specialty sets.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter encouraged CMS to clarify the measure numerator as to whether a patient is up to date on his or her COVID-19 vaccinations as defined by the CDC. Because this definition may change throughout the performance year, the commenter stated it is inappropriate to hold physicians accountable for COVID-19 vaccination rates when the recommendations keep changing. The commenter indicated no other measure within MIPS relies on clinical recommendations that are known to change frequently, which increases complexity and could negatively impact the reliability and validity of the measure. It is also

[975] CDC. (2024). COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services. https://covid.cdc.gov/covid-data-tracker.
[976] Ahmad, F.B., Cisewski, J.A., Anderson, R.N. (2022). Provisional Mortality Data — United States, 2021. MMWR Morb Mortal Wkly Rep 71,597-600. http://dx.doi.org/10.15585/mmwr.mm7117e1.
[977] CDC. (2024). Vaccination Trends – Children. https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html?CDC_AAref_Val=https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-children.html.
[978] CDC. (2024). Vaccination Trends – Adults. https://www.cdc.gov/respiratory-viruses/data/vaccination-trends.html?CDC_AAref_Val=https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults.html.
[979] Centers for Disease Control and Prevention (CDC). (2023). Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons ages ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States. https://www.cdc.gov/mmwr/volumes/72/wr/mm7242e1.htm.
[980] CDC. (2024). Stay Up to Date with COVID-19 Vaccines. https://www.cdc.gov/covid/vaccines/stay-up-to-date.html?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.
[981] Fitzpatrick, M. C., Moghadas, S. M., Pandey, A., & Galvani, A. P. (2022). Two Years of US COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths. To the Point (blog), Commonwealth Fund. December 13. https://doi.org/10.26099/whsf-fp90.
[982] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W., Jr, Hammitt, L. L., Türeci, Ö., … C4591001 Clinical Trial Group. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. The New England Journal of Medicine, 383(27), 2603–2615. https://doi.org/10.1056/NEJMoa2034577.
[983] Graña, C., Ghosn, L., Evrenoglou, T., Jarde, A., Minozzi, S., ... & Boutron, I. (2022). Efficacy and Safety of COVID-19 Vaccines. Cochrane Database of Systematic Reviews, 2023(3). https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015477/full.
[984] CMS. (2023). Measure Implementation – Measure Selection. https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection.
[985] See 2024 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.
[986] World Health Organization. (2021, July). Vaccine Efficacy, Effectiveness and Protection. https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection.
[987] CDC. (2023, December 12). Vaccine Recommendations and Guidelines of the ACIP: COVID-19 ACIP Vaccine Recommendations. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.
[988] See 2024 MIPS Quality Measures List: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.
[989] Department of Health & Human Services. Vaccines Federal Implementation Plan for the United States: 2021-2025. https://www.hhs.gov/sites/default/files/vaccines-federal-implementation-plan-2021-2025.pdf.

difficult to track this measure because a large percentage of patients do not receive their COVID-19 vaccinations from their primary care clinician.

A second commenter stated that measurement programs, particularly MIPS, include static measures, making it impossible to modify a measure once new evidence becomes available. Although the numerator defines "up to date" as determined by the CDC recommendations, this definition cannot account for changing recommendations nor the patient's willingness to get a booster, which was the CDC's recommendation for the fall of 2023/winter of 2024.

Response: We recognize the COVID-19 PHE was an unprecedented event that contributed to the frequency of recent vaccine guideline changes necessary for supporting public health. The measure therefore holds a clinician accountable for the most current guidelines on the date of the denominator eligible encounter. The measure does not judge clinicians by standards that are not known to the clinician and not applicable at the time of the encounter.

While we appreciate the commenter's preference for static guidelines during the performance year—and we have not traditionally adopted measures specified in this manner—the proposed approach is necessary for the creation of a COVID-19 vaccination measure to ensure all clinicians are held accountable for the care recommended at the time of the encounter. The measure's specifications were revised during the 2023 Annual Call for MIPS Quality Measures in response to the 2022 MAP feedback to track to the most current CDC guidelines. We understand COVID-19 vaccination guidelines have changed and may continue to change. Specifying the measure by referring to "up to date" guidelines ensures the measure remains current and valid despite future guidelines updates.

The measure, like all MIPS measures, will undergo an annual maintenance process to ensure alignment with the most current evidence; guidelines, if they have changed in a way that requires the measure to be respecified; and clinical practices around COVID-19 vaccination. The measure may also undergo additional reliability and validity testing as determined necessary. The measure accepts patient self-reports of vaccine receipt, particularly since many COVID-19 vaccinations are administered outside of clinician offices. Current vaccination status can also often be determined through accessing the jurisdiction's Immunization Information System.

Comment: Several commenters noted regional variation in vaccine hesitancy. The lack of exclusion for patient choice and the ability of clinicians to choose which measures to report in MIPS may lead to skewed results and data that is not reflective of performance as only clinicians with high vaccination rates in their patient population will choose to report the measure. One commenter requested that CMS consider an exclusion criterion to address patient refusal and ensure appropriate benchmarks for the measure so that clinicians are not unfairly penalized for factors outside their control. Another commenter noted while it is the primary care physician's responsibility to combat misinformation from social media, a physician cannot force a patient to get the vaccine.

Response: MIPS provides clinician choice in which measures clinicians select to report. This ensures clinicians choose measures that are most meaningful to their scope of care and clinical practice. Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination. As discussed in the proposal, clinical evidence supports widespread vaccination to prevent a severe COVID-19 infection. The measure encourages clinicians to explore relationships with their patients, which is important for ensuring patients are vaccinated and providing useful information about the success of vaccination efforts at the point of care. While research related to COVID-19 vaccination hesitancy is still needed, existing evidence indicates that clinician counseling can lead to vaccination uptake by vaccine-hesitant patients.[990] [991] [992] Excluding patients who refuse the vaccine would conflict with the measure's purpose of incentivizing clinicians to educate and encourage their patients to get vaccinated. Additionally, this approach aligns with other current MIPS quality measures assessing vaccination administration.

Comment: One commenter highlighted the well-documented vaccine hesitancy throughout the U.S., particularly among communities of color and in rural areas. Another commenter requested that the measure be risk-adjusted to account for the geographic and racial/ethnic disparities, or it will lead to misclassifications of a clinician's performance. The commenter stated that COVID-19 vaccination statistics from CDC in 2022 show that only eight States with 25 percent or higher of residents have proper vaccination. If a State with extremely low COVID-19 vaccination rates improves, its score would still reflect poorly compared to the national mean score.

Response: Currently, due to evolving evidence related to vaccination uptake by subpopulations, we have not included measure stratifications or risk-adjustments. However, we may consider stratifying or risk-adjusting future versions of the measure by race

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[990] Shay, L. A., Baldwin, A. S., Betts, A. C., Marks, E. G., Higashi, R. T., Street, R. L., Jr, Persaud, D., & Tiro, J. A. (2018). Parent-Provider Communication of HPV Vaccine Hesitancy. *Pediatrics*, *141*(6), e20172312. https://doi.org/10.1542/peds.2017-2312.

[991] Lu, P. J., Srivastav, A., Amaya, A., Dever, J. A., Roycroft, J., Kurtz, M. S., O'Halloran, A., & Williams, W. W. (2018). Association of Provider Recommendation and Offer and Influenza Vaccination Among Adults Aged ≥18 Years - United States. *Vaccine*, *36*(6), 890–898. https://doi.org/10.1016/j.vaccine.2017.12.016.

[992] Gilkey, M. B., Calo, W. A., Moss, J. L., Shah, P. D., Marciniak, M. W., & Brewer, N. T. (2016). Provider Communication and HPV Vaccination: The Impact of Recommendation Quality. *Vaccine*, *34*(9), 1187–1192. https://doi.org/10.1016/j.vaccine.2016.01.023.

and ethnicity, age, and/or other risk factors to account for and allow clinicians to monitor different subpopulations. While risk-adjustment is not a MIPS quality measurement requirement, clinicians may stratify results within their own patient population to identify trends and targeting subpopulations of need. The measure may provide an opportunity for clinicians to address health disparities and equity issues by monitoring trends and intervening to improve care opportunities for at-risk subpopulations. This is an important assessment and drives quality outcomes for community and population health, making this measure appropriate for inclusion within MIPS. However, clinicians can select which MIPS quality measures to report and determine if the measure is the most meaningful to their practice.

Comment: Several commenters expressed concerns about the lack of measure testing and validation of the measure. One commenter stated the measure has not established validity, reliability, and risk adjustments at the individual clinician level, and consequently, any assessment of data for this measure at the individual clinician level would produce invalid and unreliable results. Until testing of the measure with precise specifications is completed, the commenters stated this measure should not be implemented in MIPS.

Response: The measure did undergo testing and validation. Clinician-level measure score reliability was assessed using a signal-to-noise approach. Measure reliability was high for the measure, with a median clinician-level reliability of 0.99, indicating the measure can be used to identify meaningful differences in performance among clinicians. Face validity is also sufficient as this is a new MIPS measure (*https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity*). Fifty percent of clinicians agreed that better performance on the measure indicates that a clinician is providing better care. As discussed in the response to the preceding comment, MIPS measures need not be risk adjusted.

Comment: Several commenters stated this measure was not supported by the MAP in 2022 and during the most recent review by the PRMR Clinician Committee, the measure did not achieve consensus on a recommendation.

Response: We acknowledge the measure was not supported by the MAP and did not reach consensus on a recommendation by the PRMR; however, we are not limited to adopting only such recommended measures. Section 1890A(a)(2) and (4) of the Act requires that we publish a list of measures we are considering for Medicare and take into consideration input on the measures from specified multi-stakeholder groups. Here, we have taken into consideration the 2022 MAP feedback by revising the measure specifications for the 2023 Annual Call for MIPS Quality Measures. As discussed in the proposal, the MAP advised that the measure allow for up to date vaccination with the most current CDC guidelines. We included this advice, as well as other MAP recommendations, into the revised measure specifications. Measures considered in the PRMR process have been tested and undergone evaluation for impact and scientific evidence.

Comment: One commenter noted that all the proposed new quality measures are MIPS CQM collection type only and relevant to a small number of specialist clinicians. The commenter cited CMS' Digital Quality Measurement Strategic Roadmap and its work with measure stewards to encourage development of new eCQMs (*https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*). However, CMS, as the measure steward, has not proposed the measure as an eCQM. Due to retirement of eCQMs that are now part of the comprehensive Q493: Adult Immunization Status measure (that is not available as an eCQM), the commenter questioned whether the Adult COVID-19 Vaccination Status measure should be included into measure Q493 rather than staying as a separate measure.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, MIPS CQMs are considered dQMs under the current definition. Separately, we note that the Call for Measures does not currently require that each submitted measure include the eCQM collection type. For this measure, we opted to develop a MIPS CQM instead of an eCQM to allow for greater flexibility in measure development and respecification, if necessary, given the rapidly evolving COVID-19 PHE and given the narrative form of the CQM specification versus the more intensive coding and logic of an eCQM. Development of an eCQM would have taken substantially more time and effort, and we wanted a measure sooner to meet the Measures Under Consideration (MUC) List deadline and follow the appropriate rulemaking process. This faster timeline also did not allow for collaboration on potential incorporation of a COVID-19 vaccination rate in measure Q493, which is stewarded by NCQA and not CMS. We encourage the commenter to reach out to NCQA to discuss revisions to measure Q493 for possible implementation in future years. We are open to considering future updates to measure Q493 to include a COVID-19 vaccination rate.

Comment: One commenter expressed concern about the feasibility of implementing the measure. The commenter indicated that many electronic health records (EHRs) do not have discrete fields or options for each of the vaccine manufacturers. As the required vaccination course varies based on whether a patient received a single- or two-dose regimen for their initial vaccination course, it would be difficult to determine if a patient is up to date. The commenter recommended CMS use one of the following strategies to allow this measure to be accurately operationalized: ensure EHR systems are capable of recording the specific COVID-19 vaccination product administered prior to finalizing this measure; allow patient attestations for recipients of the original COVID-19 vaccine series as sufficient data; or focus the measure's requirements only on vaccine doses given subsequent to the original series.

Response: We clarify that the measure accepts patient self-reports of vaccine receipt. We determined this measure is feasible and implementable in MIPS as a MIPS CQM collection type, which allows for the utilization of a variety of data sources to collect the measure information and can include EHR discrete data fields where available or alternate mapping methodologies that align with the measure specification. It is at the clinician's discretion to choose this measure based upon its appropriateness to their

scope of care and case-mix, and the ability to integrate within their current workflows and systems as specified. Feasibility testing indicated that test sites were able to capture data needed to report the measure and registries can support submission to MIPS; therefore, it is feasible to report the measure utilizing the MIPS CQM collection type.

Comment: One commenter agreed with the intent of the measure but stated it may not be "attributable" to specialists as many do not have the COVID-19 inventory to administer the vaccine, which will impact their compliance with the measure. Although specialists will advise their patients to update their vaccination status, they may not receive notifications or follow-up reminders to complete this update.

Response: No clinician is required to report this measure. Clinicians, including specialists, have the choice to select which measures they report. This ensures clinicians choose measures that are most meaningful to their scope of care and clinical practice.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62259 through 62261), we are finalizing the *Adult COVID-19 Vaccination Status* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

A.6. Melanoma: Tracking and Evaluation of Recurrence

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	509
Description:	Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years in which the operating clinician examines and/or diagnoses the patient for recurrence of melanoma.
Measure Steward:	American Academy of Dermatology
Numerator:	NUMERATOR CRITERIA 1: Documentation by the clinician who performed the surgery that an exam for recurrence of melanoma was performed on the patient within the performance period. NUMERATOR CRITERIA 2: All patients that were diagnosed with a recurrent melanoma in the current performance period.
Denominator:	DENOMINATOR CRITERIA 1 & 2: All patients that the clinician has performed a type of excisional surgery for melanoma or melanoma in situ in the past 5 years with an initial AJCC staging of 0, I, or II.
Exclusions:	Patients who died during the performance period
Measure Type:	Process
High Priority Measure:	Yes
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure

Category	Description
Rationale:	We proposed this measure because it evaluates the frequency and type of recurrence for melanoma after an excisional procedure, in addition to driving communication regarding the recurrence status of melanoma patients. Additionally, the measure addresses a CMS high priority process measure for care coordination on the clinical topic as miscommunication between the excising clinician and the clinician continuing care has been identified as a gap. This measure allows for and promotes the development of a system in which melanomas can be accurately tracked to increase the effectiveness of understanding melanoma recurrence and follow-up care. Melanoma recurrence requires precise evaluation. As indicated by one study, patients who have undergone treatment of primary melanoma, early detection of a local recurrence has important implications. An isolated local recurrence in a patient with favorable features can be treated with repeat wide local excision, with good oncologic outcomes. For these patients, long-term prognosis is not adversely affected by the local recurrence if it is detected and treated early, and 5-year survival continues to be a function of primary tumor thickness.[993] [994] [995] [996] Regular clinical examination offers the highest diagnostic yield in detecting melanoma recurrences.[997] Common follow-up recommendations for all patients indicate the follow-up schedule is influenced by risk of recurrence, prior primary melanoma, and family history of melanoma. It also includes other factors such as atypical moles/dysplastic nevi.[998] For patients who present with stage I-II melanoma and are rendered free of disease after initial treatment, recurrence rates are distributed as follows: approximately 15 to 20 percent are local or in transit.[999] Data suggests the time between the risk of recurrence to reach its low plateau depends on the stage of disease at first presentation.[1000] In a retrospective study of patients who initially presented with stage I melanoma (N = 1568), 80 percent of the 293 recurrences developed within the first 3 years, but some recurrences (<8 percent) were detected 5 to 10 years after the initial treatment.[1001] A prospective study found that for patients with stage I or II at initial presentation, the risk of recurrence reached a low level by 4.4 years after initial diagnosis.[1002] Therefore, we proposed this measure to incentivize clinicians who treat patients with melanoma to perform these potentially lifesaving exams. The PRMR Clinician Recommendation Committee did not reach consensus in recommending the measure for inclusion in MIPS. The committee agreed with the importance of the measure's intent. There was significant concern raised about the burden of tracking and reporting, reliability of the measure and interpretation of testing results, and the impact of lower reliability on clinician compensation. However, the measure was fully tested at the clinician level and has been determined to be implementable in MIPS. The measure has been available for MIPS reporting as a QCDR measure since 2022, which attests to its feasibility as no implementation issues have been identified. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. This measure aligns with National Comprehensive Cancer Network (NCCN) guidelines. This measure fills a gap in MIPS within the dermatologic clinical topic, as there are no other dermatology measures related to the outcome of melanoma recurrence. This more robust outcome measure will replace current structure measure Q137: Melanoma: Continuity of Care as indicated in Table C.2 of this Appendix. While the MIPS Dermatology specialty set includes 13 measures, only 6 are specialty specific. This measure is relevant to specialty clinicians and will provide a new measure option for a specialty area that currently encompasses many topped-out measures, while also potentially aiding in the development of a meaningful MVP. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2024-02/PRMR-Final-MUC-Recommendation-Spreadsheet%20%283%29.xlsx*.

[993] Rueth, N. M., Cromwell, K. D., & Cormier, J. N. (2015). Long-term Follow-up for Melanoma Patients: Is There Any Evidence of a Benefit? Surgical Oncology Clinics of North America, 24(2), 359–377. https://doi.org/10.1016/j.soc.2014.12.012.

[994] Benvenuto-Andrade, C., Oseitutu, A., Agero, A. L., & Marghoob, A. A. (2005). Cutaneous Melanoma: Surveillance of Patients for Recurrence and New Primary Melanomas. *Dermatologic Therapy*, *18*(6), 423–435. https://doi.org/10.1111/j.1529-8019.2005.00049.x.

[995] Garbe, C., Paul, A., Kohler-Späth, H., Ellwanger, U., Stroebel, W., Schwarz, M., Schlagenhauff, B., Meier, F., Schittek, B., Blaheta, H. J., Blum, A., & Rassner, G. (2003). Prospective Evaluation of a Follow-up Schedule in Cutaneous Melanoma Patients: Recommendations for an Effective Follow-up Strategy. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, *21*(3), 520–529. https://doi.org/10.1200/JCO.2003.01.091.

[996] Rhodes A. R. (2006). Cutaneous Melanoma and Intervention Strategies to Reduce Tumor-related Mortality: What we know, what we don't know, and what we think we know that isn't so. *Dermatologic Therapy*, *19*(1), 50–69. https://doi.org/10.1111/j.1529-8019.2005.00056.x.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of the Melanoma: Tracking and Evaluation of Recurrence measure.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter did not support the addition of the new melanoma measure. The commenter indicated this new measure would replace measure Q137: Melanoma: Continuity of Care – Recall System, which the commenter believed provides "an effective and comprehensive system for tracking the follow-up of patients with a history of melanoma." The commenter noted the proposed measure does not include exclusions for other scenarios in which a clinician may be unable to conduct follow-up, such as patients who relocate, begin care with a different dermatologist, exhibit noncompliance, or enter hospice care.

Response: We thank the commenter for their feedback. The intent of this measure overlaps with measure Q137, leading to the positive outcome of determining recurrence in a timely manner. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive better quality of care provided and continue to drive quality, which is achieved by offering measures with more robust evaluation methods. This measure is more robust because it requires a quality action of documentation that a follow up exam was completed. We recognize this measure represents an important component in early identification of recurrence for melanoma that will drive timely and appropriate care. We also recognize that due to nuances in clinician specialization, scope of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter, in opposing the removal of measure Q137 under Table C.2 of this Appendix, stated this new measure would require practices to conduct a retrospective review of records spanning 5 years, specifically identifying cases of melanoma and melanoma *in situ* with completed excisions and appropriate grading. According to the commenter, this requirement would impose a substantial burden on smaller practices, which may lack the necessary time, resources, and infrastructure to fulfill this obligation. According to the commenter, the process of running standard reports to identify melanoma cases based on diagnosis codes is "far more feasible and practical for these practices, ensuring that patients continue to receive timely and appropriate follow-up care." Another commenter indicated the proposed measure lacked sufficient detail concerning the timing of the initial melanoma surgery and the subsequent follow-up period.

Response: We thank the commenters for their feedback. We recognize that due to nuances in clinician specialization, scope of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty, so smaller practices may not choose this measure. We acknowledge this measure may require the review of additional information for clinicians to successfully report it. This is inextricably part of the adoption of a more robust measure that we think better evaluates care than measure Q137. For practices that do elect to participate in this measure, coding within the measure specification will allow clinicians to map their system to identify the appropriate patient population which includes patients with an excisional surgery for melanoma or melanoma *in situ* in the past 5 years with an initial AJCC Staging of 0, I, or II. Removal of measure Q137 does not preclude clinicians from continued use of a recall system which enables providers to ensure that patients receive follow-up appointments in accordance with their individual needs.

Comment: One commenter was concerned about the implications of the proposed measure on patients who undergo melanoma evaluations but do not have excisional surgeries. By specifically identifying the "operating clinician," the measure excludes general dermatologists who often refer out for melanoma excisions, particularly for surgeries on sensitive areas such as the face or neck. In such cases, the operating clinician may not be responsible for ongoing follow-up, which is typically conducted by the referring dermatologist. This division of responsibilities is common even in larger practices, where surgeons perform excisions, and general dermatologists manage follow-up care. The proposed measure, as currently drafted, would limit the scope of patients and clinicians being evaluated for performance, leading to incomplete and potentially misleading assessments of care quality. The commenter urged CMS to reconsider the proposed changes and work with the dermatology community to develop a more feasible and inclusive measure that accurately reflects the realities of melanoma care.

Similarly, a second commenter expressed concerns that the proposed measure does not reflect clinical practice. For example, in many cases, the surgeon who performed the procedure may not be available for subsequent follow-ups, or the patient may have

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[997] See footnote Rueth et al., 2015.
[998] Trotter, S. C., Sroa, N., Winkelmann, R. R., Olencki, T., & Bechtel, M. (2013). A Global Review of Melanoma Follow-up Guidelines. *The Journal of Clinical and Aesthetic Dermatology*, *6*(9), 18–26.
[999] See footnote Trotter et al., 2013.
[1000] See footnote Trotter et al., 2013.
[1001] See footnote Trotter et al., 2013.
[1002] NCCN. NCCN Guidelines – Melanoma: Cutaneous. https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1492.

been referred to a specialist for the initial surgery. It is common practice for patients to return to their primary dermatologist for ongoing care.

Response: We acknowledge that in many cases the clinician who follows up with a patient who has had excisional surgery may not be the same clinician who performed the procedure. The measure does allow for the surgeon to utilize medical record documentation to determine numerator compliance and measure performance. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years that would specifically address general dermatologists who refer out for melanoma excisions.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62262 through 62264), we are finalizing the *Melanoma: Tracking and Evaluation of Recurrence* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

A.7. First Year Standardized Waitlist Ratio (FYSWR)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	510
Description:	The number of newly initiated patients on dialysis in a practitioner group who are under the age of 75 and were either listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1. Patients who initiated dialysis and had documentation of status at the end of the first year after initiating dialysis. Numerator 2. The ratio of the observed number of waitlist events in a practitioner group to the model-based expected number of waitlist events.
Denominator:	Denominator 1. Patients aged 75 years of age or less who have initiated dialysis during January 1st – December 31st of the previous performance period. Denominator 2. The denominator for the First Year Standardized Waitlist Ratio (FYSWR) is the total number of patients under the age of 75 in the practitioner group according to each patient's treatment history for patients within the first year following initiation of dialysis.
Exclusions:	Patients admitted to a skilled nursing facility (SNF). Patients in hospice on their initiation of dialysis date or during the month of evaluation. Patients that were on the kidney or kidney-pancreas waitlist prior to initiation of dialysis. Patients who had a transplant prior to initiation of dialysis.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients or 2 expected events, then the dialysis practitioner group is excluded from reporting outcomes.

Category	Description
Rationale:	This measure was originally proposed in the CY 2024 PFS proposed rule (88 FR 52771 through 52772) but was not finalized in the CY 2024 PFS final rule (88 FR 79565 through 88 FR 79566) due to implementation issues within MIPS regarding timing and application of the risk adjustment methodology. Additionally, we proposed this measure again because it addresses a CMS high priority clinical topic: patients with end-stage renal disease (ESRD). We indicated we will allow further refinement and streamlining of the measure analytic for future MIPS implementation. The measure and measure analytic have been revised to include two submission criteria, allowing for determination of data completeness and the full utilization of the risk-adjusted model in the second submission criterion to create a continuous variable analytic, assessing the ratio of observed to expected waitlist events. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[1003] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[1004] This measure assesses whether patients who are in their first year of dialysis, and are found to be an expected waitlist event based upon the Cox model, were placed on either the kidney or kidney-pancreas transplant waitlist or received a living donor kidney transplant. Data submitted by the measure developer indicates a performance gap for a process that can be directly linked to improved patient outcomes. This measure is separate from the other transplant waitlist measure, finalized under Table A.8 of this Appendix, as it is limited to assessing the first year after initiation of dialysis and the timely addition of those patients to the transplant waitlist—a crucial step in driving positive outcomes in the patient population. National and large regional studies provide strong empirical support for the association between processes within the clinical scope and control of dialysis practitioners followed by subsequent patient transplant wait listing. For example, the clinical assessments, provisions and/or referrals made by a dialysis practitioner are contributing factors for consideration in patient transplant wait listing. In one large regional study conducted on facilities in the State of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics, and comorbidities.[1005] There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant ($r=0.35$, $p<0.001$).[1006] A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation based on reporting on the Medical Evidence Form 2728 *(https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2728.pdf*) and subsequent access to kidney transplantation (wait listing or receipt of a live donor transplant).[1007] Approximately 30 percent of patients were uninformed about kidney transplantation, which was associated with half the rate of access to transplantation compared to patients who were informed.[1008] In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients.[1009] The provision of such information was associated with a near threefold increase in likelihood of wait listing.[1010] The intent of this measure is to track the initial placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant within the first year after dialysis initiation, with the objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant represents a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. Waitlisting is a direct step in the process of transplantation which drives quality by progressing patients towards the goal of transplantation and better health outcomes. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities, which may include providing education to patients about the option(s) of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis practitioner groups. Aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The PRMR (formerly the MAP), did not support this measure for rulemaking with the potential for mitigation to update the measure and address the concern from the Renal Standing Committee regarding the evidence base and specifications, and thus recommended this measure be resubmitted for endorsement by a CBE. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As discussed above, studies suggest a significant positive correlation between the clinician activities and the addition of patients to a transplant waitlist, which are necessary for patients to receive the improved outcomes associated with kidney transplant. Note: Refer to the 2022 MUC List-Final Recommendations to CMS and HHS at *https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fmmshub.cms.gov%2Fsites%2Fdefault%2Ffiles%2F2022-MUC-List.xlsx&wdOrigin=BROWSELINK*.

[1003] National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). (2023). Kidney Disease Statistics for the United States. https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.

[1004] Wouk N. (2021). End-Stage Renal Disease: Medical Management. *American Family Physician*, *104*(5), 493–499.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the First Year Standardized Waitlist Ratio (FYSWR) measure. A second commenter supported both waitlist measures under Tables A.7 and A.8 of this Appendix. Nephrology nurses are dedicated to their patients and to ending the disparities in transplant access for their patients with ESRD. The commenter supported addressing these disparities by collecting transplant waitlist data. The commenter indicated that CMS must work directly with nephrology nurses who have on the ground knowledge of these impacts on their patients. Data collection will be coming from these nurses but there must be follow up to collect their feedback on solutions or disparities will remain.

Another commenter strongly supported adding both waitlist measures and stated these measures will help payers understand if providers are connecting patients who have ESRD with the additional care and support they need to prepare for organ transplant. Measures are needed to understand if patients are being referred to transplantation and if they are being appropriately supported while they are on the waiting list for an organ. These measures could help ensure clinicians are working with patients to help them access transplant waitlists and if facilities are proactively reaching out to patients on the waitlist.

Response: We thank the commenters for supporting this new measure in MIPS and value the experience of all clinicians supporting patients. These measures were proposed for the MIPS CQM collection type, and data should be reported as outlined within the measure specification, however, the measure does not dictate workflow for data collection. We agree that continued dialogue is important to ensure high quality care and sustained meaningful implementation of quality measures. We encourage interested parties to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter supported this new measure and the measure under Table A.8 of this Appendix as an important quality measurement tool in the effort to ensure that all patients are evaluated and waitlisted in a timely fashion. Nephrologists play a significant role in referral to transplant centers, which is a necessary, but not a sufficient step in eventual waitlisting. The commenter stated that timely referral of every appropriate patient for transplant evaluation will result in more equitable access to the transplant waitlist and that nephrologists do have control over this initial referral and there should be accountability. Furthermore, these measures maintain consistency with other CMS programs including the ESRD Quality Incentive Program (*https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program*) and the ESRD Treatment Choices Model (*https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model)*. However, the commenter indicated that some aspects of waitlisting are out of a nephrologist's control. Transplant centers are variable in the rates at which they place patients on the waitlist. The ultimate decision to waitlist lies with the transplant center and transplant surgeon, not the nephrologist. The nephrologist often has little to no access to a transplant center's waitlist. These are all valid arguments, and the commenter recommended that performance on these measures be closely monitored so that physicians are not unfairly penalized for behavior of other individuals.

Response: We thank the commenter for supporting this new measure in MIPS. We acknowledge the commenter's concern and reaffirm that all MIPS measures are evaluated annually for performance and any updates that may be required to ensure the measure specification aligns with the measure's intent and current clinical guidelines. Additionally, while we acknowledge there are aspects of this measure that are not directly in the clinician/group's control, the outcome can be influenced through coordination of care, strong communication with transplant centers and advocacy for patients, and optimization of a patient's health and comorbid conditions.[1011] While determining transplantation candidacy is complex and multidisciplinary, the referring nephrologist remains cardinal to this process, as the most significant barrier to pre-emptive kidney transplantation is timely

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[1005] Paul, S., Plantinga, L. C., Pastan, S. O., Gander, J. C., Mohan, S., & Patzer, R. E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. Clinical Journal of the American Society of Nephrology, 13(2), 282-289. https://doi.org/10.2215/CJN.04690417.

[1006] See footnote Paul et al., 2018.

[1007] Kucirka, L. M., Grams, M. E., Balhara, K. S., Jaar, B. G., & Segev, D. L. (2012). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351-357. https://doi.org/10.1111/j.1600-6143.2011.03865.x.

[1008] See footnote Kucirka et al., 2012.

[1009] Salter, M. L., Orandi, B., McAdams-DeMarco, M. A., Law, A., Meoni, L. A., Jaar, B. G., ... & Segev, D. L. (2014). Patient-and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871-2877. https://doi.org/10.1681/ASN.2013121298.

[1010] See footnote Salter et al., 2014.

[1011] Moe, S. M., Brennan, D. C., Doshi, M. D., Gaston, R. S., Gurley, S. B., Mujtaba, M. A., Schmidt, R. J., Segal, M. S., Tucker, J. K., Wiseman, A. C., & Josephson, M. A. (2022). The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. *Clinical Journal of the American Society of Nephrology : CJASN*, *17*(9), 1403–1406. https://doi.org/10.2215/CJN.02000222.

referral to the transplantation program.[1012] It is incumbent on all caregivers responsible for the patient to work towards this goal.

Comment: One commenter recognized the critical importance of improving kidney transplantation rates, and that inequities exist among regions and patient populations. The commenter was concerned that the measures do not reflect patient-centered care as they do not account for patient choice. There is no exclusion from the denominators for patients who chose not to consider transplantation. Instead, the measures inappropriately assume all patients should be referred and waitlisted, regardless of the patients' wishes or their medical status.

A second commenter stated that the waitlist measures are largely outside of nephrologist's ability to influence as well as outside the scope of the dialysis facility's sphere of influence. While patients can be referred, being waitlisted is under the control of the transplant center. The commenter believed this measure does not appropriately address factors within a nephrologist's control – neither in the determination to waitlist by a transplant facility or to perform a living donor transplant as determined by a transplant surgeon.

Response: Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. There is a significant association between the clinician activities described in this measure and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved health outcomes associated with kidney transplant.[1013] As stated in the above rationale, aspects that are not directly in the clinician/groups control can be influenced through coordination of care, strong communication with transplant centers, and advocacy for patients. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. In regard to an exclusion for patients who chose not to consider transplantation, we recognize the decision to pursue kidney transplant as a kidney replacement modality is a multifaceted, individual decision; however, it is difficult to account for patient choice in the measure given the measure's construction and risk adjustment methodology. Based on the literature, we expect this to be a small number of patients that may be found across dialysis centers, thus affecting each at a similar rate and this is an area of great interest for future work.[1014]

Comment: Two commenters were concerned about the lack of CBE endorsement for this measure. One commenter indicated this measure was not endorsed by the CBE Renal Standing Committee during the Spring 2022 measure cycle, citing concerns regarding exclusions and attribution. In particular, the Renal Standing Committee raised concerns about how the measure developer identified the physician caring for the patient. The CBE Consensus Standards Approval Committee (CSAC) upheld the decisions of the Renal Standing Committee during their review and voted not to reconsider this measure during the appeals process. Therefore, the commenters stated this measure is not appropriate for inclusion in MIPS.

Response: While we agree CBE endorsement is preferred, this measure should nonetheless be added to MIPS as it meets the statutory standard for inclusion as a non-endorsed measure Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities and may include education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. There is a significant association between the clinician activities described in this measure and the addition of patients to a transplant waitlist, which is necessary for patients to receive the improved health outcomes associated with kidney transplant.[1015] Inclusion of this measure in MIPS also aligns with the ESRD Quality Incentive Program as indicated in a prior response.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62264 through 62266), we are finalizing the *First Year Standardized Waitlist Ratio (FYSWR)* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1012] Virmani, S., & Asch, W. S. (2020). The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020. *American Journal of Kidney Diseases: The Official Journal of the National Kidney Foundation*, *76*(4), 567–579. https://doi.org/10.1053/j.ajkd.2020.01.001.

[1013] See footnote Salter et al., 2014.

[1014] Lentine, K. L., Smith, J. M., Miller, J. M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D. K., Temple, K., Israni, A. K., & Snyder, J. J. (2023). OPTN/SRTR 2021 Annual Data Report: Kidney. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *23*(2 Suppl 1), S21–S120. https://doi.org/10.1016/j.ajt.2023.02.004.

[1015] See footnote Salter et al., 2014.

A.8. Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	511
Description:	The measure tracks dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). This measure is a risk-adjusted percentage of waitlist events among dialysis patients**.**
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Numerator 1: Percentage of Prevalent Patients Waitlisted (PPPW): Patients in the practitioner group's denominator with observed months on the waitlist for each month. Numerator 2: Percentage of Prevalent Patients Waitlisted in Active (aPPPW): Patients in the practitioner group's denominator with observed months on the waitlist in active status for each month.
Denominator:	Denominator 1 and 2: All risk-adjusted patient-months for patients who are under the age of 75 in the reporting month and who are assigned to a dialysis practitioner or practitioner group practice according to each patient's treatment history on the last day of each reporting month during the performance year.
Exclusions:	Patients who were admitted to a skilled nursing facility (SNF) during the month of evaluation were excluded from that month. Patients who were admitted to a skilled nursing facility (SNF) within one year of dialysis initiation according to the CMS-2728 form. Patients determined to be in hospice were excluded from month of evaluation and the remainder of reporting period. Patients with dementia at any time prior to or during the month.
Measure Type:	Process
High Priority Measure:	No
Collection Type:	MIPS CQM Specifications
Measure-Specific Case Minimum/Performance Period:	If a dialysis practitioner group has fewer than 11 patients during the performance year, the dialysis practitioner group is excluded from reporting outcomes.

Category	Description
Rationale:	This measure was originally proposed in the CY 2024 PFS proposed rule (88 FR 52773 through 52774) but was not finalized in the CY 2024 PFS final rule (88 FR 79567 through 79568) due to implementation issues within MIPS regarding timing and application of the risk adjustment methodology. Additionally, we proposed this measure again because it addresses a CMS high priority clinical topic: patients with ESRD. We indicated we will allow further refinement and streamlining of the measure analytic for future MIPS implementation. The measure, including component calculations, was revised to allow for a proportional analytic to be used for the purposes of determining measure performance, while still incorporating the risk-adjusted model to ensure the appropriate denominator eligible patient population for numerator assessment. ESRD affects nearly 786,000 Americans, and dialysis for ESRD patients represents a significant portion of annual Medicare expenditures.[1016] While dialysis is a treatment for ESRD, it is associated with increased mortality and lower quality of life for ESRD patients when compared to kidney transplant.[1017] This measure will capture the adjusted count of patient months on the kidney and kidney-pancreas transplant waitlists for all dialysis patients in a dialysis practitioner or group practice by assessing patient status on the last day of each month during the reporting year, and those on the transplant waitlist in active status as of the last day of the month during the reporting year. This process measure is directly linked to driving positive outcomes and measure data indicates a performance gap. Most ESRD patients have to wait for access to a deceased donor transplant, with the national median being roughly 4 years.[1018] Maintenance of 'active status' on the transplant list requires ongoing collaboration between dialysis practitioners, transplant centers, and transplant networks, thereby ensuring sustained suitability for a transplant while optimizing the health of patients.[1019] This maintenance process is associated with higher transplantation rates and lowered mortality rates while on the waitlist.[1020] Additionally, the maintenance of 'active status' is an important health equity issue. Research has found disparities in access to kidney transplant by race.[1021] Race-neutral efforts by clinicians to encourage maintenance of patients on the waitlist may reduce such disparities while improving their performance on this measure.[1022] This measure and the finalized measure under Table A.7, the First Year Standardized Waitlist Ratio measure, work in tandem to assess initial and on-going care. This measure will assess monthly wait listing in active status of patients. It also will evaluate and encourage maintenance of patients on the waitlist. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. In contrast to this measure, the First Year Standardized Waitlist Ratio measure will focus solely on new wait listings and living donor kidney transplants to incentivize early action, rather than ongoing maintenance on the waitlist, which this measure assesses. The PRMR conditionally supported this measure for rulemaking pending an update of the measure's specifications to include only the PPPW (CBE 3695) rate that was recommended for endorsement by the CBE's Renal Standing Committee. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. The CBE recommended endorsement for the PPPW subset of this measure. It is important to include the aPPPW rate in this measure as well to capture patients in active waitlist status, and the full scope of the transplant list with movement of patients between active and inactive status. The studies cited above provide the evidentiary basis for the adoption of this measure. After review, it was determined that the testing provided by the measure steward demonstrated statistically sufficient results for the reliability and validity of each of the numerator actions, meeting requirements described within the CMS MMS Hub (*https://mmshub.cms.gov/*) regarding quality measure testing. Note: Refer to the 2022 MUC List-Final Recommendations to CMS and HHS at *https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fmmshub.cms.gov%2Fsites%2Fdefault%2Ffiles%2F2022-MUC-List.xlsx&wdOrigin=BROWSELINK*.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

[1016] See footnote NIDDK, 2023.
[1017] See footnote Wouk, 2021.
[1018] Johansen, K. L., Chertow, G. M., Foley, R. N., Gilbertson, D. T., Herzog, C. A., Ishani, A., ... & Wetmore, J. B. (2021). US Renal Data System 2020 Annual Data Report: Epidemiology of Kidney Disease in the United States. American Journal of Kidney Diseases, 77(4), A7-A8. https://www.ajkd.org/article/S0272-6386(21)00024-X/fulltext.
[1019] Grams, M. E., Massie, A. B., Schold, J. D., Chen, B. P., & Segev, D. L. (2013). Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. American Journal of Transplantation, 13(4), 1012-1018. https://onlinelibrary.wiley.com/doi/pdf/10.1111/ajt.12143.
[1020] See footnote Grams et al., 2013.
[1021] Kulkarni, S., Ladin, K., Haakinson, D., Greene, E., Li, L., & Deng, Y. (2019). Association of Racial Disparities with Access to Kidney Transplant after the Implementation of the New Kidney Allocation System. JAMA Surgery, 154(7), 618-625. https://jamanetwork.com/journals/jamasurgery/fullarticle/2729436.
[1022] See footnote Kulkarni et al., 2019.

Comment: Several commenters supported the proposed addition of the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure. As mentioned above under Table A.7, one commenter noted nephrology nurses are dedicated to their patients and to ending the disparities in transplant access for their patients with ESRD. The commenter supported addressing these disparities by collecting transplant waitlist data. The commenter indicated that CMS must work directly with nephrology nurses who have on the ground knowledge of these impacts on their patients. Data collection will be coming from these nurses but there must be follow up to collect their feedback on solutions or disparities will remain.

Another commenter strongly supported adding both waitlist measures and stated these measures will help payers understand if providers are connecting patients who have ESRD with the additional care and support they need to prepare for organ transplant. Measures are needed to understand if patients are being referred to transplantation and if they are being appropriately supported while they are on the waiting list for an organ. These measures could help ensure clinicians are working with patients to help them access transplant waitlists and if facilities are proactively reaching out to patients on the waitlist.

Response: We thank the commenters for supporting this new measure in MIPS and value the experience of all clinicians supporting patients who have ESRD, such as nephrology nurses. These measures were proposed for the MIPS CQM collection type, and data should be reported as outlined within the measure specification, however, the measure does not dictate workflow for data collection. We agree that continued dialogue is important to ensure high quality care and sustained meaningful implementation of quality measures. We encourage interested parties to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter indicated this measure was previously two separate measures: Percentage of Prevalent Patients Waitlisted (PPPW), which received CBE endorsement in Spring 2022, and the Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW), which was not endorsed by the CBE Renal Standing Committee during the Spring 2022 measure cycle. A second commenter was concerned this measure was only conditionally supported by the PRMR. Concerns with the testing data, which showed extreme variation in the transplant center practice, are real and foster disparities among potential transplant candidates. The commenter stated that these measures make it even harder for smaller transplant programs to risk listing more complicated patients. The commenter was concerned that the two waitlist measures have been combined with no evidence of review or testing as a composite measure for feasibility and validity, and therefore, it is inappropriate to include this measure in MIPS. Another commenter stated there is substantial variability in listing rates among transplant centers, with standardized waitlisting rates differing widely, which further undermines the validity of this measure.

Response: While we agree CBE endorsement is preferred, this measure should nonetheless be added to MIPS, as it meets the statutory standard for inclusion as a non-endorsed measure because it has a focus that is evidenced-based. Section 1848(q)(2)(D)(v) of the Act requires, in relevant part, that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidenced-based. As stated above, this measure is in part CBE endorsed (the PPPW (CBE 3695)) and this rate was recommended for endorsement by the CBE's Renal Standing Committee. The testing provided by the measure steward was reviewed and demonstrated statistically sufficient results for the reliability and validity of each of the numerator actions, meeting requirements described within the CMS MMS Hub (*mmshub.cms.gov*) regarding quality measure testing. This measure also demonstrated feasibility through data elements being generated via the care process and being electronically available. The measure will utilize two submission criteria to assess performance across dialysis clinician groups, creating a robust quality measure driving positive outcomes for ESRD patients. Additionally, this measure utilizes a risk adjustment model so that clinicians are not unfairly penalized for listing more complex patients.

Comment: One commenter stated that nephrologists play a crucial role in referring patients for transplantation; however, they have no influence over the selection process for waitlisting. Most nephrologists are unable to access and navigate the transplant center's waitlist even for patients they referred. Furthermore, it is unfair to tie physician practices success to a patient's active status when they lack any control or input regarding a patient's status as active or inactive, as reflected in the proposed Increasing Organ Transplant Access Model (*https://www.cms.gov/priorities/innovation/innovation-models/iota*) and organ offer metrics. The commenter stated that active or inactive status is completely controlled by the transplant center – not the practicing nephrologist. The commenter indicated that both waitlist measures in their current proposed forms underscore the need for measures that align incentives across the entire continuum of care. The commenter believed the current proposed measures fall short of achieving this alignment. The commenter urged CMS to implement measures that more accurately reflect the role of nephrologists in the transplantation process and promote high-quality care for patients. Another commenter did not support the waitlist measures as written, as they imply that the nephrologist can control both the management of the active wait list, and the movement to and from active status by the transplant team. In reality, transplant facilities have their own metrics and decision algorithms, which are not public, transparent, or harmonized. The nephrologist does not control the transplant team's decision to place a patient on the active wait list and usually is not involved in and often not aware of the decision to reclassify their waitlist status.

Response: We acknowledged that patient selection from the waitlist for transplantation is not determined by the nephrologist and as such, this measure is not assessing this aspect of the transplant workflow. This is an important area to which nephrologists leading a team of dialysis practitioners, including but not limited to dialysis nurses and physician assistants, are responsible for care of patients during dialysis treatments, and can contribute by ensuring patients remain healthy and completing any ongoing testing activities required to remain active on the waitlist. Maintenance of active status requires ongoing attention by dialysis practitioners to optimize the health of patients and to ensure sustained suitability for transplant waitlisting. Maintenance of active

status on the waitlist is additionally important given demonstrated disparities[1023] and positive association with subsequent transplantation.[1024]

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62266 through 62267), we are finalizing the *Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)* measure as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1023] See footnote Kulkarni et al., 2019.
[1024] See footnote Grams et al., 2013.

Table Group B: New Specialty Measure Sets Finalized for Addition and Modifications to Previously Finalized Specialty Measure Sets Finalized for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

In the CY 2025 PFS proposed rule (89 FR 62268), we proposed to add one new specialty measure set: Optometry. In the CY 2023 PFS final rule, we finalized a combined Ophthalmology/Optometry specialty set (87 FR 70275 and 87 FR 70434 through 70439). Based on interested parties' request, we proposed to revert this combined specialty set to "Ophthalmology" under Table B.28 of this Appendix with all measures retained as finalized under the CY 2024 PFS final rule (88 FR 79777 through 79784). We simultaneously proposed to create a separate Optometry specialty set with a more limited number of quality measures based on differences in scope of practice to ophthalmology. The Optometry specialty set is finalized under Table B.29 of this Appendix.

In the CY 2025 PFS proposed rule (89 FR 62268), we also proposed to modify the below previously finalized specialty measure sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures had proposed substantive changes in Table Group D of this Appendix. In the first column, existing measures with substantive changes described in Table Group D of this Appendix are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). The Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. Additionally, eCQMs that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Under § 414.1305, a high priority measure means an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related quality measure. Further details of these types of measures may be found in the CMS Measures Management System Hub (*https://mmshub.cms.gov/*).

NOTE:

- Updates to measure titles and/or measure descriptions under Table Group B in this final rule may or may not be considered substantive in nature, therefore may not be proposed or updated under Table Group D. If the change was considered substantive in nature, it was finalized under Table Group D.
- Under Table Group B, we responded to comments related to new measures that were proposed for addition to measure sets, as well as measures proposed for removal. Any comments received on previously finalized measures that have no substantive changes are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and have been removed from the applicable Removal table. The reason for their retention was addressed under Table Group C. For some specialty sets, this resulted in the Removal Table being removed in its entirety in this final rule if no measures proposed for removal were finalized for removal. As a result, the Removal Table was removed for the following specialty set: Radiation Oncology due to the retention of measure Q144: Oncology: Medical and Radiation – Plan of Care for Pain that was not finalized for removal under Table C.3 of this Appendix.
- For each specialty set, measures in the Previously Finalized tables and any new measures finalized under applicable Addition tables will be available for reporting in CY 2025.

The following specialty sets had no measures added, no measures removed, and no substantive changes for the CY 2025 performance period/2027 MIPS payment year: Anesthesiology and Dentistry.

The following specialty sets had no measures added and no measures removed, but had substantive changes as addressed under Table Group D: Audiology, Electrophysiology Cardiac Specialist, Certified Nurse Midwife, Chiropractic Medicine, Diagnostic Radiology, General Surgery, Hospitalists, Mental/Behavioral Health and Psychiatry, Neurology, Nutrition/Dietician, Ophthalmology, Orthopedic Surgery, Pathology, Pediatrics, Physical Medicine, Physical Therapy/Occupational Therapy, Plastic Surgery, Podiatry, and Thoracic Surgery.

Note: In the CY 2024 PFS final rule, new measure Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level) was finalized with a 1-year delay to the 2025 performance period (88 FR 79556 through 79560). As a result, measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques was finalized for removal with a 1-year delay to the 2025 performance period (88 FR 79896). These decisions are reflected within table B.10 Diagnostic Radiology specialty set of this Appendix.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure

tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS31 4v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**
* § ! (Efficiency)	N/A / N/A	340	CMS1157v1	eCQM Specifications, MIPS CQM Specifications	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Allergy/Immunology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1025] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1026] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the

[1025] Ikeokwu, A. E., Lawrence, R., Osieme, E. D., Gidado, K. M., Guy, C., & Dolapo, O. (2023). Unveiling the Impact of COVID-19 Vaccines: A Meta-Analysis of Survival Rates Among Patients in the United States Based on Vaccination Status. *Cureus*, *15*(8), e43282. https://doi.org/10.7759/cureus.43282.

[1026] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the Adult COVID-19 Vaccination Status measures to this specialty set.

Response: We thank the commenter for supporting the addition of this measure to the Allergy/Immunology specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62271 through 62272), we are finalizing the above measure(s) for addition to the *Allergy/Immunology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, as applicable. This specialty set had no proposed changes.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	404	N/A	MIPS CQM Specifications	Intermediate Outcome	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQM Specifications	Outcome	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQM Specifications	Process	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQM Specifications	Process	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	477	N/A	MIPS CQM Specifications	Process	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Care Coordination)	NA / NA	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	2152/ N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS14 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS14 4v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy**: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Efficiency)	N/A / N/A	322	N/A	MIPS CQM Specifications	Efficiency	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR; •Patients aged 40 to 75 years with a diagnosis of diabetes; OR; •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Cardiology specialty set as it will be clinically relevant to this clinician type. This PRO-PM will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[1027] This measure is predicated on existing guidelines and conceptual models[1028] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure will improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure

[1027] Kilic, Y., Smer, A., & Goldstein, N. (2020). The Importance of Palliative Care in Cardiology: Differences Between Countries. JACC. Case Reports, 2(2), 326–329. https://doi.org/10.1016/j.jaccas.2019.11.069.
[1028] National Consensus Project for Quality Palliative Care. (2018). Clinical Practice Guidelines for Quality Palliative Care, 4th edition. https://www.nationalcoalitionhpc.org/ncp.

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								would not have been finalized for inclusion within this specialty measure set.
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Cardiology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1029] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1030] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical

[1029] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.
[1030] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.4a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. Commenters supported the expanded use of this palliative care-developed measure. One commenter indicated that this measure will help ensure patient care is holistic, patient-centered, responsive to the needs of those with serious illnesses in ambulatory settings.

Response: We thank the commenters for supporting the addition of measure Q495 to the Cardiology specialty set.

Comment: One commenter supported the proposed addition of measure Q495 as it aligns with patient-centered care, crucial in areas such as heart failure, advanced cardiovascular disease, and end-of-life care. The commenter indicated it is important to evaluate if this measure overlaps with existing ones or adds redundant reporting requirements, which could dilute the focus on more specific cardiovascular quality metrics. Potential challenges include resource allocation, as small practices or those with limited resources may struggle to implement this measure without additional support. It is also important to ensure the measure is applicable to most patients and does not disproportionately affect subspecialties where it might be less relevant.

Response: We acknowledge the concerns left by the commenter; however, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure provides clinicians an opportunity to review current workflows and determine potential changes clinicians can make to positively assess the need for patient centered palliative care that will improve patient outcomes. Each year we review the MIPS quality measure inventory to determine if there is duplication between measures, however, we found measure Q495 does not add redundant reporting requirements as it is the only measure specific to a patient's experience with palliative care, in addition to being diagnosis agnostic. Furthermore, this measure does not add redundant reporting requirements, because it is not required and therefore, the clinician can choose whether it is appropriate and applicable to them.

Comment: One commenter supported the proposed addition of the Adult COVID-19 Vaccination Status measure to this specialty set but requested that CMS consider adding measures that are subspecialty-specific.

Response: We thank the commenter for supporting the addition of the Adult COVID-19 Vaccination status measure to the Cardiology specialty set. We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures will be applicable or appropriate to all clinicians. The goal is to ensure we have a comprehensive set of measures that drive positive health outcomes while also providing clinician choice when determining the appropriateness of each measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62284 through 62285), we are finalizing the above measure(s) for addition to the *Cardiology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQM Specifications	Outcome	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
* ! (Outcome)	N/A / N/A	393	N/A	MIPS CQM Specifications	Outcome	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Certified Nurse-Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
	N/A / N/A	496	N/A	MIPS CQM Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine

B.5. Certified Nurse-Midwife

PREVIOUSLY FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS15 9v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS17 7v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.7. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINICAL SOCIAL WORK SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM ®) Scores at 12 Months**: The Patient Activation Measure® (PAM ®) is a 10- or 13-item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Clinical Social Work specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[1031] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed addition of measure Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months to this specialty set. One of the commenters indicated that challenges may arise in terms of the resources required to administer and score the PAM® questionnaire consistently across different settings. To address these challenges, the commenter encouraged CMS to provide training and support for social workers to effectively implement and interpret the measure. For example, integrating this measure into existing EHR systems could streamline data collection and enhance feasibility.

Response: We thank the commenter for their feedback. We encourage the commenter to reach out to the measure steward to determining if there are any trainings available now or in future years to ensure proper implementation of this measure. Additionally, we encourage specific feedback to help ensure measure specifications are clearly written to support consistent implementation. Clinicians have the flexibility to choose which measures to report based upon the appropriateness of the measure to their scope of care and resources available to help clinicians understand and prepare for measure implementation and reporting. Accordingly, this measure is not required for reporting; however, the addition of this measure enhances clinician choice on which measures to report.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62298), we are finalizing the above measure(s) for addition to the *Clinical Social Work Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1031] Phreesia. (2024). Patient Activation Measure (PAM). https://www.phreesia.com/patient-activation-measure/?utm_source=google&utm_%20medium=paid_%20search&utm_%20destinationmedium=mql_form&utm_campaign=payer_care_management_paid_search&utm_vendor=phreesia&utm_audience1=payer&utm_content=648172611574&utm_destinationco.

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. This specialty set has no proposed changes.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	378	CMS 75v13	eCQM Specifications	Outcome	**Children Who Have Dental Decay or Cavities:** Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services
	N/A / N/A	379	CMS 74v14	eCQM Specifications	Process	**Primary Caries Prevention Intervention as Offered by Dentists:** Percentage of children, 1 – 20 years of age, who received two fluoride varnish applications during the measurement period as determined by a dentist.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A/ N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	410	N/A	MIPS CQM Specifications	Outcome	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	485	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Psoriasis – Improvement in Patient-Reported Itch Severity:** The percentage of patients, aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to four, and who achieve a score reduction of three or more points at a follow up visit.	American Academy of Dermatology
* ! (Outcome)	N/A / N/A	486	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Dermatitis – Improvement in Patient-Reported Itch Severity:** The percentage of patients aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow up visit.	American Academy of Dermatology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.9. Dermatology

MEASURES FINALIZED FOR **ADDITION** TO THE DERMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A / N/A	509	N/A	MIPS CQM Specifications	Process	**Melanoma: Tracking and Evaluation of Recurrence:** Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.	American Academy of Dermatology	We proposed to include this measure in the Dermatology specialty set as it will be clinically relevant to this clinician type. Clinicians within this specialty care for patients diagnosed with melanoma and are most likely to be the clinician to evaluate the frequency of melanoma recurrence following excisional procedures for this patient population.[1032] This measure addresses the CMS high priority outcome for care coordination, as a lack of communication has been recognized between the excising clinician and clinician continuing care. This measure will allow for the development of a system in which melanomas can be accurately tracked to increase the understanding of the effectiveness of care. The incorporation of this measure in this specialty set will help promote communications between the dermatologist treating the melanoma and the clinicians continuing care. Melanoma recurrence is an outcome that needs precise evaluation.[1033] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.6 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the Melanoma: Tracking and Evaluation of Recurrence measure to this specialty set.

Response: We thank the commenter for supporting the addition of this measure to the Dermatology specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62303), we are finalizing the above measure(s) for addition to the *Dermatology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1032] Rebecca, V. W., Sondak, V. K., & Smalley, K. S. (2012). A Brief History of Melanoma: From Mummies to Mutations. *Melanoma Research*, *22*(2), 114–122. https://doi.org/10.1097/CMR.0b013e328351fa4d.

[1033] Freeman, M., & Laks, S. (2019). Surveillance Imaging for Metastasis in High-Risk Melanoma: Importance in Individualized Patient Care and Survivorship. *Melanoma Management*, *6*(1), MMT12. https://doi.org/10.2217/mmt-2019-0003.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DERMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	137	N/A	MIPS CQM Specifications	Structure	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62304), we are finalizing the above measure(s) for removal from the *Dermatology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D. As indicated in the Table Group B introduction, measure Q494 has been added to the previously finalized measure set below and measure Q436 has been removed from the measure set as previously finalized through the CY 2024 PFS final rule (88 FR 79556 through 79560 and 88 FR 79896).

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQM Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQM Specifications	Process	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3633e, 3662e / N/A	494	CMS1056v2	eCQM Specifications	Intermediate Outcome	**Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level):** This measure provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of patients with CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient, outpatient and ambulatory care settings are eligible. This measure is not telehealth eligible. This eCQM requires the use of additional software to access primary data elements stored within radiology electronic health records and translate them into data elements that can be ingested by this eCQM. Additional details are included in the Guidance field.	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069/ N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQM Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
! (Efficiency)	N/A / N/A	416	N/A	MIPS CQM Specifications	Efficiency	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.11. Emergency Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Emergency Medicine specialty set as it will be clinically relevant to this clinician type. "Emergency departments (EDs) are a potentially important setting for elder mistreatment identification because they provide care for a large number of older adults who may be elder mistreatment victims especially given that the ED is sometimes the only clinical setting that the patient may visit."[1034] The process of standardized screening using one or a combination of validated assessment(s) and/or instrument(s) should be done to ensure that signs of abuse or neglect are not overlooked.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of measure Q181: Elder Maltreatment Screen and Follow up Plan because hospitals are increasingly faced with older patients who have complex medical, physiological, and psychosocial needs that are often inadequately addressed by the current health care infrastructure to this specialty set. The commenter is encouraged that CMS recognizes the benefits of having EDs that focus on the care and needs of the geriatric population.

Response: We thank the commenter for supporting the addition of this measure to the Emergency Medicine specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62311), we are finalizing the above measure(s) for addition to the *Emergency Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1034] Rosen, T., Platts-Mills, T. F., & Fulmer, T. (2020). Screening for Elder Mistreatment in Emergency Departments: Current Progress and Recommendations for Next Steps. *Journal of Elder Abuse & Neglect*, *32*(3), 295–315. https://doi.org/10.1080/08946566.2020.1768997.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE EMERGENCY MEDICINE SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services	We proposed to remove this measure from the Emergency Medicine specialty set beginning with the CY 2025 performance period/2027 MIPS payment year. Complete emergency medicine applicable coding is not available within this quality measure. Therefore, this measure has minimal eligibility for this clinician type.
N/A / N/A	254	N/A	MIPS CQM Specifications	Process	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan and agreed this measure is not clinically relevant to the practice of emergency medicine because emergency medicine clinicians do not typically conduct this comprehensive screening in the emergency department. The commenter also supported the removal of measure Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain as topped out from this specialty set.

Response: We thank the commenter for supporting the removal of these two measures from the Emergency Medicine specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62312), we are finalizing the above measure(s) for removal from the *Emergency Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS12 2v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	N/A / N/A	438	CMS347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS645v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.12. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Endocrinology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1035] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1036] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62317), we are finalizing the above measure(s) for addition to the *Endocrinology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1035] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1036] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS1 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS1 35v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0070 / 0070e	007	CMS1 45v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS1 44v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS1 28v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. A. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS1 54v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS1 46v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS1 31v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS6 8v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2 days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within 2 days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS1 65v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first 6 months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS1 56v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS1 37v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS1 24v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS1 39v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS3 14v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS1 59v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS5 0v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS9 0v14	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients – all considered at high risk of cardiovascular events – who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg – AND • Most recent tobacco status is Tobacco Free – AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS3 49v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS7 71v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items – to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS9 51v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.13. Family Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Family Medicine specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1037] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1038] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[1037] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.
[1038] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62333), we are finalizing the above measure(s) for addition to the *Family Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62334), we are finalizing the above measure(s) for removal from the *Family Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQM Specifications	Process	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	NA / N/A	275	N/A	MIPS CQM Specifications	Process	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22v 13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTEROLOGY SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / N/A	439	N/A	MIPS CQM Specifications	Efficiency	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62338), we are finalizing the above measure(s) for removal from the *Gastroenterology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQM Specifications	Process	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQM Specifications	Outcome	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least one of their HRSNs within 60 days after screening.	OCHIN

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to 2days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association

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PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
! (Patient Safety)	0101 / N/A	318	CMS139 v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS159 v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Outcome)	N/A / N/A	476	CMS771 v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951 v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy**: Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
*	NA / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.16. Geriatrics

MEASURES FINALIZED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Geriatrics specialty set as it will be clinically relevant to this clinician type. This PRO-PM will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[1039] This measure is predicated on existing guidelines and conceptual models[1040] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure will improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[1039] See footnote Kilic et al., 2020 in Table B.4a of this Appendix.
[1040] See footnote National Consensus Project for Quality Palliative Care, 2018 in Table B.4a of this Appendix.

B.16. Geriatrics

MEASURES FINALIZED FOR **ADDITION** TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Geriatrics specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[1041] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[1041] See footnote Phreesia, 2024 in Table B.7 of this Appendix.

B.16. Geriatrics

MEASURES FINALIZED FOR ADDITION TO THE GERIATRICS SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Geriatrics specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1042] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1043] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood being added to this specialty set. Commenters supported the expanded use of this palliative care-developed measure. One commenter indicated that this measure would help ensure patient care is holistic, patient-centered, responsive to the needs of those with serious illnesses in ambulatory settings. One commenter supported measure Q503:

[1042] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1043] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

Gains in PAM® Scores at 12 Months being added to this specialty set as it will offer a high value, cross cutting and clinically significant patient-reported measure to participating clinicians.

Response: We thank the commenters for supporting the addition of these measures to the Geriatrics specialty set.

Comment: One commenter stated the exclusions for measure Q495 should include diagnoses of cognitive impairment, dementia, and Alzheimer's disease before finalizing the measure to take into consideration the limitations with patients who are not as engaged in their own decision-making as they may not be able to appropriately respond to the survey administered that determines the top-box score for this measure.

Response: We thank the commenter for their feedback. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Per the measure steward, the measure applies a person-centered approach that recognizes the person beyond the disease and prioritizes peoples' health concerns as they see them. The measure includes an exclusion for surveys filled out by proxy as well as an exception for patient who did not respond to the questions.[1044]

Comment: One commenter expressed concerns about the addition of measure Q503 to this specialty set, stating that the measure may pose challenges for use by geriatricians, who treat older adults with medical complexities and living with multiple chronic conditions. Due to the comprehensive approach needed in addressing and individualizing care in older adults with multimorbidity and the potential accumulation of disease states and medications, it may be difficult for patients to keep track of and build ability to manage their own health and health care. The commenter encouraged CMS to reconsider the inclusion of measure Q503 in the Geriatrics specialty set.

Response: The MIPS quality measure inventory does not currently include a measure with an alternate activation survey, and, as such, we are including this measure to fill a gap in care within the Geriatrics specialty set. Because clinicians have the flexibility to choose which measures to report, the adoption of this measure is not a requirement for clinicians. Instead, the addition of this measure enhances clinician choice when they select which measures to report. The PAM® is a disease-agnostic measure meant to provide meaningful information about changes in activation across many patient populations and aligns with CMS health priorities of capturing the patient voice and ensuring the patients can be partners in healthcare decisions with their clinicians. This will be a valuable tool for all patients within this scope of practice. This measure does contain exclusions for dementia and cognitive impairment to maintain an appropriate patient population for the measure's assessment.

Comment: One commenter agreed with CMS that vaccination is important to reduce morbidity and mortality caused by COVID-19 and recommends vaccination for older adults particularly those who are at higher risk of poor outcomes but was concerned that the Adult COVID-19 Vaccination Status measure will add burden to clinicians without meaningful improvements in care, quality, or vaccination rates. Given the fluctuating landscape of COVID-19 and related interim guidelines, the commenter believed that complying with the CDC recommendations that are not yet final would be difficult. If finalized, the commenter recommended CMS explore qualifiers that take into consideration these challenges as well as that the evidence is based on retrospective data that reflects the experience during a PHE when the disease was more deadly.

Response: MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure provides an opportunity to discuss vaccines with the patient. This measure represents an important clinical topic following the recently ended PHE for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). Due to the measure being new, there are not yet any benchmarks for MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62347 through 62349), we are finalizing the above measure(s) for addition to the *Geriatrics Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1044] American Academy of Hospice and Palliative Medicine. (2024). Palliative Care Quality Measures Project: Implementation Guide. https://aahpm.org/wp-content/uploads/2024/03/AAHPM22_PRO-PM_IMPLEMENTATION_GUIDE.pdf.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0081 / 0081e	005	CMS13 5v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0083 / 0083e	008	CMS14 4v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the 7-day period from three days prior to the episode date through 3 days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
§	N/A / 3755e	205	CMS1188v2	eCQM Specifications, MIPS CQM Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the 6 months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS11 7v13	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
§ ! (Outcome)	NA / N/A	338	CMS31 4v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
* § ! (Efficiency)	N/A / N/A	340	CMS11 57v1	eCQM Specifications, MIPS CQM Specifications	Process	**HIV Annual Retention in Care:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the performance period	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
§	N/A / N/A	475	CMS349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia	We proposed to include this measure in the Infectious Disease specialty set as it will be clinically relevant to this clinician type. The addition of this measure to this specialty set will be feasible given its use through the continuum of care and across different clinical settings. This measure addresses chronic conditions and outcomes, both of which are high priority areas for measure consideration for MIPS. It is utilized in research within the U.S. and internationally and has also been shown to be valid and reliable in different clinical settings and under different payment models.[1045] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[1045] See footnote Phreesia, 2024 in Table B.7 of this Appendix.

B.18. Infectious Disease

MEASURES FINALIZED FOR **ADDITION** TO THE INFECTIOUS DISEASE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Infectious Disease specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1046] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1047] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed addition of measure Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months to this specialty set. One of these commenters noted that the inclusion of this measure in the specialty set will offer a high value, cross cutting and clinically significant patient-reported measure to participating clinicians.

[1046] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1047] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

Response: We thank the commenters for supporting the addition of this measure to the Infectious Disease specialty set.

Comment: One commenter did not support the addition of the Adult COVID-19 Vaccination Status measure to this specialty set. The commenter stated that given the unique concerns surrounding COVID-19 immunization, it may be difficult to achieve high-quality benchmarks. Many patients will accept other vaccines but will not accept the COVID-19 vaccine. If clinicians are benchmarked against a national average for this measure, the regional variation of views toward COVID-19 immunizations will cause a disadvantage for infectious disease clinicians in certain geographic regions of the country.

Response: We acknowledge commenters' concerns; however, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure provides an opportunity to discuss vaccines with the patient. This measure represents an important clinical topic following the recently ended PHE for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). Due to the measure being new, there are not yet any benchmarks for MIPS.

For the reasons stated above and in the proposed rule (89 FR 62355 through 62356), we are finalizing the above measure(s) for addition to the *Infectious Disease Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
§	0081 / 0081e	005	CMS135v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS145v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0083 / 0083e	008	CMS144 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS128 v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68v 14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v1 4	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordinat ion)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	236	CMS165 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS137 v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124 v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
! (Patient Safety)	0101 / N/A	318	CMS139 v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	N/A / N/A	338	CMS314 v2	eCQM Specifications, MIPS CQM Specifications	Outcome	**HIV Viral Suppression:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first 90 days of the performance period, with an eligible encounter in the first 240 days of the performance period, whose last HIV viral load test result was less than 200 copies/mL during the performance period.	Health Resources and Services Administration
§ ! (Outcome)	0710 / 0710e	370	CMS159 v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	377	CMS90v 14	eCQM Specifications	Process	**Functional Status Assessments for Heart Failure:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM Specifications	Process	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	401	N/A	MIPS CQM Specifications	Process	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic Hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS347 v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) – Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§	N/A / N/A	475	CMS349 v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Outcome)	N/A / N/A	476	CMS771 v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3568 / N/A	483	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.	The American Board of Family Medicine
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951 v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association

B.19. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Internal Medicine specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1048] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the (ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1049] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62373), we are finalizing the above measure(s) for addition to the *Internal Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1048] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1049] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62374), we are finalizing the above measure(s) for removal from the *Internal Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices.	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQM Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM Specifications	Process	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQM Specifications	Process	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INTERVENTONAL RADIOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	409	N/A	MIPS CQM Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62376), we are finalizing the above measure(s) for removal from the *Interventional Radiology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS12 8v13	eCQM Specifications	Process	**Antidepressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
§	N/A / N/A	366	CMS13 6v14	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0710 / 0710e	370	CMS159v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / N/A	382	CMS177v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQM Specifications	Intermediate Outcome	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	400	N/A	MIPS CQM Specifications	Process	**One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation:** Percentage of patients age >= 18 years have never been tested for Hepatitis C Virus (HCV) infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if tested positive for HCV.	American Gastroenterological Association
! (Outcome)	N/A/ N/A	482	N/A	MIPS CQM Specifications	Intermediate Outcome	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis (HD) patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
	1662/ N/A	489	N/A	MIPS CQM Specifications	Process	**Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (Stages 1-5, not receiving Renal Replacement Therapy (RRT)) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.	Renal Physicians Association
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)	We proposed to include this measure in the Nephrology specialty set as it will be clinically relevant to this clinician type. This PRO-PM will help to fill a gap for patients receiving palliative care by capturing the patient's voice and experience of care by assessing communication and shared decision making with the clinician. This is an important patient-centered measure that helps patients feel heard and understood which can effectively improve the quality of care received and outcomes for patients in palliative care. Allowing patients to feel heard and understood adds an important dimension to the care planning for this unique patient population commonly cared for by clinicians in this specialty. As more patients are living longer with multiple comorbidities, especially true for the advanced heart disease patient population, early emergence of palliative care into the overall care of cardiac patients can notably improve their quality of life, patient satisfaction, and reduction in symptoms.[1050] This measure is predicated on existing guidelines and conceptual models[1051] and can facilitate and improve effective patient-clinician communication that engenders trust, acknowledgement, and a whole-person orientation to the care that is provided. Through the benefits of enhanced patient-provider communication, this measure will improve the quality of care received and outcomes for patients receiving palliative care. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[1050] See footnote Kilic et al., 2020 in Table B.4a of this Appendix.
[1051] See footnote National Consensus Project for Quality Palliative Care, 2018 in Table B.4a of this Appendix.

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1052] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1053] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[1052] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.
[1053] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	510	N/A	MIPS CQM Specifications	Process	**First Year Standardized Waitlist Ratio (FYSWR):** The number of newly initiated patients on dialysis in a practitioner group who are under the age of 75 and were either listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. The practitioner group is inclusive of physicians and advanced practice providers. The measure is the ratio-observed number of waitlist events in a practitioner group to its expected number of waitlist events. The measure uses the expected waitlist events calculated from a Cox model, which is adjusted for age, patient comorbidities, and other risk factors at the time of dialysis.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as it will be clinically relevant to this clinician type. The measure's intended objective consists of improving the overall health of patients on dialysis, with nephrologists at the forefront of caring for this patient population. Clinicians within this specialty are responsible for the education of patients about the option of transplantation, referral of patients to a transplant center for evaluation, completion of the evaluation process, and optimizing the health of the patient while on dialysis. All clinicians should be involved and actively work towards providing patients with high quality care including ensuring placement on the transplant list as quickly as possible. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.7 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

B.22. Nephrology

MEASURES FINALIZED FOR **ADDITION** TO THE NEPHROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	511	N/A	MIPS CQM Specifications	Process	**Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW):** The measure tracks dialysis patients who are under the age of 75 in a practitioner group and on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status). This measure is a risk-adjusted percentage of waitlist events among dialysis patients.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Nephrology specialty set as will be clinically relevant to this clinician type. The maintenance of end stage renal disease patients on active status on the waitlist is additionally important given demonstrated disparities and positive association with subsequent transplantation. These practices are important for nephrologists who are at the forefront of caring for this patient population. This is an important area to which dialysis practitioners can contribute through ensuring patients remain healthy and complete any ongoing testing activities required to remain active on the waitlist. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set. See Table A.8 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed addition of measure Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood to this specialty set. Commenters supported the expanded use of this palliative care-developed measure. One commenter indicated that this measure would help ensure patient care is holistic, patient-centered, and responsive to the needs of those with serious illnesses in ambulatory settings.

Response: We thank the commenters for supporting the addition of this measure to the Nephrology specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62386 through 62389), we are finalizing the above measure(s) for addition to the *Nephrology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM Specifications	Process	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
*	N/A / N/A	290	N/A	MIPS CQM Specifications	Process	**Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQM Specifications	Process	**Rehabilitative Therapy Referral for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare and Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression).	American Academy of Neurology
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQM Specifications	Process	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQM Specifications	Process	**Stroke and Stroke Rehabilitation**: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 3.5 hours of time last known well and for whom IV thrombolytic therapy was initiated within 4.5 hours of time last known well.	American Heart Association
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQM Specifications	Intermediate Outcome	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROSURGICAL SPECIALTY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title And Description	Measure Steward	Rationale for Removal
NA / NA	260	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / N/A	409	N/A	MIPS CQM Specifications	Outcome	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62397), we are finalizing the above measure(s) for removal from the *Neurosurgical Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	NA / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS15 5v13	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. ● Percentage of patients with height, weight, and body mass index (BMI) percentile documentation ● Percentage of patients with counseling for nutrition ● Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	309	CMS124v13	eCQM Specifications	Process	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed within the last 3 years • Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v13	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	335	N/A	MIPS CQM Specifications	Outcome	**Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQM Specifications	Process	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** . The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	432	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQM Specifications	Process	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQM Specifications	Process	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM Specifications	Process	**Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument:** Percentage of pregnant or postpartum patients who received a cardiovascular disease (CVD) risk assessment with a standardized instrument.	University of California, Irvine
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
* ! (Safety)	N/A / N/A	504	N/A	MIPS CQM Specifications	Process	**Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.	American Psychiatric Association
! (Outcome)	N/A / N/A	505	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Reduction in Suicidal Ideation or Behavior Symptoms:** The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.	American Psychiatric Association

B.26. Obstetrics/Gynecology

MEASURES FINALIZED FOR **ADDITION** TO THE OBSTRETRICS/GYNECOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Obstetrics/Gynecology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1054] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1055] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62407), we are finalizing the above measure(s) for addition to the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1054] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1055] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OBSTRETRICS/GYNECOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	433	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogyneco-logic Society	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / 3475e	472	CMS249v7	eCQM Specifications	Process	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62408), we are finalizing the above measure(s) for removal from the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v13	eCQM Specifications, MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient experience)	0383 / N/A	144	N/A	MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	**CAHPS for MIPs Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE).	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQM Specifications	Process	**Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer:** Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	1859 / N/A	451	N/A	MIPS CQM Specifications	Process	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.	American Society of Clinical Oncology
§ ! (Appropria te Use)	0210 / N/A	453	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Appropriat e Use)	0216 / N/A	457	N/A	MIPS CQM Specifications	Process	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS6 45v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	490	N/A	MIPS CQM Specifications	Process	**Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors:** Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.	Society for Immunotherapy of Cancer (SITC)
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
! (Outcome)	3665 / N/A	495	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood:** The percentage of top-box responses among patients aged 18 years and older who had an ambulatory palliative care visit and report feeling heard and understood by their palliative care clinician and team within 2 months (60 days) of the ambulatory palliative care visit.	American Academy of Hospice and Palliative Medicine (AAHPM)
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.27a. Oncology/Hematology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Appropriate Use)	N/A / N/A	506	N/A	MIPS CQM Specifications	Process	**Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy:** Percentage of patients, aged 18 years and older, with a diagnosis of metastatic non-small cell lung cancer (NSCLC) or squamous cell carcinoma of head and neck (HNSCC) on first-line immune checkpoint inhibitor (ICI) therapy, who had a positive PD-L1 biomarker expression test result prior to giving ICI therapy.	Society for Immunotherapy of Cancer (SITC)	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type. Immunotherapy is a rapidly developing and changing subspecialty in the realm of oncology, and this measure will fill a gap within the oncologic clinical topic. The incorporation of this measure in this specialty set will help promote appropriate intervention and timeliness of PD-L1 biomarker expression testing prior to initiation of first-line treatment for the metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck. This timeliness of treatment initiation can lead to improvements in patient mortality and morbidity.[1056] It's important to address the proper diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma that may impact treatment decisions so that appropriate treatment delivery is not delayed, nor ineffective therapies prescribed which could both result in poor clinical outcomes and unnecessary healthcare costs.[1057] See Table A.1 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[1056] See footnote Pai et al., 2020 in Table A.1 of this Appendix

[1057] See footnotes Lim et al., 2015 and Pai et al., 2020 in Table A.1 of this Appendix.

B.27a. Oncology/Hematology

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	507	N/A	MIPS CQM Specifications	Process	**Appropriate Germline Testing for Ovarian Cancer Patients:** Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.	American Society of Clinical Oncology	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type and will fill a gap within the oncologic clinical topic. This measure addresses patients diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of their diagnosis and is predicated on existing clinical guidelines and recommendations. It also addresses a CMS priority that could allow for more personalized diagnostic, predictive, prognostic, and therapeutic strategies for the patient. Current recommendations for all women diagnosed with ovarian cancer is to receive genetic testing, however, only approximately 30 percent of women undergo any genetic testing.[1058] The high incidence of these mutations and the advent of therapy targeted toward BRCA mutations warrant testing in all individuals diagnosed with ovarian cancer for the purpose of determining treatment recommendations, risk of other cancers, and need for cascade testing of family members. See Table A.2 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[1058] See footnote Konstantinopoulos et al., 2020 in Table A.2 of this Appendix.

B.27a. Oncology/Hematology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	CBE 3718 / N/A	N/A	N/A	MIPS CQM Specifications	Patient-Reported Outcome-based Performance Measure (PRO-PM)	**Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer:** The PRO-PM will assess pain interference following chemotherapy administered with curative intent to adult patients with breast cancer.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type and will fill a gap within the oncologic clinical topic. This measure addresses a CMS high priority as a patient-reported outcome-based performance quality measure accounting for patient experience of care for this patient population. It is predicated on existing clinical guidelines and recommendations.[1059] For the breast cancer patient population, it's important to routinely assess pain to properly identify barriers to acceptable pain management and to intervene appropriately, which can improve the patient's health outcome and quality of life.[1060] See Table A.3 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.
! (Outcome)	CBE 3720 / N/A	N/A	N/A	MIPS CQM Specifications	Patient-Reported Outcome-based Performance Measure (PRO-PM)	**Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer:** The PRO-PM will assess fatigue following chemotherapy administered with curative intent to adult patients with breast cancer.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type, addresses a CMS high priority as a PRO-PM, and will fill a gap within the oncologic clinical topic. It takes into consideration the patient voice/experience of care for those patients with breast cancer with fatigue experienced following chemotherapy. PRO assessment in routine care remains underutilized, and very few PRO-PMs have been validated for the cancer population. By taking into consideration patient voice, necessary interventions can be completed to help improve their quality of life during cancer treatment. See Table A.4 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

[1059] Tegegn, H. K., & Gebreyohannes, E. A. (2017). Adequacy of Cancer Pain Management and Pain Interference With Daily Functioning Among Patients Visiting the Oncology Ward of an Ethiopian University. *Journal of Global Oncology*, *3(2)*. https://ascopubs.org/doi/10.1200/JGO.2017.009738.

[1060] See footnote Tegegn & Gebreyohannes, 2017.

B.27a. Oncology/Hematology

MEASURES FINALIZED AND NOT FINALIZED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Oncology/ Hematology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1061] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1062] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported proposed addition of the Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy and the Appropriate Germline Testing for Ovarian Cancer Patients measures to this

[1061] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1062] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

specialty set. One of these commenters also supported the Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer and Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer measures being added to this specialty set.

Response: We thank the commenters for supporting these measures being added to the Oncology/Hematology specialty set.

Comment: One commenter supported the addition of the Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer and Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer measures to this specialty set. However, the commenter noted that these measures are currently limited to one tool for data collection (PROMIS). The commenter indicated licensing and fees are required to use the screening tool, which creates a barrier to adoption when there are additional screening tools available that are equally useful to manage patient care. The commenter recommended that the measure developers broaden the measure numerators to include other validated screening tools so that more clinicians can report on the measures. There are additional validated tools that are widely used in oncologic care.

Response: We acknowledge the commenter's concerns; however, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure addresses a CMS high priority as a patient-reported outcome-based performance quality measure accounting for patient experience of care for this patient population. The current measure has been fully developed and tested utilizing the PROMIS tool for data collection, showing it is a reliable and valid tool for the purposes of reporting this measure. We recognize that the measures are limited to one tool for data collection; however, the tool is publicly available at no cost in paper form. Licensing fees may be applicable for permissions to integrate into electronic platforms but are not required for use for measure reporting. As performance for these measures is based upon the outcome of the assessment, it is important the same tool is being utilized across submissions to ensure continuity in data and allowing for appropriate comparisons. However, because the measure steward is no longer able to maintain the quality measures, we are not finalizing these measures under Tables A.3 and A.4 of this Appendix.

Comment: Two commenters did not support the proposed addition of the Adult COVID-19 Vaccination measure to this specialty set. Recommendations for vaccinations and boosters are changing frequently, and therefore, measure specifications need to be updated accordingly to comport with this frequently changing landscape. Lastly, the commenters stated that measures within this specialty set should align with those in the Advancing Cancer Care MVP.

Response: We acknowledge the commenters' concerns; however, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure provides an opportunity to discuss vaccines with the patient. This measure represents an important clinical topic following the recently ended PHE for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). We also note that while there is generally measure alignment between the specialty measure sets and MVPs, this is not a requirement, and the MVP is not meant to be a copy of the specialty measure set. We understand COVID-19 vaccination guidelines have changed and may continue to change. Specifying the measure by referring to "up to date" guidelines ensures the measure remains current and valid despite future guideline updates. As specified, the measure holds a clinician accountable for the most current guidelines on the date of the denominator eligible encounter. We consider this to be a fair approach as it does not judge clinicians by standards that are not known to the clinician and not applicable at the time of the encounter.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62415 through 62418), we are finalizing measures Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy, Q507: Appropriate Germline Testing for Ovarian Cancer Patients, and Q508: Adult COVID-19 Vaccination Status for addition to the *Oncology/Hematology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. However, we are not finalizing the Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer and Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer measures for addition to this specialty set because the measure steward is no longer able to maintain the quality measures. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED AND NOT FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
1860 / N/A	452	N/A	MIPS CQM Specifications	Process	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62419), we are finalizing the above measure(s) for removal from the *Oncology/Hematology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years: measure Q452. As indicated under Table C.3 of this Appendix, measure Q144: Oncology: Medical and Radiation – Plan of Care for Pain was not finalized for removal from MIPS. Measure Q144 has been removed from this removal table and added back to the previously finalized measures table. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable. Measure Q144: Oncology: Medical and Radiation – Plan of Care for Pain was not finalized for removal under Table C.3 of this Appendix. Therefore, the measure has been added back into the previously finalized specialty set and removed from the Removal table, which resulted in the Removal table being removed in its entirety in this final rule. The reason for retaining measure Q144 was addressed under Table Group C.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	102	CMS 129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS 157v13	eCQM Specifications, MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQM Specifications	Process	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D. As indicated in the Table Group B Introduction, we proposed to rename this specialty set from "Ophthalmology/ Optometry" to "Ophthalmology" under the CY 2025 PFS proposed rule (89 FR 62422). We also proposed a new Optometry specialty set under Table B.29 of this Appendix.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 0086e	012	CMS143v13	eCQM Specifications	Process	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more visits within 12 months.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v13	eCQM Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS13 1v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Outcome	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0565 / 0565e	191	CMS13 3v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	303	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQM Specifications	Patient Engagement/ Experience	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	384	N/A	MIPS CQM Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	385	N/A	MIPS CQM Specifications	Outcome	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQM Specifications	Outcome	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	499	N/A	MIPS CQM Specifications	Process	**Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy:** Percentage of patients who had an intravitreal or periocular corticosteroid injection (e.g., triamcinolone, preservative-free triamcinolone, dexamethasone, dexamethasone intravitreal implant, or fluocinolone intravitreal implant) who, within seven (7) weeks following the date of injection, are screened for elevated intraocular pressure (IOP) with tonometry with documented IOP =<25 mm Hg for injected eye OR if the IOP was >25 mm Hg, a plan of care was documented.	American Society of Retina Specialists
*	N/A / N/A	500	N/A	MIPS CQM Specifications	Process	**Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.	American Society of Retina Specialists
*	N/A / N/A	501	N/A	MIPS CQM Specifications	Process	**Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up:** Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.	American Society of Retina Specialists

B.29. Optometry

As indicated in the introductory language of Table Group B of this Appendix to this final rule, we proposed to add a new Optometry specialty set. In addition to the considerations discussed in the introductory language of Table Group B, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we proposed to add to this specialty set.

B.29. Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A / N/A	019	CMS 142v13	eCQM Specifications	Process	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.	American Academy of Ophthalmology	We proposed to include this measure in the Optometry specialty set as it will be clinically relevant to this clinician type. An Optometrist is needed to inform a primary care clinician about a particular patient's retinopathy severity, possible diabetic macular edema, or other ocular co-morbidities. Retinopathy serves as a strong predictor of other serious medical conditions such as heart attack, stroke, kidney failure, amputation, and others.[1063] Without regular reporting from the optometrist on this issue, the primary care clinician lacks valuable information key to the overall management of the patient. This measure is essential to patient safety and completes the feedback essential for treating a deadly, common disease.[1064] Better communication between eye specialists and primary care clinicians can play a critical role in patient care, as it's an important mechanism for clinicians to communicate with one another about a patients' disease symptoms, adherence to care plan, and treatment plans.[1065] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure

[1063] Nag, S., Bilous, R., Kelly, W., Jones, S., Roper, N., & Connolly, V. (2007). All-cause and Cardiovascular Mortality in Diabetic Subjects Increases Significantly with Reduced Estimated Glomerular Filtration Rate (eGFR): 10 Years' Data from the South Tees Diabetes Mortality Study. *Diabetic Medicine: A Journal of the British Diabetic Association*, *24*(1), 10–17. https://doi.org/10.1111/j.1464-5491.2007.02023.x.

[1064] Reutens A. T. (2013). Epidemiology of Diabetic Kidney Disease. *The Medical Clinics of North America*, *97*(1), 1–18. https://doi.org/10.1016/j.mcna.2012.10.001.

[1065] Storey, P., and Haller, J. (2016). The Significance of Physician Communication in the Care of Patients With Diabetes. Retina Today. https://retinatoday.com/articles/2016-sept/the-significance-of-physician-communication-in-the-care-of-patients-with-diabetes.

B.29. Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								would not have been finalized for inclusion within this specialty measure set.
* §	0055 / N/A	117	CMS 131v13	eCQM Specifications, MIPS CQM Specifications	Process	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance	We proposed to include this measure in the Optometry specialty set as it will be clinically relevant to this clinician type. This measure could help accurately assess a clinician's ability to diagnose and treat patients safely and efficiently. The numerator options give more granular data that can be captured to discern between patients with and without evidence of retinopathy. This information could give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Documentation of current medications in the medical record facilitates the process of medication review and reconciliation by the clinician, which is necessary for reducing ADEs and promoting medication safety. The need for clinician-to-clinician coordination regarding medication records, and the existing gap in implementation, is highlighted in the American Medical Association's Physician's Role in Medication Reconciliation, which states that "critical patient information, including medical and medication histories, current medications

B.29. Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
								the patient is receiving and taking, and sources of medications, is essential to the delivery of safe medical care."[1066] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance	We proposed to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Tobacco use is the leading preventable cause of disease, disability, and death in the U.S. cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every 5 deaths.[1067] Due to the harmful effect tobacco use can have on patients' health, clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
* ! (Patient Safety)	0022 / N/A	238	CMS 156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered	National Committee for Quality Assurance	We proposed to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Treating patients with high-risk medications such as anti-depressants or pain medications, may be associated with increased risk of harm from drug side-

[1066] American Medical Association. (2007). The Physician's Role in Medication Reconciliation: Issues, Strategies, and Safety Principles. Retrieved from https://brucelambert.soc.northwestern.edu//book_reviews/med-rec-monograph.pdf.

[1067] CDC. (2023). Smoking and Tobacco Use – Adult Data. https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/?CDC_AAref_Val=https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

B.29. Optometry

MEASURES FINALIZED FOR ADDITION TO THE OPTOMETRY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
						at least two high-risk medications from the same drug class.		effects and toxicity.[1068] Medication errors can occur anywhere throughout the many steps in the medication management process, with one of the most common error sources being poor interprofessional communication resulting in poor collaborative medication management.[1069] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Optometry specialty set as it is clinically relevant to this clinician type. Including this measure will ensure patients referred to Optometrist for a consultation complete the encounter with a consult report being returned to the referring physician. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the creation of separate specialty sets for ophthalmology and optometry. The commenter thanked CMS for addressing their concerns that including optometry in the Ophthalmology specialty set could encourage providers to report on treatments outside their expertise, licensure, or experience.

Response: We thank the commenter for supporting this update in the specialty sets.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62428 through 62431), we are finalizing the above measure(s) for addition to the *Optometry Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1068] Zhan, C., Sangl, J., Bierman, A. S., Miller, M. R., Friedman, B., Wickizer, S. W., & Meyer, G. S. (2001). Potentially Inappropriate Medication Use in the Community-Dwelling Elderly: Findings from the 1996 Medical Expenditure Panel Survey. *JAMA*, *286*(22), 2823–2829. https://doi.org/10.1001/jama.286.22.2823.

[1069] Pereira, F., Bieri, M., Del Rio Carral, M., Martins, M. M., & Verloo, H. (2022). Collaborative Medication Management for Older Adults After Hospital Discharge: A Qualitative Descriptive Study. *BMC Nursing*, *21*(1), 284. https://doi.org/10.1186/s12912-022-01061-3.

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments**: A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQM Specifications	Process	**Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQM Specifications	Process	**Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v13	eCQM Specifications	Process	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	459	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Back Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	461	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Leg Pain After Lumbar Surgery:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy or fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale or a numeric pain scale at three months (6 to 20 weeks) for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy/laminectomy or fusion procedure.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
§ ! (Outcome)	N/A / N/A	471	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status After Lumbar Surgery:** For patients age 18 and older who had lumbar discectomy/laminectomy or fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively for discectomy/laminectomy or at one year (9 to 15 months) postoperatively for lumbar fusion patients. Rates are stratified by procedure type; lumbar discectomy or fusion procedure.	Minnesota Community Measurement

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	3493 / N/A	480	N/A	Administrative Claims	Outcome	**Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS):** This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.31. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.31. Otolaryngology

MEASURES FINALIZED FOR ADDITION TO THE OTOLARYNGOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Otolaryngology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1070] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1071] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62446), we are finalizing the above measure(s) for addition to the *Otolaryngology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1070] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1071] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.32. Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQM Specifications	Process	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology
! (Care Coordination)	3661 / N/A	491	N/A	MIPS CQM Specifications	Process	**Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status:**	College of American Pathologists

B.32. Pathology

PREVIOUSLY FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
						Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.	

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / 3755e	205	CMS1188v2	eCQM Specifications, MIPS CQM Specifications	Process	**Sexually Transmitted Infection (STI) Testing for People with HIV:** Percentage of patients 13 years of age and older with a diagnosis of HIV who had tests for syphilis, gonorrhea, and chlamydia performed within the performance period.	Health Resources and Services Administration

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	239	CMS15 5v13	eCQM Specifications	Process	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS11 7v13	eCQM Specifications	Process	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DtaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (HepB); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (HepA); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A / N/A	305	CMS13 7v13	eCQM Specifications	Process	**Initiation and Engagement of Substance Use Disorder Treatment:** Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported): a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode. b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or medication treatment events for SUD, or one long-acting medication event for the treatment of SUD, within 34 days of the initiation.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS15 3v13	eCQM Specifications	Process	**Chlamydia Screening in Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
§	N/A / N/A	366	CMS13 6v14	eCQM Specifications	Process	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly prescribed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. (a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
§ ! (Outcome)	0710 / 0710e	370	CMS15 9v13	eCQM Specifications, MIPS CQM Specifications	Outcome	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement

B.33. Pediatrics

PREVIOUSLY FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	382	CMS177v13	eCQM Specifications	Process	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 16 years at the start of the measurement period with a diagnosis of major depressive disorder (MDD) with an assessment for suicide risk.	Mathematica
§	N/A / N/A	394	N/A	MIPS CQM Specifications	Process	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the Human Papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQM Specifications	Process	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.34. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	217	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS14 9v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	318	CMS139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	478	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Neck Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
! (Outcome)	N/A / N/A	502	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder:** The percentage of patients aged 18 and older with a mental and/or substance use disorder who demonstrated improvement or maintenance of functioning based on results from the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0) or Sheehan Disability Scale (SDS) 30 to 180 days after an index assessment.	American Psychiatric Association

B.35. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	N/A / N/A	355	N/A	MIPS CQM Specifications	Outcome	**Unplanned Reoperation within the 30-Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons

B.36. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	219	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Focus on Therapeutic Outcomes, Inc.

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS 139v13	eCQM Specifications	Process	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.37. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS 122v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Diabetes: Glycemic Status Assessment Greater Than 9%**: Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	126	N/A	MIPS CQM Specifications	Process	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS 2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQM Specifications	Process	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	438	CMS 347v8	eCQM Specifications, MIPS CQM Specifications	Process	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: •All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR •Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR •Patients aged 40 to 75 years with a diagnosis of diabetes; OR •Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS 349v7	eCQM Specifications	Process	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human Immunodeficiency Virus (HIV).	Centers for Disease Control and Prevention
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS 951v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.38. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	497	N/A	MIPS CQM Specifications	Process	**Preventive Care and Wellness (composite):** Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).	Centers for Medicare and Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performanc e Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Preventive Medicine specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1072] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1073] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62473), we are finalizing the above measure(s) for addition to the *Preventive Medicine Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1072] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1073] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQM Specifications	Process	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD with a documented FEV1/FVC < 70% measured by spirometry, who are symptomatic and were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months after initial evaluation for suspected obstructive sleep apnea.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQM Specifications	Process	**Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea (OSA) that were prescribed an evidence-based therapy that had documentation that adherence to therapy was assessed at least annually through an objective informatics system or through self-reporting (if objective reporting is not available).	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50 v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQM Specifications	Outcome	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.39. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.39. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Pulmonology Medicine specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1074] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1075] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62477), we are finalizing the above measure(s) for addition to the *Pulmonology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1074] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1075] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.40. Rheumatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of women aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) test to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	176	N/A	MIPS CQM Specifications	Process	**Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy:** If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
*	2523 / N/A	177	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQM Specifications	Process	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period.	American College of Rheumatology

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.40. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee Quality Assurance
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

MEASURES FINALIZED FOR ADDITION TO THE RHEUMATOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Rheumatology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1076] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1077] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the Adult COVID-19 Vaccination Status measure to this specialty set.

Response: We thank the commenter for supporting the addition of this measure to the Rheumatology specialty set.

[1076] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1077] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62482), we are finalizing the above measure(s) for addition to the *Rheumatology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070 / 0070e	007	CMS1 45v13	eCQM Specifications, MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.	American Heart Association
§	0083 / 0083e	008	CMS1 44v13	eCQM Specifications, MIPS CQM Specifications	Process	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) ≤ 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQM Specifications	Process	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) ≤ 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0101 / N/A	155	N/A	MIPS CQM Specifications	Process	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
§	N/A / N/A	326	N/A	MIPS CQM Specifications	Process	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	3620 / N/A	493	N/A	MIPS CQM Specifications	Process	**Adult Immunization Status**: Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance

B.41. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.41. Skilled Nursing Facility

MEASURES FINALIZED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Skilled Nursing Facility specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1078] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1079] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62485), we are finalizing the above measure(s) for addition to the *Skilled Nursing Facility Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1078] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1079] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68 v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v 14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	MIPS CQM Specifications	Process	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS13 8v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	291	N/A	MIPS CQM Specifications	Process	**Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.	American Academy of Neurology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.42. Speech Language Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / 2872e	281	CMS149v13	eCQM Specifications	Process	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology	We proposed to include this measure in the Speech Language Pathology specialty set as it would be clinically relevant to this clinician type. Speech language pathologists (SLPs) utilize standardized instruments with demonstrated reliability for dementia screening. These instruments typically assess orientation to time, place, and person.[1080] Other tests (for example, story recall/story retelling) assess episodic memory and can be useful for screening early dementia.[1081] If screening reveals cognitive impairment, the individual is referred to an SLP for a comprehensive evaluation of communicative function. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. Appropriate coding was not included in the final specification; therefore, this measure is not being finalized for addition to this specialty measure set.

[1080] Rabin, L. A., Paré, N., Saykin, A. J., Brown, M. J., Wishart, H. A., Flashman, L. A., & Santulli, R. B. (2009). Differential Memory Test Sensitivity for Diagnosing Amnestic Mild Cognitive Impairment and Predicting Conversion to Alzheimer's Disease. *Aging, Neuropsychology, and Cognition, 16*(3), 357–376. https://doi.org/10.1080/13825580902825220.

[1081] See footnote Rabin et al., 2009.

B.42. Speech Language Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	282	N/A	MIPS CQM Specifications	Process	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology/ American Psychiatric Association	We proposed to include this measure in the Speech Language Pathology specialty set as it will be clinically relevant to this clinician type. SLPs play a critical role in diagnosis and management of dysphagia in patients with dementia through comprehensive assessment, diet consistency modifications, educating their caregiver on the use of compensatory strategies, prescribing exercise programs, and referring them to other professionals as needed. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

B.42. Speech Language Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQM Specifications	Process	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology	We proposed to include this measure in the Speech Language Pathology specialty set as it will be clinically relevant to this clinician type. Dementia patients are at high risk for safety concerns due to underlying cognitive communication impairment which may impact judgment, reasoning, and memory as well as physical weakness resulting from other medical conditions.[1082] SLPs work directly with individuals with dementia and their caregivers to screen, assess, and establish care plans to address these issues through cognitive-communication exercises, use of compensatory strategies, environmental modifications, referrals to other professionals, and providing caregiver training. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

[1082] Thyrian, J. R., Hertel, J., Wucherer, D., Eichler, T., Michalowsky, B., Dreier-Wolfgramm, A., Zwingmann, I., Kilimann, I., Teipel, S., & Hoffmann, W. (2017). Effectiveness and Safety of Dementia Care Management in Primary Care: A Randomized Clinical Trial. *JAMA Psychiatry*, *74*(10), 996–1004. https://doi.org/10.1001/jamapsychiatry.2017.2124.

B.42. Speech Language Pathology

MEASURES FINALIZED AND NOT FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQM Specifications	Process	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology / American Psychiatric Association	We proposed to include this measure in the Speech Language Pathology specialty set as it will be clinically relevant to this clinician type. SLPs provide information about the nature of dementia and its course of progression. SLPs make recommendations for environmental modifications, such as using alarms and pill boxes for medication reminders, visual aids, and provide education on communication strategies and modifications to caregiver behaviors to ensure the safety of the patient and compliance with the plan of care. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQM Specifications	Process	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression).	American Academy of Neurology	We proposed to include this measure in the Speech Language Pathology specialty set as it will be clinically relevant to this clinician type. Over the course of the disease, individuals with ALS exhibit difficulty producing intelligible speech to communicate basic needs and wants.[1083] SLPs are trained to address communication deficits via exercise programs, use of communication strategies, and introducing augmentative and alternative communication (AAC) methods. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

[1083] National Institute of Neurological Disorders and Stroke. (2024). Amyotrophic Lateral Sclerosis. https://www.ninds.nih.gov/health-information/disorders/amyotrophic-lateral-sclerosis-als.

Comment: One commenter supported the proposed addition of measure Q281: Dementia: Cognitive Assessment, measure Q282: Dementia: Functional Status Assessment, measure Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia, measure Q288: Dementia: Education and Support of Caregivers for Patients with Dementia, and measure Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences to this specialty set.

Response: We thank the commenter for supporting the addition of these measures to the Rheumatology specialty set.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 624 62488 through 62490), we are finalizing the above measure(s) for addition to the *Speech Language Pathology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years: measures Q282, Q286, Q288, and Q386. Measure Q281 was not finalized for addition to this specialty set because applicable coding was not added for the measure to be reported by this specialty. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set. This specialty set had no measures proposed for addition or removal. Measures with substantive changes as marked with an asterisk (*) are addressed under Table Group D.

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0115 / N/A	168	N/A	MIPS CQM Specifications	Outcome	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization.	Society of Thoracic Surgeons
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	356	N/A	MIPS CQM Specifications	Outcome	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.43. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQM Specifications	Outcome	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic order.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	066	CMS146v13	eCQM Specifications, MIPS CQM Specifications	Process	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic order on or within 3 days after the episode date and a group A Streptococcus (Strep) test in the seven-day period from three days prior to the episode date through three days after the episode date.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQM Specifications	Process	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQM Specifications	Process	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQM Specifications	Process	**Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.44. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.44. Urgent Care

MEASURES FINALIZED FOR **ADDITION** TO THE URGENT CARE SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	488	CMS95 1v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation	We proposed to include this measure in the Urgent Care specialty set as it will be clinically relevant to this clinician type. This measure encourages an estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR) evaluation annually for patients diagnosed with diabetes. The measure aims for early detection which can reduce associated health risk of the co-morbidities of diabetes and CKD. Having an established source of care is important in this high-risk population, however, in the general US population, approximately 15 percent of adults do not have a primary care physician.[1084] According to the American Diabetes Association annual assessment of glomerular filtration rate (GFR) in adolescents, in addition to adults, with diabetes is necessary to appropriately screen for early diabetic nephropathy, and the assessment of GFR is essential to accurately diagnose diabetic kidney disease early in the disease process.[1085] Including this measure in this specialty set could assist in capturing at-risk patients who may lack a primary care physician.

We received no public comments on the measure(s) proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (89 FR 62497), we are finalizing the above measure(s) for addition to the *Urgent Care Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

[1084] Toth-Manikowski, S. M., Hsu, J. Y., Fischer, M. J., Cohen, J. B., Lora, C. M., Tan, T. C., He, J., Greer, R. C., Weir, M. R., Zhang, X., Schrauben, S. J., Saunders, M. R., Ricardo, A. C., Lash, J. P., & Chronic Renal Insufficiency Cohort (CRIC) Study Investigators (2022). Emergency Department/Urgent Care as Usual Source of Care and Clinical Outcomes in CKD: Findings From the Chronic Renal Insufficiency Cohort Study. *Kidney Medicine*, *4*(4), 100424. https://doi.org/10.1016/j.xkme.2022.100424.

[1085] Bjornstad, P., Cherney, D. Z., & Maahs, D. M. (2015). Update on Estimation of Kidney Function in Diabetic Kidney Disease. *Current Diabetes Reports*, *15*(9), 57. https://doi.org/10.1007/s11892-015-0633-2.

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	MIPS CQM Specifications	Process	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	N/A / N/A	102	CMS129v14	eCQM Specifications, MIPS CQM Specifications	Process	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Safety)	N/A / N/A	130	CMS68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	134	CMS2v14	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022/ N/A	238	CMS156v13	eCQM Specifications, MIPS CQM Specifications	Process	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	**CAHPS for MIPS Clinician/Group Survey**: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The CBE endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by CBE) • How well Providers Communicate; (Not endorsed by CBE) • Patient's Rating of Provider; (CBE endorsed # 0005) • Access to Specialists; (Not endorsed by CBE) • Health Promotion and Education; (Not endorsed by CBE) • Shared Decision-Making; (Not endorsed by CBE) • Health Status and Functional Status; (Not endorsed by CBE) • Courteous and Helpful Office Staff; (CBE endorsed # 0005) • Care Coordination; (Not endorsed by CBE) • Stewardship of Patient Resources. (Not endorsed by CBE)	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQM Specifications	Process	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	432	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogyneco-logic Society
§ ! (Appropriate Use)	0210/ N/A	453	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0216/ N/A	457	N/A	MIPS CQM Specifications	Process	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645v8	eCQM Specifications	Process	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	476	CMS771v6	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute
! (Appropriate Use)	N/A/ N/A	481	CMS646v5	eCQM Specifications	Process	**Intravesical Bacillus-Calmette Guerin for Non-Muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.	Oregon Urology
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services
*	N/A / N/A	488	CMS951v3	eCQM Specifications, MIPS CQM Specifications	Process	**Kidney Health Evaluation:** Percentage of patients aged 18-85 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the performance period.	National Kidney Foundation
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.45. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	2483 / N/A	503	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Gains in Patient Activation Measure (PAM®) Scores at 12 Months:** The Patient Activation Measure® (PAM®) is a 10 – or 13 – item questionnaire that assesses an individual´s knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.45. Urology

MEASURES FINALIZED FOR **ADDITION** TO THE UROLOGY SPECIALTY SET								
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	508	N/A	MIPS CQM Specifications	Process	**Adult COVID-19 Vaccination Status:** Percentage of patients aged 18 years and older seen for a visit during the performance period that are up to date on their COVID-19 vaccinations as defined by Centers for Disease Control and Prevention (CDC) recommendations on current vaccination.	Centers for Medicare & Medicaid Services	We proposed to include this measure in the Urology specialty set as it will be clinically relevant to this clinician type. Widespread vaccination against SARS-CoV-2, the virus that causes COVID-19, is critically important to stemming the morbidity and mortality caused by this disease.[1086] Clinicians are uniquely positioned to encourage uptake of COVID-19 vaccination, and clinicians are still a major driving force in promoting patient vaccination. The addition of this quality measure in this specialty set will help strengthen compliance with recommended COVID-19 vaccination, leading to improvement in the quality of patient care and prevention of disease for the general population. This quality measure aligns with clinical guidelines and the evidence-based recommendations of the ACIP, where there is general agreement about the safety and efficacy of the COVID-19 vaccine, preventing costly and potentially harmful hospitalizations.[1087] Broadening vaccination status awareness to this clinician type is valuable as it can help drive an increase in the adult vaccination rates. The COVID-19 vaccination included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2025 PFS final rule. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty set. See Table A.5 of this Appendix for rationale, including clinical evidence supporting the inclusion of this measure in MIPS.

We received public comments on the measure(s) proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed the proposed addition of the Adult COVID-19 Vaccination Status measure to the Urology specialty set as it is not clear why this vaccination status measure has been proposed for inclusion when other vaccination-focused measures have not.

[1086] See footnote Ikeokwu et al., 2023 in Table B.1 of this Appendix.

[1087] See footnotes Fitzpatrick et al., 2022; Polack et al., 2020; and Graña et al., 2022 in Table A.5 of this Appendix.

Response: We acknowledge the commenters concerns; however, MIPS eligible clinicians will not be required to report this measure because they have the flexibility to choose measures that are relevant and meaningful to their practice. This measure provides an opportunity to discuss vaccines with the patient. This measure represents an important clinical topic following the recently ended PHE for COVID-19. This process measure represents a CMS high priority clinical topic and fills a gap in MIPS by addressing COVID-19 vaccination status for all patients and ensuring clinician vaccination efforts at the point of care (for example, care for wellness and prevention against COVID-19). The COVID-19 vaccination is relevant for inclusion to the Urology specialty set because it is recommended for everyone 6 months and older including cancer patients who are at an increased risk for severe COVID-19. As a urologist's case mix may include cancer patients (for example, prostate and bladder cancers), it is in alignment with other measures within the specialty set. We acknowledge that other vaccinations are recommended for this patient population; however, cancer patients may be more vulnerable to COVID-19 related illness. Given the vaccination rate for COVID-19 is lower than the vaccination rate for other viruses, such as the vaccination rate for influenza, it is important to continue to drive administration, especially within the "at-risk" population.

For the reasons stated above and in the proposed rule (89 FR 62504), we are finalizing the above measure(s) for addition to the *Urology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Where applicable, see Table Group A of this Appendix for any comments and responses pertaining to new measures that were proposed for addition to MIPS.

B.45. Urology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE UROLOGY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	104	N/A	MIPS CQM Specifications	Process	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.
N/A / N/A	433	N/A	MIPS CQM Specifications	Outcome	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received public comments on the measure(s) proposed for removal from this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed the proposed removal of measure Q104 from the Urology specialty set and disagreed that the measure covers a limited patient population.

Response: We acknowledge the concerns expressed by the commenter. While we agree the concept is important to quality care, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. As mentioned in Table C.1 of this Appendix, the low adoption of this quality measure due to the complexity of reporting, resulting in a limited denominator eligible patient population, has not allowed for the creation of a benchmark. Additionally, when the measure was able to produce a benchmark in past performance periods it showed continued high performance, establishing this measure as a standard of care. By removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the benchmark files.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62505), we are finalizing the above measure(s) for removal from the *Urology Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines, and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures we are maintaining within the set, measures proposed to be added, and measures proposed for removal, as applicable.

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQM Specifications	Process	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Patient Safety)	N/A / N/A	130	CMS 68v14	eCQM Specifications, MIPS CQM Specifications	Process	**Documentation of Current Medications in the Medical Record:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	226	CMS 138v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 12 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention during the measurement period or in the six months prior to the measurement period if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS 165v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Intermediate Outcome	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	259	N/A	MIPS CQM Specifications	Outcome	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgery
*	N/A / N/A	317	CMS 22v13	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications	Process	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	344	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery
! (Outcome)	N/A / N/A	357	N/A	MIPS CQM Specifications	Outcome	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQM Specifications	Process	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS 50v13	eCQM Specifications, MIPS CQM Specifications	Process	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	420	N/A	MIPS CQM Specifications	Patient-Reported Outcome-Based Performance Measure	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
§ ! (Outcome)	N/A / N/A	441	N/A	MIPS CQM Specifications	Intermediate Outcome	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
! (Equity)	N/A / N/A	487	N/A	MIPS CQM Specifications	Process	**Screening for Social Drivers of Health:** Percent of patients 18 years and older screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.	Centers for Medicare & Medicaid Services

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* ! (Equity)	N/A / N/A	498	N/A	MIPS CQM Specifications	Process	**Connection to Community Service Provider:** Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.	OCHIN

B.46. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE VASCULAR SURGERY SPECIALTY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.							
CBE # / eCQM CBE #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
NA / NA	260	N/A	MIPS CQM Specifications	Outcome	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgery	This measure was proposed for removal beginning with the CY 2025 performance period/2027 MIPS payment year. See Table Group C for rationale.

We received no public comments on the measure(s) proposed for removal from this specialty set. For the reasons stated above and in the proposed rule (89 FR 62509), we are finalizing the above measure(s) for removal from the *Vascular Surgery Specialty Set* as proposed for the CY 2025 performance period/2027 MIPS payment year and future years. Note: Where applicable, see Table Group C of this Appendix for any comments and responses pertaining to measures that were proposed for removal from MIPS.

Table Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

In this final rule, we are removing 10 of the 11 previously finalized MIPS quality measures proposed for removal for the CY 2025 performance period/2027 MIPS payment year and future years. These measures are discussed in detail in the removal tables below. We note measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques was already finalized for removal with a 1-year delay to the CY 2025 performance period as noted in the Table Group B introduction (89 FR 62268); therefore, measure Q436 does not have a removal table in this final rule and there are 10 removal tables under Table Group C.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discusses our incremental approach to removing process measures. Under section IV.A.4.e.(1)(d)(ii)of this final rule, removal criteria are being finalized at 414.1330(c).

NOTE: Since publication of the measures in Table Group C in the CY 2025 PFS proposed rule (89 FR 62509 through 62515), we have determined the following measure will be retained in the CY 2025 performance period/2027 MIPS payment year: Q144 as detailed under Table C.3 of this Appendix.

As noted in the introduction to Table Group B, measures that were not finalized for removal under Table Group C have been added back to the Previously Finalized tables, where applicable, and removed from the Removal tables, under the appropriate specialty set in Table Group B.

C.1. Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	104
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.
Measure Steward:	American Urological Association Education and Research
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the limited patient population as well as adoption of this quality measure does not allow for the creation of a benchmark. For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf*. The current 2024 MIPS benchmarking data is located at *https://qpp.cms.gov/benchmarks.*
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q104: Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter opposed removal of measure Q104 because it focuses on a "must-do" clinical process linked to overall survival over many years, as supported by multiple randomized controlled trials. While the commenter acknowledged the low uptake of the measure, they disagreed with CMS that it covers a limited patient population and noted the American Cancer Society recently reported an increase in incidence of advanced-stage disease for prostate cancer (*https://pressroom.cancer.org/FactsandFigures23*), making this measure even more relevant for urologists and others who provide care to those with prostate cancer. A second commenter did not support the removal of measure Q104.

Response: While we agree the measure concept is important to quality care, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. As mentioned above, the low adoption of this quality measure due to complexity of reporting, resulting in a limited denominator eligible patient population, has not allowed for the creation of a benchmark. Additionally, when the measure was able to produce a benchmark in past performance periods it showed continued high performance, establishing this as a standard of care. By removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped-out status would limit the score awarded per the benchmark files.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62510), we are finalizing the removal of measure Q104 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.2. Melanoma: Continuity of Care – Recall System

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	137
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of the Melanoma: Tracking and Evaluation of Recurrence measure being proposed in Table A.6 of this Appendix. Measure Q137 establishes a recall system linked to the process of notifying patients, with a current diagnosis or history of melanoma, when their next physical exam is due, as well as to follow up with patients who did not make an appointment within the specified timeframe or who missed a scheduled appointment. It does not assess whether the patient completed an annual skin exam nor if the process to follow up for those patients who missed an appointment is effective. The new measure proposed in Table A.6 of this Appendix is a process measure that not only assesses a significantly similar patient population, but also assesses patients who had excisional surgery for melanoma or melanoma in situ in the past 5 years for completion of an exam and/or diagnosed for recurrence of melanoma. The new measure provides a more meaningful impact to quality improvement for this patient population.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q137: Melanoma: Continuity of Care – Recall System.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter did not support the removal of measure Q137 because the new measure Melanoma: Tracking and Evaluation of Recurrence under Table A.6 of this Appendix seemed more in-depth and complex. The commenter indicated the new measure is limited to the operating clinician who completes the excisional surgery, which in many cases is not the clinician who follows up with the patients for regular skin exams and had concerns of who would be responsible for tracking and reporting the new measure. The commenter requested clarification on whether CMS would use numerator criteria 1 or numerator criteria 2 for the scoring of the new measure, stating their concern that data completeness would be hard to meet as they do not want to diagnose 20+ melanoma recurrences for each MIPS eligible clinician annually. The commenter suggested instead of removing measure Q137 that CMS drop measure Q137 to the 7-point threshold for topped-out measures so it can still be reported.

Response: We thank the commenter for their feedback and acknowledge that this measure addresses a critical element in ensuring patients receive annual follow-up appointments. We agree that in many cases the clinician who follows up with a patient who has had excisional surgery may not be the same clinician who performed the procedure. The measure does allow for the surgeon to utilize medical record documentation to determine numerator compliance and measure performance. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Based on the comments received, we recognize that this measure represents an important component in early identification of recurrence for melanoma that will drive timely and appropriate care. The Dermatology specialty set does not meet the threshold, which is 75 percent of available quality achievement points, to be considered 'at-risk'; therefore, this measure does not meet the criteria to be reviewed for possible 7-point cap removal (89 FR 62079). As such, the measure will not allow clinicians to reach maximum points for their quality score.

Comment: One commenter stated the new measure is not duplicative of measure Q137. Measure Q137 ensures the necessary infrastructure is in place for scheduling follow-up exams for melanoma patients, complementing the new measure that tracks the occurrence of these exams. Retaining measure Q137 addresses different aspects of patient care and supports dermatologists in participating in MIPS with a relevant, specialty-specific measure that is not topped out, enhancing quality improvement and positive patient outcomes.

Response: Both the new measure proposed in Table A.6 of this Appendix and measure Q137 assess a similar patient population with a diagnosis or history of melanoma. As noted earlier, while measure Q137 establishes a recall system linked to the process of notifying patients, when their next physical exam is due, as well as follows up with patients who did not make an appointment within the specified timeframe or who missed a scheduled appointment, it does not assess whether the patient completed an annual skin exam. In addition, the new proposed measure assesses patients who had excisional surgery for melanoma or melanoma in situ in the past 5 years for completion of an exam and if they're diagnosed for recurrence of melanoma. It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care.

Comment: One commenter opposed removal of measure Q137 due to the complexity and potential unintended consequences of the proposed measure. The proposed measure introduces a level of depth and complexity that may prove prohibitive for many clinicians, potentially leading to a reduction in the quality of care for the melanoma patient population. Without the existing structured recall system in place, there is a considerable risk that patients may experience a higher incidence of melanoma recurrence due to lapses in follow-up care. To address this concern, the commenter requested that CMS consider lowering the threshold for measure Q137 to the 7-point threshold for topped-out measures.

Response: It is important to ensure duplicative measures are removed from MIPS to develop an ecosystem of quality measures that drive value-based care. This measure was previously included within MIPS as a QCDR measure and was shown to be implementable. We encourage clinicians to provide care as they determine best supports all patients during their healthcare journey even if the patient population is not included within the targeted denominator of a given measure specification. This measure does not meet the criteria to have the 7-point cap removed and as such, will not allow for clinicians to reach maximum allowed points for their quality score.

Comment: One commenter opposed removal of measure Q137, stating that the type of data currently being used by practices to satisfy this measure is difficult to translate to the new proposed measure. The American Joint Committee on Cancer (AJCC) staging references (*https://www.facs.org/quality-programs/cancer-programs/american-joint-committee-on-cancer/cancer-staging-systems/)* are usually documented in PDF files, rather than in structured text that can be easily mapped to EHR fields. As a result, identifying the appropriate denominator population for the new proposed measure would be very challenging for practices. In addition, the commenter indicated that the 5-year lookback period for the new Melanoma: Tracking and Evaluation of Recurrence measure could further complicate accurate denominator calculations due to transitions between EHR systems. When practices switch to new EHR systems, historical data from the previous EHR is often retained as PDF attachments rather than as structured data fields. The commenter also noted that dermatology has limited benchmarked quality measures and urged CMS to take this into account and maintain sufficient specialty-specific MIPS quality measures.

Response: We thank the commenter for their feedback. The intent of this measure overlaps with the new measure proposed in Table A.6 of this Appendix, leading to the positive outcome of determining recurrence in a timely manner. Coding within the new measure specification would allow clinicians to map their system to identify the appropriate patient population which includes patients with an excisional surgery for melanoma or melanoma in situ in the past 5 years with an initial AJCC Staging of 0, I, or II. Removal of measure Q137 does not preclude clinicians from continued use of a recall system which enables providers to ensure that patients receive follow-up appointments in accordance with their individual needs. We recognize that due to nuances in clinician specialization, scope of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62510), we are finalizing the removal of measure Q137 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.3. Oncology: Medical and Radiation – Plan of Care for Pain

Category	Description
CBE# / eCQM CBE #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. Measure Q143 specifically questions cancer patients, currently receiving chemotherapy or radiation therapy, to quantify their pain intensity at each visit using a standardized tool. This measure is more robust than measure Q144 as it encourages the clinician to initiate a discussion regarding pain intensity with the patient at every denominator eligible visit. Measure Q144 is narrower in scope focusing on cancer patients identified with pain. To identify this patient population, a clinician will still need to screen their patients. Measure Q143 promotes screening of a broader patient population for pain, which still allows clinicians to administer care if pain is present. Additionally, measure Q143 is available for reporting within the eCQM collection type, allowing clinicians more measure options if reporting via eCQMs.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q144: Oncology: Medical and Radiation – Plan of Care for Pain.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: A number of commenters opposed the removal of measure Q144 from MIPS. Key opposition to removing the measure was that measure Q144 is not duplicative of, but rather paired with, Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. Commenters indicated the measures should be implemented sequentially to achieve a comprehensive clinical quality outcome, with measure Q143 confirming that the patient's pain was evaluated and measure Q144 validating that a patient care plan for pain was developed based on that assessment. The intent is for clinicians to report on both measures as a unit, while resulting in individual measure scores.

Commenters also indicated that both measures were recently re-endorsed by the CBE as part of its Fall 2023 Endorsement and Maintenance cycle, and the observed performance rates of measure Q144 from the 2019-2021 performance periods indicate opportunity for improvement at both the individual clinician and practice level. One commenter recommended that measures Q143 and Q144 be combined into one combined measure. Additional reasons that commenters cited for opposing the removal of measure Q144 included: it would cause misalignment with CMMI's Enhancing Oncology Model *(https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model);* the measure strengthens the Advancing Cancer Care MVP under Appendix 3, Table B.2; it would be difficult to meet MIPS reporting requirements under traditional MIPS or MVPs for practices limited by their EHR's quality measure selection; practices would need to train staff on new workflows for quality measures; and pain management and improvement in pain are top health care priorities.

Response: The measure steward is currently evaluating respecifying measures Q143 and Q144 into a single, combined measure and requested that both measures be retained at this time. We encourage the commenters to work with the measure steward as these measures are considered for revision.

Based on the potential for revision to these measures in future rulemaking, and after consideration of public comments, we are not finalizing the removal of measure Q144 as proposed for the CY 2025 performance period/2027 MIPS payment year. Therefore, the measure has been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix. If the measure is not combined for CY2026, we will revisit the removal of measure Q144 for the CY2026 performance period/2028 MIPS payment year and future years.

C.4. Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	254
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Measure Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286).[1088] This measure's continued topped-out status is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf*.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: One commenter requested that CMS retain topped out measures proposed for removal, such as measure Q254. The commenter urged CMS to work with interested parties to come up with a reasonable solution for maintaining measures with a median performance rate of 95 percent or higher, whether it is (a) subjecting them to the newly proposed defined topped out measure benchmark; (b) maintaining them as pay-for-reporting measures (which would allow a clinician to continue to earn points and track performance even if they are not being scored on performance); or, (c) some other innovative solution to ensure high performance on these measures is monitored and maintained over time.

Response: We thank the commenter for their feedback. However, the data shows the measure has reached the end of its topped-out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2024 Benchmark File. Under the finalized methodology for determining which specialty measure sets may be considered 'at-risk', the Emergency Medicine specialty set does not meet the 'at-risk' threshold, which is 75 percent of available quality achievement points; therefore, this measure does not meet the criteria to be reviewed for possible 7-point cap removal (89 FR 62079).

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62511), we are finalizing the removal of measure Q254 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1088] See the 2024 MIPS Call for Measures Fact Set: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2711/2024-MIPS-Call-for-Measures-and-Activities.zip.

C.5. Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	260
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.
Measure Steward:	Society for Vascular Surgery
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure will be duplicative of measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) if the proposed changes to the measure are finalized. We proposed in Table D.34 of this Appendix substantive changes to measure Q344, which describe the inclusion of the measure concept represented in Q260. Measure Q260 is focused on performing CEA on asymptomatic patients who are at low risk for morbidity and therefore are expected to have very low complication rates as indicated by patients being discharged to home by post-operative day #2. As a result, we proposed to maintain measure Q344 and remove measure Q260 from MIPS.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2).

Response: We thank the commenter for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62511 through 62512), we are finalizing the removal of measure Q260 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.6. Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	409
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q409: Clinical Outcome Post Endovascular Stroke Treatment.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62512), we are finalizing the removal of measure Q409 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.7. Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	433
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure will be duplicative of measure Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair, if the proposed changes to the measure are finalized. We proposed in Table D.46 of this Appendix substantive changes to measure Q432, which describe the inclusion of the measure concept represented in measure Q433. In addition, we proposed to update the measure title and description for measure Q432 to include patients who sustain a bowel injury at the time of any pelvic organ prolapse repair.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q433: Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62513), we are finalizing the removal of measure Q433 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.8. Age Appropriate Screening Colonoscopy

Category	Description
CBE# / eCQM CBE #:	N/A / N/A
Quality #:	439
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because the quality action being measured has become standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.15 percent for the MIPS CQM collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQM collection type is considered extremely topped out. The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks.* For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf.*
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q439: Age Appropriate Screening Colonoscopy.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: Two commenters opposed removal of measure Q439. The commenters did not believe MIPS performance data is an accurate assessment to determine whether this measure was topped out and stated that CMS' analysis was insufficient to make the determination. CMS' analysis was based on one year of benchmarking data following the substantive changes made to the measure specification in PY2022. The amount of time to verify the extremely topped-out status should be based on multiple years, not one performance year cycle, and no other multi-year data was used to validate the topped-out status or extremely topped-out status, which typically occurs over multiple performance year cycles. Furthermore, the commenters stated that measure Q439 has been designated by CMS as a high-priority measure and as the only colorectal cancer screening measure that specifically addresses the vulnerable population of older adults.

The commenters indicated that measure Q439 is one of six measures included in the GIQuIC qualified clinical data registry (QCDR) measure set, three of which are QPP measures and three of which are GIQuIC QCDR measures. It is the six quality measures that make up the GIQuIC QCDR measure set that balance the only specialty-specific cost measure included in the candidate GI Care MVP, the Screening/Surveillance Colonoscopy episode-based cost measure. The commenters requested that this measure be given an appropriate glidepath for removal, so gastroenterologists have time to determine an alternative meaningful measure on which to assess their practice and report.

Response: While we agree that the intent of measure Q439 is to encourage age-appropriate colonoscopy screenings, this measure is extremely topped out which further demonstrates that age-appropriate colonoscopies have become a standard of care. Our analysis was sufficient in determining that this measure was topped out because both a historical benchmark for PY2024 and a performance period benchmark for PY2023 was produced showing extremely topped out performance in both instances. Additionally, removal of this measure leaves a sufficient number of measures available, 13, within the gastroenterology specialty set. This measure was previously proposed for removal for the CY 2023 performance period/2025 MIPS payment year due to low adoption, however, we did not remove it at that time based on comments received including the request to maintain the measure for two years to ascertain performance based upon the measure revisions requested (see 87 FR 70541). The updated measure specification has been available for use in MIPS for multiple years and has continued to demonstrate extremely high performance. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2024 Benchmark File. While this measure was updated for PY2022, both an historical benchmark for PY2024 and a performance period benchmark for PY2023 was produced showing extremely topped out performance in both instances. We encourage the GIQuIC QCDR to adopt alternate quality measures or develop new quality measures to ensure a robust offering for their clients.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62513), we are finalizing the removal of measure Q439 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.9. Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Category	Description
CBE# / eCQM CBE #:	1860 / N/A
Quality #:	452
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM Specifications
Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 81 FR 77558 through 77675) because this measure is duplicative of measure Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy. Measures Q451 and Q452 ask the same clinical question but approach questioning from different clinical perspectives. Measure Q451 assesses patients who have already received anti-EGFR monoclonal therapy to determine if they received RAS gene mutation testing prior to initiation of therapy, while measure Q452 is a standard-of-care measure, as well as the counter clinical perspective to measure Q451. Measure Q452 only evaluates for patients who received anti-EGFR monoclonal treatment. Therefore, measure Q452 is a component of the quality action within measure Q451. The molecular biomarkers for the evaluation of colorectal cancer guidelines[1089] strongly recommend "Patients with colorectal carcinoma being considered for anti-EGFR therapy must receive RAS mutational testing," which is the standard of care being evaluated by this measure. Measure Q451 provides an opportunity for a retrospective review and has the potential to improve clinical outcomes. For example, if the performance rates show there is a gap in medical care or high incidence of initiating therapy without first testing for the RAS gene mutation, clinical processes can be revised to improve practice. "Clinical care review is the process of retrospectively examining potential errors or gaps in medical care, with a goal of future practice improvement." [1090]
In the Circumstance the Measure Was Retained:	If the measure was not finalized for removal in the CY 2025 PFS final rule, we proposed to apply the following substantive changes to the measure specifications: (1) add denominator instructions to clarify the denominator eligible timeframe for diagnosis and (2) only patients who have been newly diagnosed with Stage IV colorectal cancer, or patients who have distant metastases at the time of colon cancer diagnosis, are to be included in the denominator of the measure to ensure the appropriate patient population is assessed for the numerator action. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for its retention would have been addressed under Table Group C. The substantive changes outlined above will be applied to the measure specifications.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed removal of measure Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

[1089] Sepulveda, A. R., Hamilton, S. R., Allegra, C. J., Grody, W., Cushman-Vokoun, A. M., Funkhouser, W. K., Kopetz, S. E., Lieu, C., Lindor, N. M., Minsky, B. D., Monzon, F. A., Sargent, D. J., Singh, V. M., Willis, J., Clark, J., Colasacco, C., Rumble, R. B., Temple-Smolkin, R., Ventura, C. B., & Nowak, J. A. (2017). Molecular Biomarkers for the Evaluation of Colorectal Cancer: Guideline From the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and the American Society of Clinical Oncology. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology, 35(13)*, 1453–1486. https://doi.org/10.1200/JCO.2016.71.9807.

[1090] Walker, L. E., Nestler, D. M., Laack, T. A., Clements, C. M., Erwin, P. J., Scanlan-Hanson, L., & Bellolio, M. F. (2018). Clinical Care Review Systems in Healthcare: A Systematic Review. *International Journal of Emergency Medicine*, *11*(1), 6. https://doi.org/10.1186/s12245-018-0166-y.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62514), we are finalizing the removal of measure Q452 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

C.10. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
CBE# / eCQM CBE #:	N/A / 3475e
Quality #:	472
CMS eCQM ID:	CMS249v7
Collection Type:	eCQM Specifications
Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS (finalized in 83 FR 60104 through 60105) because the quality action being measured has become standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 1.1 percent for the eCQM collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the eCQM collection type is considered extremely topped out. The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks.* For more information on benchmarks, see the MIPS 2024 Quality Benchmarks User Guide at *https://www.cms.gov/files/document/2024-quality-benchmarks-user-guide-scoring-examples-pdf.pdf*.
In the Circumstance the Measure Was Retained:	There were no substantive changes or specialty set movement proposed for this measure. If the measure was not finalized for removal in the CY 2025 PFS final rule, it would have been added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed removal of measure Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture. One of these commenters agreed with the proposed removal of this measure, particularly given that it is topped out.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

Comment: One commenter did not support the removal of measure Q472. The commenter was concerned about the significant number of measure removals from certain specialties and urged CMS to be mindful when removing multiple measures from specialties so as to ensure sufficient measures remain in MIPS that are pertinent to those specialties

Response: We acknowledge that removal of this measure decreases the number of available measures for certain specialists; however, there are policies in place, such as Eligible Measure Applicability (EMA) and denominator reduction to account for this when working to meet MIPS quality performance category requirements. Additionally, these nuances are considered when reviewing the MIPS quality measure inventory.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62515), we are finalizing the removal of measure Q472 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

Table Group D: Finalized Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

The D Tables within this final rule provide the substantive changes finalized for the MIPS quality measures in CY 2025. We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in section IV.A.4.c.(3) of this final rule. For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group D.

The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2025 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2025 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2026. The 2025 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*. In addition, eCQMs that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2025 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has also been added, to all applicable 2025 quality measure specifications, in the form of an 'Instructions Note' to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only where telehealth encounters previously were not allowed as denominator eligible will the D table corresponding to a measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the finalized substantive changes, there may be revisions within the logic that are not considered substantive in nature, however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

D.1. Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
CBE # / eCQM CBE #:	0059 / N/A
Quality #:	001
CMS eCQM ID:	CMS122v13
Current Collection Type:	Medicare Part B Claims Measure Specifications/ eCQM Specifications/ MIPS CQM Specifications/ Medicare CQM Specifications (collection type available only in the APP and/or APP Plus)
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**The measure title is revised from "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)" to:** Diabetes: Glycemic Status Assessment Greater Than 9%. **The measure description is revised to read: For all collection types:** Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period. **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion. **The measure numerator is revised to read: For all collection types:** Patients whose most recent glycemic status assessment (HbA1c or GMI) (performed during the measurement period) is > 9.0% or is missing, or was not performed during the measurement period. **Updated guidance: For the eCQM Specifications collection type: Revised:** If the glycemic status assessment (HbA1c or GMI) is in the medical record, the test can be used to determine numerator compliance. **Added:** Glycemic status assessment (HbA1c or GMI) must be reported as a percentage (%). If multiple glycemic status assessments were recorded for a single date, use the lowest result. **Updated numerator instructions: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** GMI as an assessment option. **Updated numerator options: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** GMI as an assessment option. **Updated numerator note: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added**: If multiple glycemic status assessments were recorded for a single date, use the lowest result.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We proposed to revise this measure to include glucose management indicators (GMI) to broaden the acceptable methods for monitoring the glycemic status of patients with diabetes. This measure revision supports those clinicians that are using this monitoring method to ensure management of persons with diabetes using continuous glucose monitoring.[1091] We also proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q001. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the frailty exclusion criteria to measure Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%). The removal of the encounter criteria will reduce reporting burden while still following through with the intent of the exclusion for patients with an indication of frailty. A second commenter appreciated the proposed substantive changes proposed to this measure.

[1091] ElSayed, N. A., Aleppo, G., Aroda, V. R., Bannuru, R. R., Brown, F. M., Bruemmer, D., Collins, B. S., Hilliard, M. E., Isaacs, D., Johnson, E. L., Kahan, S., Khunti, K., Leon, J., Lyons, S. K., Perry, M. L., Prahalad, P., Pratley, R. E., Seley, J. J., Stanton, R. C., Gabbay, R. A., … on behalf of the American Diabetes Association (2023). 7. Diabetes Technology: Standards of Care in Diabetes-2023. *Diabetes Care*, *46*(Suppl 1), S111–S127. https://doi.org/10.2337/dc23-S007.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: One commenter supported the proposed substantive changes exclusion because aggressive glycemic control may not be appropriate for all older adults, especially those with advanced illness. A second commenter appreciated the proposed substantive changes to update the measure title and specifications, per revised HEDIS specifications, so that it now includes glycemic status indicator (GMI). However, the commenter requested clarification regarding how the exclusions for frailty and/or advanced illness will work at an operational level in medical clinics. The commenter questioned whether these exclusions occur automatically based on claims, and if so, how will CMS communicate the exclusions back to each patient's clinician?

Response: To meet the exclusion for frailty and/or advanced illness, the measure still requires patients 66 years of age and older to have at least one claim/encounter for frailty during the measurement period AND an advanced illness diagnosis during the measurement period or the year prior to the measurement period. As noted above, removal of the additional requirement for patients to have had either one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. When submitting this measure, the clinician would report on patients based upon the information within the medical record in accordance with the current measure specification. The update to the denominator exclusion does not change how the measure data may be captured and reported only the criteria to determine whether a patient is appropriate for the quality action assessment.

If reporting via the Medicare Part B Claims Measure collection type, the exclusion is factored into the calculation of the measure based upon the information submitted on the claim(s) forms in accordance with the measure specification. However, if reporting via MIPS CQM or eCQM collection types, the MIPS eligible clinician would be required to meet the measure requirements as posted and ensure the patient's medical record substantiates all data submitted. While eCQM collection type is specific to data abstraction from the electronic health record as a data source, MIPS CQM collection type is constructed to be instructional for use within any data source available, and how a system is mapped to pull the information, as specified, is at the discretion of the reporting clinician/group.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62517), we are finalizing the changes to measure Q001 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.2. Anti-Depressant Medication Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	009
CMS eCQM ID:	CMS128v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**The measure initial patient population is revised to read:** Patients 18 years of age and older as of the IPSD who were dispensed antidepressant medications during the Intake Period, and were diagnosed with major depression 60 days prior to, or 60 days after the dispensing event and had a visit 60 days prior to, or 60 days after the dispensing event. **Updated logic and logic definition: Revised:** logic to base it on age and IPSD.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the initial patient population look-back window to evaluate the age of the patient when medication is dispensed during the intake period. The updated timeframe distinguishes between a new prescription and a continuing prescription to ensure the measure logic is more accurate in determining the antidepressant treatment has met the numerator's quality action. We also proposed to update the logic to look at the age and IPSD so that the look-back window allows all patients to be assessed for the exclusion criteria related to previous anti-depression medication.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62518), we are finalizing the changes to measure Q009 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.3. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
CBE # / eCQM CBE #:	N/A/ N/A
Quality #:	019
CMS eCQM ID:	CMS142v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once during the performance period.
Substantive Change:	**Modified collection type**: eCQM Specifications collection type. **Updated Guidance: Revised:** The communication of results, including the level of severity of diabetic retinopathy and presence or absence of macular edema to the primary care physician providing ongoing care of a patient's diabetes should be completed soon after the dilated exam is performed.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to remove the MIPS CQM collection type as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate and topped-out status is based on the current MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*. However, the benchmarking data continues to show a gap for the eCQM collection type and as such, we proposed to retain that collection type. Additionally, we proposed to revise the measure guidance to define required information to be included within the report for the purposes of numerator compliance. This ensures all appropriate information is being communicated for patient care coordination.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed the proposed substantive changes to remove the MIPS CQM collection type to measure Q019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care.

Response: We acknowledge the commenter's concerns; however, the MIPS CQM collection type has not only reached the end of the topped-out life cycle, but it also showed an average performance rate of 100 percent which does not allow for meaningful benchmarks to be established.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62518), we are finalizing the changes to measure Q019 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.4. Advance Care Plan

Category	Description
CBE # / eCQM CBE #:	0326 / N/A
Quality #:	047
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Spcifications, MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Updated the denominator criteria: For the MIPS CQM Specifications and the Medicare Part B Specifications collection types: Added:** coding for neuropsychology.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update denominator criteria to include coding for neuropsychology as this measure is applicable to their scope of care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q047: Advance Care Plan but requested clarification regarding whether these revisions apply only for MIPS or whether they apply across all payers and programs. The commenter indicated that measure specification changes and reporting mechanisms should align across all payers and programs.

Response: We thank the commenter for their supporting the substantive changes to this measure. The revisions in this final rule apply only to MIPS; however, we strive to align measures across programs where possible.

After considerations of public comments, and for the reasons stated above and in the proposed rule (89 FR 62519), we are finalizing the changes to measure Q047 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.5. Diabetes: Eye Exam

Category	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v13
Current Collection Type:	eCQM Specifications/ MIPS CQM Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q117. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed substantive changes to update to the frailty exclusion to measure Q117: Diabetes: Eye Exam. The commenters agreed this update will make it easier and less burdensome to capture the intended patient population for this measure.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: One commenter supported the proposed substantive changes to this measure but requested clarification regarding how the clinician will know when their patient went somewhere else and obtained a frailty and/or advanced illness diagnosis which then removes them from the clinician's denominator.

Response: We thank the commenter for supporting the substantive changes to this measure. As noted above, removal of the additional requirement for patients to have had either one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. We encourage clinicians to provide care as they determine best supports all patients during their healthcare journey. When submitting this measure, the clinician would report on patients based upon the information within the medical record in accordance with the current measure specification. The update to the denominator exclusion does not change how the measure data may be captured and reported only the criteria to determine whether a patient is appropriate for the quality action assessment.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62519), we are finalizing the changes to measure Q117 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.6. Documentation of Current Medications in the Medical Record

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	130
CMS eCQM ID:	CMS68v14
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. **Updated guidance: For the eCQM specifications collection type: Revised**: allows for documentation to be completed on the day of the encounter. **Updated initial patient population: For the eCQM specifications collection type: Removed**: age criteria. **Updated denominator: For the MIPS CQM Specifications collection type: Removed:** age criteria. **Updated denominator criteria: For the MIPS CQM Specifications collection type: Removed:** age criteria. **Added:** coding for pediatric audiology services. **Updated numerator note: For the MIPS CQM Specifications collection type: Revised:** allows for documentation to be completed on the day of the encounter.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update multiple components of the measure to remove the age criteria so that all patients, regardless of age, are assessed for having a list of their current medications documented in their medical record. This revision broadens the denominator, supporting assessment of current medications for all patient age ranges. Assessing for missing information about the dosage, route, or frequency of a medication supports clinical communication and may assist in avoiding patient harm.[1092] Additionally, we proposed to update the measure to allow for the quality action to occur on the day of the encounter rather than limiting to during the encounter. This will allow for flexibility to align with the clinician's workflows and systems. We also proposed to update the denominator criteria to include coding for pediatric audiology services as this measure is applicable to their scope of care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes to measure Q130: Documentation of Current Medications in the Medical Record. One commenter supported the proposed modification to the timing of the numerator action to allow practices to perform quality actions on the encounter day rather than solely during the encounter itself. If finalized, the commenter requested that CMS ensure qualified registries can map to a date stamp, thereby verifying that the quality action took place on the encounter day.

Response: We thank the commenters for supporting the substantive changes to this measure. Prior to selecting or using any third party intermediary or its products, the individual clinician, group, virtual group, subgroup, and/or APM Entity should perform their own due diligence on the intermediary and its products to ensure congruency in workflow and data transfer. It is incumbent upon MIPS eligible clinicians to ensure the accuracy of their data.

Comment: One commenter appreciated the proposed substantive changes to measure Q130 but requested clarification regarding whether a nurse can complete the documentation. Additionally, the commenter encouraged CMS to consider scenarios such as when a clinician may complete a medication reconciliation the day after an encounter (rather than same day), as often occurs when clinicians work to catch up on their documentation. With this scenario in mind, the commenter encouraged CMS to expand the timeframe so that the documentation may occur beyond the actual day of the encounter. The commenter also acknowledged that this measure is a "check box" measure.

[1092] Owen, M. C., Chang, N. M., Chong, D. H., & Vawdrey, D. K. (2011). Evaluation of Medication List Completeness, Safety, and Annotations. *AMIA Annual Symposium Proceedings. AMIA Symposium*, *2011*, 1055–1061. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243276/.

Response: We thank the commenter for their feedback. The measure does not dictate a clinician's workflow and which clinical staff, such as a nurse, may complete the documentation of current medications. However, the MIPS eligible clinician must attest to documenting, updating, or reviewing the patient's current medications to meet the measures quality action. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62520), we are finalizing the changes to measure Q130 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.7. Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality #:	143
CMS eCQM ID:	CMS157v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated initial patient population: For the eCQM Specifications collection type: Revised:** Population 1: All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy. Population 2: All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving radiation therapy.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to revise this measure to split the initial patient population to delineate between patients who are receiving radiation therapy and are assessed for pain intensity and their pain level quantified. This additional patient population will allow clinicians reporting this measure the ability to distinguish their performance between patients receiving chemotherapy and those receiving radiation services. It will also align the measure across all collection types.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters opposed the proposed substantive changes to measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified to split the initial population to distinguish between patients who receive chemotherapy and patients who receive radiation therapy. The commenters sought clarification from CMS on whether the intent of this proposed change is to have a multi strata measure or two separate measures. This measure is comprised of two patient populations, but it is intended to result in one reporting rate. Pain is one of the most common and debilitating symptoms reported amongst cancer patients, and both chemotherapy and radiation specifically are associated with several distinct pain syndromes. Splitting this patient population into two populations resulting in two performance rates would essentially create two different measures, and the intent of the measure is to encompass both therapies into one rate to comprehensively assess pain in cancer patients. The commenters believed the division of one measure into two contradicts CMS policy, which seeks to restrict the number of measures pertaining to specific subjects and populations.

Response: As noted, the split in the initial population is intended to allow clinicians the ability to distinguish their performance between patients receiving chemotherapy and those receiving radiation therapy. This is not a change in how the measure is implemented, but rather a clarification that allows the logic in the eCQM collection type to better identify the patients who are receiving either chemotherapy or radiation. The measure will remain a single measure with a single performance rate for the purposes of benchmarking. This also better aligns the eCQM and MIPS CQM collection types.

As noted under Table C.3 of this Appendix, the measure steward is currently evaluating a proposal to respecify measures Q143 and Q144: Oncology: Medical and Radiation – Plan of Care for Pain into a single, combined measure. The measure steward can evaluate whether it would be appropriate to split the measure into separate medical oncology and radiation oncology measures. The request was to keep two separate measures pending their revision.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62521), we are finalizing the changes to measure Q143 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.8. Falls: Plan of Care

Category	Description
CBE # / eCQM CBE #:	0101 / N/A
Quality #:	155
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to revise this measure by removing the Medicare Part B Claims Measure collection type for this measure as it has reached the end of the topped-out lifecycle (82 FR 53640). The average performance rate is based on the current 2024 MIPS benchmarking data located at *https://qpp.cms.gov/benchmarks*.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes to measure Q155: Falls: Plan of Care.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62521), we are finalizing the changes to measure Q155 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.9. Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration

Category	Description
CBE # / eCQM CBE #:	0115 / N/A
Quality #:	168
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization. **The measure numerator is revised to read:** Patients undergoing isolated CABG surgery who require a return to the OR for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization. **Updated numerator options: Added:** unplanned coronary artery intervention (native vessel, graft, or both) and aortic reintervention
Measure Steward:	Society of Thoracic Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to revise this measure to broaden the scope of cardiac complications that may require a return to the operating room following isolated CABG surgery. These revisions support the measure to decrease surgical re-exploration following CABG surgery, which is a serious complication and impacts length of stay, efficient use of resources, and increases risk for additional injury and death.[1093] Although rates of re-exploration after cardiac surgery have significantly declined recently, it has been linked to much higher complications, mortality, and hospitalizations.[1094]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration that broaden the scope of cardiac complications that may require a return to the operating room following isolated CABG surgery. The commenter supported these revisions aiming to decrease surgical re-exploration following CABG surgery. Surgical re-exploration following a CABG surgery is a serious complication and impacts risk of mortality, new-onset renal failure, and increased blood use, which may adversely affect long-term survival. Although rates of re-exploration after cardiac surgery have significantly declined recently, it has been linked to much higher complications, mortality, and hospitalizations.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62522), we are finalizing the changes to measure Q168 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1093] Tran, Z., Williamson, C., Hadaya, J., Verma, A., Sanaiha, Y., Chervu, N., Gandjian, M., & Benharash, P. (2022). Trends and Outcomes of Surgical Reexploration After Cardiac Operations in the United States. *The Annals of Thoracic Surgery*, *113*(3), 783–792. https://doi.org/10.1016/j.athoracsur.2021.04.011.

[1094] See footnote Tran et al., 2022.

D.10. Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions: Added:** new biosimilar medications.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the list of medications by adding new biosimilar medications to the existing list in the denominator instructions. This expansion will provide an up-to-date list of appropriate biologics and/or immune response modifiers that clinicians may have prescribed for their patients, thereby ensuring that the right patients are identified in the denominator of this measure. These targeted immunotherapies are associated with a high risk of progression to active TB infection, therefore screening for latent TB prior to initiating first course therapy is highly recommended since it has been shown to effectively reduce the incidence of progression in patients with latent TB.[1095]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to include new biosimilar medications to measure Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy as requested. A second commenter also supported the substantive changes to this measure and requested that CMS clearly communicate a comprehensive list of the additional biosimilar medications that will be added to this measure by December 2024. The commenter noted this information was not included in this proposed rule and practices will need time to implement these changes.

Response: We thank the commenters for supporting the substantive changes to this measure. The list of additional biosimilar medications is included in the measure specifications that will be posted mid December 2024.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62523), we are finalizing the changes to measure Q176 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1095] CDC. (2020). Latent Tuberculosis Infection – A Guide for Primary Health Care Providers. https://www.cdc.gov/tb/media/pdfs/Latent-TB-Infection-A-Guide-for-Primary-Health-Care-Providers.pdf.

D.11. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
CBE # / eCQM CBE #:	2523 / N/A
Quality #:	177
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used without a telehealth modifier (i.e., only non-telehealth visits are to be considered for this measure). Additional encounter - An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** An additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period. **Updated numerator definition: Revised:** A result within the valid range of the selected tool qualifies for meeting numerator performance as long as a result is captured at ≥50% of each patient's qualified encounters. If the result of a recorded disease activity assessment is outside the valid range of scores for the tool (e.g., a CDAI score of 101 when the maximum possible score is 76.0) or is only recorded as a disease activity level (e.g., low, moderate, or high) in place of a calculated numerical score, this score should not be included in the count to meet the ≥50% requirement in the numerator.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[1096] Therefore, this change will align more closely with the workflow of clinicians and allows the assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes. We proposed to revise the definition for 'Assessment of Disease Activity' to confirm that only those assessments where the disease activity is correctly recorded are included in the numerator quality action for the purposes of meeting performance. Not only do the results need to be within the range of the selected validated qualifying tool, but also a calculated numeric score and not simply a disease activity level. This will ensure that all assessment information is correctly captured to drive appropriate care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the numerator and denominator to measure Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity.

[1096] Brody, B. (2020). The American College of Rheumatology Updated Its Approved Disease Activity Measures for Rheumatoid Arthritis — Here's What That Means. https://creakyjoints.org/living-with-arthritis/symptoms/approved-disease-activity-measures-for-rheumatoid-arthritis/.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62524), we are finalizing the changes to measure Q177 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.12. Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	178
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used. Additional encounter – An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** an additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[1097] Therefore, this change will align more closely with the workflow of clinicians and allows assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the denominator to measure Q178: Rheumatoid Arthritis (RA): Functional Status Assessment.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62525), we are finalizing the changes to measure Q178 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1097] See footnote Brody, 2020 in Table D.11 of this Appendix.

D.13. Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	180
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan during the performance period. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA diagnoses documented at least 90 days apart with at least one encounter with an RA diagnosis occurring during the performance period and an additional encounter with an RA diagnosis occurring in the performance period or prior performance period. **Updated denominator definition: Added:** Encounter – An encounter during the performance period where one of the CPT or HCPCS codes listed in the patient encounter criteria is used. Additional encounter -– An additional encounter during the performance period or prior performance period where one of the CPT or HCPCS codes listed in the patient encounter is used to confirm an RA diagnosis with ICD-10-CM diagnosis codes as listed in the Denominator criteria. **Updated denominator criteria: Added:** An additional encounter with an RA diagnosis during the performance period or prior performance period that is at least 90 days before or after an encounter with an RA diagnosis during the performance period.
Measure Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the denominator to provide greater specificity on the timeframe and criteria for denominator coding and how it should be captured to ensure the appropriate patients are being identified for this measure. Diagnosing RA requires "a combination of physical exams, blood tests for inflammatory markers, and imaging tests (like X-rays and MRIs), in addition to patient-reported symptoms," which can take multiple visits to determine an accurate assessment of RA disease activity.[1098] Therefore, this change will align more closely with the workflow of clinicians and allows assessment of a patient for RA disease activity during more than one clinical visit. These changes support a comprehensive perspective of the patient's disease activity level and should promote optimal treatment outcomes.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the denominator to measure Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62526), we are finalizing the changes to measure Q180 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1098] See footnote Brody, 2020 in Table D.11 of this Appendix.

D.14. Elder Maltreatment Screen and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	181
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 60 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for emergency department.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to add encounter codes for emergency department (ED) visits to the denominator criteria as the emergency department is an appropriate setting for screening for elder maltreatment. "EDs are a potentially important setting for elder mistreatment identification because they provide care for a large number of older adults who may be elder mistreatment victims" especially given that the ED is sometimes the only clinical setting that the patient may visit.[1099] Expanding the denominator to include ED visits ensures a more complete denominator patient population and provides support and delivery of interventions that could prevent actual abuse.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes for measure Q181: Elder Maltreatment Screen and Follow-up Plan. One commenter supported adding encounter codes for ED visits to the denominator. The commenter agreed that the ED is a prime setting for elder maltreatment identification and follow-up planning.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62527), we are finalizing the changes to measure Q181 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1099] See footnote Rosen et al., 2020 in Table B.11 of this Appendix.

D.15. Functional Outcome Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	182
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies within two days of the date of the identified deficiencies.
Substantive Change:	**Updated numerator definition: Revised:** Functional Outcome Assessment: Patient completed questionnaires designed to measure a patient's limitations in performing the usual human tasks of living and to directly quantify functional and behavioral symptoms. If a patient is unable to complete a questionnaire, a standardized clinical assessment tool may be used to measure a patient's limitations. **Added:** To Table 1. Definitions for Magnitude of Effects, Based on Mean Between-Group Differences – Modified*: clarification that list of standardized tools is not exhaustive.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the numerator definition to clarify that clinicians may use a standardized clinical assessment tool to measure a patient's limitation if they are unable to complete a questionnaire. This change will allow flexibility in performing the quality action and clarify that the list of standardized tools named in the measure are only examples, not an exhaustive list. The National Institute of Health indicates that it supports the use of standardized tools, stating they offer a clinician-designed approach to promoting care standardization that accommodates patients' individual differences, respects clinicians' clinical judgement, and keeps pace with the rapid growth of medical knowledge.[1100]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes to measure Q182: Functional Outcome Assessment.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62528), we are finalizing the changes to measure Q182 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1100] Farias, M., Jenkins, K., Lock, J., Rathod, R., Newburger, J., Bates, D. W., Safran, D. G., Friedman, K., & Greenberg, J. (2013). Standardized Clinical Assessment and Management Plans (SCAMPs) Provide a Better Alternative to Clinical Practice Guidelines. *Health Affairs (Project Hope)*, *32*(5), 911–920. https://doi.org/10.1377/hlthaff.2012.0667.

D.16. Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	185
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Substantive Change:	**Updated denominator exception: Added:** To the 'Documentation of system reasons(s): patient cannot provide precise date or details from previous colonoscopy.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator exception to exclude patients that are unable to provide the precise date or details from a previous colonoscopy. This addition will assist with data collection when a patient with a history of adenomatous polyps is unable to provide information regarding their last colonoscopy.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62529), we are finalizing the changes to measure Q185 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.17. Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	236
CMS eCQM ID:	CMS165v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications/ MIPS CQM Specifications/ Medicare CQM Specifications (collection type available only in the APP and/or APP Plus)
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committtee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q236. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q236: Controlling High Blood Pressure. Two commenters supported the proposed update to the frailty exclusion criteria. One of these commenters requested clarification regarding how the clinician will know when their patient saw a different clinician at a different medical practice and obtained a frailty and/or advanced illness diagnosis, which then removes them from the clinician's denominator.

Response: We thank the commenter for supporting the substantive changes to this measure. As noted above, removal of the additional requirement for patients to have had either one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. We encourage clinicians to provide care as they determine best supports all patients during their healthcare journey. When submitting this measure, the clinician would report on patients based upon the information within the medical record in accordance with the current measure specification. The update to the denominator exclusion does not change how the measure data may be captured and reported only the criteria to determine whether a patient is appropriate for the quality action assessment.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62529), we are finalizing the changes to measure Q236 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.18. Use of High-Risk Medications in Older Adults

Category	Description
CBE # / eCQM CBE #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class.
Substantive Change:	**Updated numerator definition: For the MIPS CQM Specifications collection type:** Numerator (Submission Criteria 1): Table 1 - High-Risk Medications at any Dose or Duration **Removed:** From Anticholinergics, first-generation antihistamines: Carbinoxamine, Clemastine, Dexbrompheniramine, Dexchlorpheniramine, Pyrilamine From Antispasmodics: Belladonna alkaloids, Methscopolamine, Propantheline From Cardiovascular, alpha agonists, central: Methyldopa From Cardiovascular, other: Disopyramide From Central nervous system, antidepressants: Protriptyline Trimipramine From Central nervous system, barbiturates: Amobarbital, Butabarbital, Pentobarbital, Secobarbital From Central nervous system, vasodilators: Isoxsuprine From Endocrine system, sulfonylureas, long-duration: Chlorpropamide From Endocrine system, other: Megestrol From Pain medications, other: Meperidine **Added:** A row with one medication is considered a group (or drug class) of one; therefore, two orders of that same medication are numerator compliant. **Added:** To Central nervous system, barbiturates: Primidone Endocrine system, megestrol: Megestrol Pain medications, meperidine: Meperidine To Pain medications, other: Ketorolac, includes parenteral and oral Table 3 – High-Risk Medications With Average Daily Dose Criteria **Removed:** Alpha agonists, central: Reserpine >0.1 mg per day Numerator (Submission Criteria 2): Table 4 – High-Risk Medications **Removed:** From Benzodiazepines, long, short and intermediate acting: Flurazepam, Quazepam **Added:** To Benzodiazepines, long, short and intermediate acting: Clobazam
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the list of high-risk medications to align with 2023 AGS Beers Criteria[1101] and ensure that older adults are not prescribed inappropriate medications. This change will also align with PY 2025 eCQM version (CMS156v13), which supports alignment between the collection types. We also proposed to add clarification that the medications found within a single row of table one, within the specification, represent a unique group or drug class. Therefore, two orders from that group or drug class will be consider numerator compliant for this measure, which has an inverse analytic for the calculation of performance.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62530), we are finalizing the changes to measure Q238 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1101] The 2023 American Geriatrics Society Beers Criteria Update Expert Panel. (2023). American Geriatrics Society 2023 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. Journal of the American Geriatrics Society, 71(7), 2052-2081. https://doi.org/10.1111/jgs.18372.

D.19. Barrett's Esophagus

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	249
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.
Substantive Change:	**Updated denominator exception: For all collection types: Added**: Specimen site other than anatomic location of esophagus. **Updated denominator exclusion**: **For all collection types: Removed**: Specimen site other than anatomic location of esophagus.
Measure Steward:	College of American Pathologists
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to remove the denominator exclusion so that all patients with a diagnosis for Barrett's Esophagus are included in the denominator of the measure and proposed to add a denominator exception for specimen sites other than the anatomic location of the esophagus. Revising the measure to include this element as a denominator exception will allow for an automated capture of the relevant cases with less manual intervention reducing overall burden of measure reporting.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62531), we are finalizing the changes to measure Q249 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.20. Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	277
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI), a respiratory disturbance index (RDI), or a respiratory event index (REI) documented or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
Substantive Change:	**Updated denominator exception: Added:** patients previously diagnosed with OSA and severity assessed by another provider.
Measure Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator exception by adding that patients previously diagnosed with obstructive sleep apnea (OSA), with severity assessed by another clinician and documented will not need to have the testing completed again. This denominator exceptions allows clinician judgement as to whether repeat testing is needed, as we do not want to promote overutilization. This revision increases clarity of this element and ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to add the denominator exclusion for patients previously diagnosed with OSA and severity assessed by another provider to measure Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis. The commenter agreed this change will remove unnecessary repeat assessments for clinicians reporting this measure.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62531), we are finalizing the changes to measure Q277 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.21. Dementia: Cognitive Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / 2872e
Quality #:	281
CMS eCQM ID:	CMS149v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**Updated guidance: Added:** The measure requires a diagnosis of dementia is present before the routine assessment of cognition once in a 12-month period.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the measure guidance to clarify that the diagnosis of dementia must be present prior to the cognitive assessment. This will ensure that any cognitive assessments performed prior to the dementia diagnosis but occurred during the 12-month lookback period will not be attributed to this measure numerator.[1102] This change will ensure consistency in the abstraction of the measure's numerator elements based upon a specific timeframe that support rigorous data for the calculation of MIPS performance rates.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed substantive changes to measure Q281: Dementia: Cognitive Assessment.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62532), we are finalizing the changes to measure Q281 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1102] Office of the Assistance Secretary for Planning and Evaluation. (2016). Examining Models of Dementia Care: Final Report. https://aspe.hhs.gov/reports/examining-models-dementia-care-final-report-0.

D.22. Dementia: Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	282
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to add encounter codes for speech language pathologists and nuclear medicine to the denominator criteria as these are appropriate specialties to identify changes in functional status in patients diagnosed with dementia. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[1103]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q282: Dementia: Functional Status Assessment.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62533), we are finalizing the changes to measure Q282 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1103] American Speech-Language-Hearing Association (ASHA). Dementia. https://www.asha.org/public/speech/disorders/dementia/.

D.23. Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	286
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[1104]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed substantive changes to measure Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62534), we are finalizing the changes to measure Q286 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1104] See footnote ASHA in Table D.22 of this Appendix.

D.24. Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	288
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology and nuclear medicine.
Measure Steward:	American Academy of Neurology/American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care. Dementia, which can be caused by "different brain diseases," affects a person's activities of daily living including, but not limited to eating and swallowing, and speech.[1105]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed substantive changes to measure Q288: Dementia: Education and Support of Caregivers for Patients with Dementia.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62535), we are finalizing the changes to measure Q288 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1105] See footnote ASHA in Table D.22 of this Appendix.

D.25. Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	290
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology and behavioral health.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for neuropsychology and behavioral health as it's clinically appropriate for these clinician types to assess for depression, anxiety, apathy, and psychosis.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantives change to add coding for neuropsychology to measure Q290: Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62536), we are finalizing the changes to measure Q290 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.26. Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology, behavioral health, and physical and occupational therapy.
Measure Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for neuropsychology, behavioral health, and physical and occupational therapy as it's clinically appropriate for these clinician types to assess for cognitive impairment or dysfunction.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantives change to add coding for neuropsychology to measure Q291: Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease. Several additional commenters appreciated the addition of coding for physical therapy for measure Q291.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62536), we are finalizing the changes to measure Q291 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.27. Rehabilitative Therapy Referral for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	293
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for neuropsychology, behavioral health, and speech language pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for neuropsychology, behavioral health, and speech language pathology as this measure is applicable to their scope of care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62536), we are finalizing the changes to measure Q293 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.28. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator criteria: For the MIPS CQM Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** coding for nutrition/dietitian clinician type. **Updated numerator definition: For all collection types: Revised:** intervals for rescreening for first and second hypertensive BP readings.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to add encounter codes for nutrition therapy to the denominator criteria for the MIPS CQM Specifications and the Medicare Part B Claims Measure collection types as this is an appropriate setting to identify people who may have elevated blood pressure (BP) readings. Nutritional approaches play a pivotal role in helping to reduce the risk of hypertension or control blood pressure in people with hypertension.[1106] We proposed to remove the minimum timeframe for follow-up screenings for patients with elevated BP readings for all collection types. This change will allow clinician discretion to recommend a follow-up plan based on the patient's current health status. Additionally, this supports stability of this measure component, as the frequency is each visit, within the specification over time, while still maintaining consistency with the current guidelines.[1107]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive change to eliminate the minimum timeframe for follow-up screenings for patients with elevated blood pressure readings for all collection types to measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. The commenter agreed this change will enable clinicians to exercise their judgment in recommending follow-up plans based on each patient's health status, thereby personalizing care to better meet individual needs and ultimately enhancing the quality of care delivered.

A second commenter thanked CMS for adding medical nutrition therapy codes to the denominator criteria as this acknowledges the important role of RDNs in managing elevated blood pressure. The commenter also supported eliminating the minimum timeframe for follow-up screenings as it gives clinicians the flexibility to tailor care to the specific needs of each patient.

Response: We thank the commenters for supporting the substantive change to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62537), we are finalizing the changes to measure Q317 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1106] Physicians Committee for Responsible Medicine. (2023). Nutrition Guide for Clinicians: Hypertension. https://nutritionguide.pcrm.org/nutritionguide/view/Nutrition_Guide_for_Clinicians/1342053/all/Hypertension.

[1107] Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Jr, Collins, K. J., Dennison Himmelfarb, C., DePalma, S. M., Gidding, S., Jamerson, K. A., Jones, D. W., MacLaughlin, E. J., Muntner, P., Ovbiagele, B., Smith, S. C., Jr, Spencer, C. C., Stafford, R. S., Taler, S. J., Thomas, R. J., Williams, K. A., Sr, Williamson, J. D., … Wright, J. T., Jr (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, *71*(19), e127–e248. https://doi.org/10.1016/j.jacc.2017.11.006.

D.29. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
CBE # / eCQM CBE #:	0658 / N/A
Quality #:	320
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report. **Updated numerator: For all collection types: Revised:** Patients who had recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report. **Updated numerator note: For all collection types: Added:** To meet the numerator, patients with a negative screening colonoscopy should have documentation that they received counseling or instruction to have a follow-up or repeat colonoscopy in 10 years. A 6 month period before or after 10 years is considered within the recommended follow-up interval. **Updated numerator options: For all collection types: Revised:** **Performance Met:** Recommended follow-up interval for repeat colonoscopy of 10 years documented in colonoscopy report and communicated with patient. **Denominator Exception:** Documentation of medical reason(s) for not recommending a 10 year follow-up interval (e.g., inadequate prep, familial or personal history of colonic polyps, patient had no adenoma and age is ≥ 66 years old, or life expectancy < 10 years, other medical reasons) **Performance Not Met:** A 10 year follow-up interval for colonoscopy not recommended, reason not otherwise specified.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the measure description, numerator, and numerator options to ensure the time frame for recommended follow up after a normal colonoscopy for the average risk patient accurately reflects current guidelines which states "[n]ew observational and modeling studies of colonoscopy confirm and strengthen the evidence base to support the conclusion that individuals with normal colonoscopy are at lower-than-average risk for CRC. Based on this reduced risk, we recommend CRC screening in average-risk individuals be repeated 10 years after a normal examination complete to the cecum with bowel preparation adequate to detect polyps >5 mm in size."[1108] Additionally, we proposed to add a numerator note to indicate inclusion of documentation that the patient has received counseling and instruction on when a repeat colonoscopy should be scheduled. This change will ensure the patient is aware of clinical recommendations to drive healthy outcomes.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62538), we are finalizing the changes to measure Q320 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1108] Gupta, S., Lieberman, D., Anderson, J. C., Burke, C. A., Dominitz, J. A., Kaltenbach, T., Robertson, D. J., Shaukat, A., Syngal, S., & Rex, D. K. (2020). Recommendations for Follow-Up After Colonoscopy and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. *Gastrointestinal Endoscopy*, *91*(3), 463–485.e5. https://doi.org/10.1016/j.gie.2020.01.014.

D.30. Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	322
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.
Substantive Change:	**The measure description is revised to read**: Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), multigated acquisition scan (MUGA), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period. **Updated instructions: Added:** multigated acquisition scan (MUGA). **Updated denominator: Added:** multigated acquisition scan (MUGA). **Updated denominator criteria: Added:** coding for multigated acquisition scan (MUGA). **Updated numerator: Added:** multigated acquisition scan (MUGA).
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale	We proposed to update multiple components of the measure to add MUGA. Even though MUGA scanning allows a clinician to evaluate many heart parameters and can be done while resting or under stress, this diagnostic imaging test will ensure this type of imaging is not performed on low-risk surgery patients since the risks of the procedure exceed the expected clinical benefit for the denominator eligible patient population.[1109] The MUGA scan is primarily used for assessing myocardial function in patients on cardiotoxic chemotherapy.[1110]

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62539), we are finalizing the changes to measure Q322 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1109] Winchester, D. E., Maron, D. J., Blankstein, R., Chang, I. C., Kirtane, A. J., Kwong, R. Y., Pellikka, P. A., Prutkin, J. M., Russell, R., & Sandhu, A. T. (2023). ACC/AHA/ASE/ASNC/ASPC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2023 Multimodality Appropriate Use Criteria for the Detection and Risk Assessment of Chronic Coronary Disease. *Journal of Cardiovascular Magnetic Resonance: Official Journal of the Society for Cardiovascular Magnetic Resonance*, *25*(1), 58. https://doi.org/10.1186/s12968-023-00958-5.

[1110] Odak, M., & Kayani, W. T. (2023). MUGA Scan. In *StatPearls*. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK564365/.

D.31. Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	331
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated the instructions: Revised:** This measure is to be submitted once for each occurrence of acute viral sinusitis (AVS) during the performance period. Each unique occurrence starts with the onset of AVS symptoms and concludes with the resolution of AVS symptoms or after 90 days if a resolution of AVS symptoms is not documented. If multiple encounters are documented within an occurrence, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent encounter during that occurrence. A new occurrence of AVS cannot start until the previous occurrence during the performance period has concluded.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the measure instructions to clarify what constitutes an occurrence for the purposes of this measure. This additional guidance will further clarify how patients are attributed to the denominator of this measure for each eligible occurrence. This change will ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62540), we are finalizing the changes to measure Q331 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.32. Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	336
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **Updated numerator: Added:** intimate partner violence screening. **Updated numerator definition: Added:** Intimate Partner Violence Screening – Patients who were screened for intimate partner violence before or at 12 weeks postpartum. Questions may be asked either directly by a health care provider or in the form of self-completed paper-or computer-administered questionnaires, and results should be documented in the medical record. Intimate partner violence screening should include a self-reported validated intimate partner violence screening tool (e.g., Abuse Assessment Screen (AAS), Extended – Hurt, Insult, Threaten, Scream (E-HITS), Humiliation, Afraid, Rape, Kick (HARK)). **Updated numerator instructions: Added:** intimate partner violence screening.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update multiple measure components to include intimate partner violence screening. "The effects of intimate partner violence (IPV) on maternal and neonatal outcomes are multifaceted and largely preventable."[1111] This type of abuse has maternal and neonatal consequences on mental and physical health that could be far reaching beyond the perinatal period;[1112] therefore, intimate partner violence screening was proposed for inclusion. This revision will support clinicians currently screening and will encourage others to begin screening for this risk within this patient population as IPV may escalate during the postpartum period.[1113] The American College of Obstetricians and Gynecologists recommend including screening for IPV at the postpartum checkup to help identify patients experiencing IPV so that support may be offered to break this cycle, leading to positive outcomes for both maternal and neonatal health.[1114]

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62541), we are finalizing the changes to measure Q336 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1111] Alhusen, J. L., Ray, E., Sharps, P., & Bullock, L. (2015). Intimate Partner Violence During Pregnancy: Maternal and Neonatal Outcomes. *Journal of Women's Health (2002)*, *24*(1), 100–106. https://doi.org/10.1089/jwh.2014.4872.
[1112] Chisholm, C. A., Bullock, L., & Ferguson, J. E. J., 2nd (2017). Intimate Partner Violence and Pregnancy: Epidemiology and Impact. *American Journal of Obstetrics and Gynecology*, *217*(2), 141–144. https://doi.org/10.1016/j.ajog.2017.05.042.
[1113] American College of Obstetricians and Gynecologists (ACOG). (2012). Committee on Health Care for Underserved Women Opinion: Intimate Partner Violence. https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2012/02/intimate-partner-violence.pdf.
[1114] See footnote ACOG, 2012.

D.33. HIV Medical Visit Frequency

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	340
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQM Specifications collection type. **The measure title is revised from "HIV Medical Visit Frequency" to:** HIV Annual Retention in Care. **The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of Human Immunodeficiency Virus (HIV) before or during the first 240 days of the performance period who had at least two eligible encounters or at least one eligible encounter and one HIV viral load test that were at least 90 days apart within the measurement period. **The measure denominator is revised to read:** Patients, regardless of age, with a diagnosis of HIV before or during the first 240 days of the performance period who had at least one eligible encounter during the first 240 days of the performance period. **The measure denominator note is revised to read:** Only patients with an eligible encounter in the first 240 days are included in this measure to allow for sufficient time to complete a second eligible encounter or viral load laboratory at least 90 days after the initial encounter during the performance period. **Updated denominator criteria: Added:** coding for telephone and home visit patient encounters. **Updated denominator exclusion: Removed:** Patient died at any time during the 24-month measurement period. **The measure numerator is revised to read**: Number of patients who had at least one eligible encounter and one HIV viral load test at least 90 days apart during the performance period, or who had at least two eligible encounters at least 90 days apart during the performance period. **Updated numerator note: Added:** A patient would be included in the measure numerator if they have either 1) two eligible encounters at least 90 days apart, or 2) one eligible encounter and one viral load test at least 90 days apart from each other. The encounter or encounters that cause a patient to be included in the numerator do not need to include the encounter that caused the patient to be included in the denominator. **The measure numerator options are revised to read:** **Performance Met:** Patient had two eligible encounters at least 90 days apart or one eligible encounter and one HIV viral load test at least 90 days apart **Performance Not Met:** Patient did not have two eligible encounters at least 90 days apart or one eligible encounter and one HIV viral load test at least 90 days apart
Measure Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the collection types available for this measure to include the eCQM collection type to provide choice in submission method. We also proposed to revise multiple components of the measure allowing for improved quality outcome which is to engage persons who are infected with HIV in regular HIV care that promote test-and-treat strategies.[1115] In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62542), we are finalizing the changes to measure Q340 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1115] Gardner, E. M., McLees, M. P., Steiner, J. F., Del Rio, C., & Burman, W. J. (2011). The Spectrum of Engagement in HIV Care and its Relevance to Test-and-treat Strategies for Prevention of HIV Infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *52*(6), 793–800. https://doi.org/10.1093/cid/ciq243.

D.34. Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	344
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.
Substantive Change:	**The measure title is revised from Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) to:** Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) **The measure description is revised to read:** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) without major complication who are discharged to home no later than post-operative day #2. **Updated instructions: Added:** CEA. **Updated denominator: Added:** CEA. **Updated denominator criteria: Added:** coding for carotid endarterectomy. **Updated numerator: Added:** CEA. **Updated numerator definition: Added:** procedure for CEA or CAS. **Updated numerator options: Added:** CEA.
Measure Steward:	Society for Vascular Surgery
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to revise this measure to include Carotid Endarterectomy (CEA) to assess for post-operative complications for asymptomatic patients who had CEA. CEA for asymptomatic carotid stenosis reduces the risk of ipsilateral stroke, and any stroke, by approximately 30 percent over 3 years.[1116] Previously, assessment of outcomes for CEA procedures was a separate measure. As both procedures are appropriate for treating asymptomatic carotid artery stenosis, these measures are being combined so that a full picture of positive outcomes can be captured for this patient population.[1117] Additionally, by combining these measures the denominator eligible patient population may increase allowing for more robust data for participating MIPS clinicians. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62542 through 62543), we are finalizing the changes to measure Q344 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1116] Chambers, B. R., & Donnan, G. A. (2005). Carotid Endarterectomy for Asymptomatic Carotid Stenosis. *The Cochrane Database of Systematic Reviews*, *2005*(4), CD001923. https://doi.org/10.1002/14651858.CD001923.pub2.

[1117] Wang, J., Bai, X., Wang, T., Dmytriw, A. A., Patel, A. B., & Jiao, L. (2022). Carotid Stenting Versus Endarterectomy for Asymptomatic Carotid Artery Stenosis: A Systematic Review and Meta-Analysis. *Stroke*, *53*(10), 3047–3054. https://doi.org/10.1161/STROKEAHA.122.038994.

D.35. Unplanned Reoperation within the 30-Day Postoperative Period

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	355
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.
Substantive Change:	**Updated denominator criteria: Revised:** coding for fissurectomy, including sphincterotomy.
Measure Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to update denominator criteria to revise coding for fissurectomy, including sphincterotomy as this is an operative procedure that could have complications requiring unplanned reoperation within 30 days postoperatively.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62544), we are finalizing the changes to measure Q355 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.36. Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	360
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.
Substantive Change:	**The measure description is revised to read:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study. **The measure denominator is revised to read:** All final reports for patients, regardless of age, undergoing a CT or cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) procedure. **Updated denominator criteria: Added:** coding for cardiology infarct imaging. **The measure numerator is revised to read:** CT and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) reports that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies that the patient has received in the 12-month period prior to the current study. **Updated numerator instructions: Added:** infarct avid imaging. **The measure numerator options are revised to read:** **Performance Met:** Count of previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies documented in the 12-month period prior to the current study. **Performance Not Met:** Count of previous CT and cardiac nuclear medicine (myocardial perfusion or infarct avid imaging) studies not documented in the 12-month period prior to the current study, reason not given.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to revise multiple components of this measure to include infarct avid imaging in the cardiac nuclear medicine imaging study that involves the use of radiation, including a radiotracer or contrast agent and/or Imaging modalities, such as positron emission tomography (PET), single-photon emission computed tomography (SPECT), or magnetic resonance imaging (MRI).[1118] Given that this imaging can expose a patient to potentially high doses of radiation,[1119] including it in the denominator of this measure requires the clinician to document a more complete count of previous cardiac nuclear medicine imaging studies, increasing patient safety by preventing continued exposure to radiation.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed the proposed substantive changes to measure Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies to expand the denominator of eligible cases by including coding for cardiology infarct imaging. The commenter stated this change will create a meaningful burden on radiologists to report all prior CT and cardiac nuclear medicine studies that a patient has received in the 12-month period prior to the current study.

Response: We acknowledge the commenter's concerns and agree that the addition of infarct avid imaging may increase the denominator. However, this measure already requires a count of cardiac nuclear medicine studies of which infarct avid imaging is a component. The inclusion of infarct avid imaging as one of the options of nuclear cardiac medicine allows for a more complete

[1118] Enabnit, A. & Warren, A. (2023). Infarct Avid Imaging Study: Purpose, Procedure, and Applications. https://www.dovemed.com/health-topics/focused-health-topics/infarct-avid-imaging-study-purpose-procedure-and-applications.

[1119] Salah, H., Alkhorayef, M., Jambi, L., Almuwannis, M., & Sulieman, A. (2023). Radiation Dose to Patients and Public Exposure in Cardiac Rest and Stress Single Photon Emission Computed Tomography Examinations. *Radiation Physics and Chemistry*. https://doi.org/10.1016/j.radphyschem.2023.111383.

count of previous cardiac nuclear medicine imaging studies, increasing patient safety by preventing continued exposure to radiation.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62545), we are finalizing the changes to measure Q360 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.37. Closing the Referral Loop: Receipt of Specialist Report

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	374
CMS eCQM ID:	CMS50v13
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for psychology and neuropsychology. **The measure numerator definition is revised to read: For the MIPS CQM Specifications collection type: Revised:** A written document prepared by the eligible clinician (and staff) to whom the patient was referred and that accounts for their findings, provides summary of care information about findings, diagnostics, assessments and/or plans of care, or states the patient did not attend the appointment, and is provided to the referring eligible clinician.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to add psychology and neuropsychology encounter codes to the denominator criteria as this measure is applicable to their scope of care. This expansion of the denominator will allow more clinician types to submit the measure leading to an increase in denominator eligibility, capturing a more complete patient population, as it is clinically appropriate for these clinician types to complete the quality action for a patient referred to a specialist. We proposed to revise the numerator definitions for the MIPS CQM collection type to clarify which information should be included in the referring clinician's report to successfully close the referral loop. This revision increases clarity of this element and ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q374: Closing the Referral Loop: Receipt of Specialist Report to require documentation of patient no-shows or missed appointments in the reports sent to referring clinicians.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62546), we are finalizing the changes to measure Q374 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.38. Functional Status Assessment for Total Hip Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	376
CMS eCQM ID:	CMS56v13
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 300 – 425 days after the surgery.
Substantive Change:	**Updated initial patient population: Revised:** encounter timeframe from November of the year prior to August of the year prior.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to revise initial patient population by changing the timing of the encounter to better align with the post-surgical assessment timeframe of 300 to 425 days after the original THA surgery. This will also harmonize the timeframe of the patient encounter with the administrative claims measure "Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" available for Hospital Inpatient Quality Reporting (88 FR 59067 through 59070), thereby aligning timing specificity and patterns across similar measures. Measure alignment, in accordance with clinical recommendations, guidelines, and best practices, allows for consistent and comparable data points, which leads to actionable data to drive quality care, through understanding where the gaps in care are within a patient population or along the continuum of care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes on the timing of the encounter to better align with the post-surgical assessment timeframe of 300 to 425 days after the original THA surgery for measure Q376: Functional Status Assessment for Total Hip Replacement. This revision aligns the timeframe for measure Q376 with that of other quality reporting programs (for example, the Hospital-Level THA/TKA Patient Reported Outcome-Based Performance Measure).

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: One commenter noted the proposed substantive changes to this measure and recommended revising the age criterion to include patients 18 years and older. This adjustment would align the measure with existing orthopedic standards and simplify the tracking process by maintaining a straightforward adult population of 18 years and older, thereby reducing complexity for clinicians and ensuring more accurate data collection across the board.

Response: We thank the commenter for their feedback. While we endeavor to align measures across reporting programs, there may be nuances within the program and/or collection type requirements that lead to small differences between specifications. The age criterion starts at 19 because this is determined at the start of the measurement period, while the denominator eligible procedure has a lookback period starting in November two years prior to the measurement period, allowing for patients age 18 at the time of the procedure to be included within the denominator eligible patient population. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62546), we are finalizing the changes to measure Q376 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.39. Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality #:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator note: Removed:** distinction of typical versus atypical, 'days' supply' notation, and medication HCPCS codes. **Updated denominator criteria: Removed:** HCPCS coding from prescription criteria.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We proposed to remove "days' supply" and HCPCS (J codes) from the list of antipsychotic medications in the measure. This revision will ensure inclusion for any duration of the listed long acting injectables permitting the clinician, or site, to obtain days' supply information from any appropriate clinical or administrative source, thus aligning the calculation of PDC with all appropriate medications listed in the measure. This revision reduces the burden of collecting this aspect of the measure from medical records. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data. Finally, we proposed to remove "typical" and "atypical" as part of the subheadings of the lists of antipsychotic medications as this distinction does not apply to the list of oral and long-acting injectable antipsychotic medications listed under each of the categories which include both typical and atypical medications.[1120]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter expressed that it had previously communicated its concern that the current version of measure Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia is not inclusive of long-acting injectable medications (LAI) with days' supply beyond 28 days, and therefore unfairly penalizes clinicians who use these treatments. While the commenter appreciated that CMS' proposal is intended to address this concern by removing 'days' supply" and HCPCS (J codes) from the list of antipsychotic medications to include any duration of long acting injectables, the commenter was concerned that this approach would create burden and confusion among providers, and variability in the measure's implementation across quality programs.

The commenter stated that the proposed substantive changes to measure Q383 do not provide sufficient clarity about the medication list and corresponding days' supply and places the onus on clinicians to determine days' supply to calculate the proportion of days covered. The commenter was concerned a lack of clarity and added administrative burden on physicians may disincentivize reporting of this quality measure if providers are unclear on the methodology for calculating adherence.

The commenter also stated in April 2024, NCQA released updates to the Adherence to Antipsychotic Medications for Individuals with Schizophrenia (SAA) measure.[1121] The commenter recommended that CMS align its proposed measure with the recently updated NCQA version. NCQA's updated measure clarifies the HCPCS codes J2794 and J2798 as 14 days' supply and 30 days' supply respectively; delete paliperidone palmitate from the "Long-acting injections 28 days' supply" row; and adds LAI products for 35 days (paliperidone palmitate – Invega Sustenna), 104 days (Paliperidone palmitate - Invega Trinza), and 201 days (Paliperidone palmitate - Invega Hafyera) supply to the LAI list. Alignment with the NCQA version of the measure will reduce burden and complexity and better align the measure across quality programs, including MIPS, Certified Community Behavior Health Centers Program, HEDIS®, and Medicaid.

Response: We thank the commenter for their feedback and concerns. The removal of days' supply and HCPCS (J codes) ensures inclusion of long-acting injectable medications as appropriate per the measure specification; therefore, permitting the clinician to obtain days' supply information from any appropriate clinical or administrative source, thus aligning the calculation of PDC with all appropriate medications listed in the measure. This revision reduces the burden of collecting this aspect of the measure from medical records. While we endeavor to align measures across reporting programs, there may be nuances within the program and/or collection type requirements that lead to small differences between specifications. The updated version of the specification removes the 'days' supply' requirement for each prescription, which should allow better flexibility in measure data capture.

[1120] Cleveland Clinic. (2023). Antipsychotic Medications. https://my.clevelandclinic.org/health/treatments/24692-antipsychotic-medications.

[1121] NCQA. (2024). HEDIS Measurement Year 2024 Volume 2: Technical Update. https://www.ncqa.org/wp-content/uploads/HEDIS-MY-2024-Volume-2-Technical-Update.pdf.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62547), we are finalizing the changes to measure Q383 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.40. Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	384
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Substantive Change:	**Updated instructions: Revised**: timeframe for when surgery for primary rhegmatogenous retinal detachment must have occurred to meet the denominator criteria. **Updated numerator note: Added:** For the purposes of meeting the numerator, complications are only those related to the following procedures: 67107, 67108, 67110.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to update the instructions to clarify that surgery for primary rhegmatogenous retinal detachment must occur between January 1st and September 30th of the performance period to allow 90 days after the surgery to assess for the numerator action for patients who have surgeries performed by September 30th. We also proposed to add a numerator note to clarify that the numerator is not required to capture only procedures covered by the three original procedure codes in the denominator, but rather any procedure that is related to complications arising from the original procedures listed.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62548), we are finalizing the changes to measure Q384 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.41. Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	386
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, lawful physician-hastened death, or hospice) or whose existing end of life plan was reviewed or updated at least once annually or more frequency as clinically indicated (i.e., rapid progression).
Substantive Change:	**Updated denominator criteria: Added:** coding for speech language pathology.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for speech language pathology and nuclear medicine as this measure is applicable to their scope of care.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62548), we are finalizing the changes to measure Q386 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.42. Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	393
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**Updated instructions: Added:** A new device would be either the first device OR a device implanted with new functionality.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to update the measure instructions to clarify the definition of a new device. This change will ensure alignment and consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to update to the measure instructions for measure Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision. The commenter agreed with CMS' rationale that the change would ensure alignment and consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62548), we are finalizing the changes to measure Q393 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.43. Door to Puncture Time for Endovascular Stroke Treatment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	413
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less.
Substantive Change:	**Updated denominator exclusion: Added:** Patients with secondary stroke within 5 days of the initial procedure.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale	We proposed to add a denominator exclusion to remove patients with secondary stroke, such as those which may occur with vasospasm in the setting of subarachnoid hemorrhage. Treatment for an initial stroke is most effective when administered very shortly after the onset of symptoms.[1122] However, the same is not the case for secondary stroke which is more challenging to manage as patients with secondary stroke may already be on "blood thinners or aspirin, medication to control cholesterol, or drugs to lower blood pressure" as a result of the initial stroke and "experience more severe and long-lasting disability."[1123] This additional exclusion will more precisely reflect the time to reperfusion for obtaining favorable outcomes in cerebral revascularization within the target patient population.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62549), we are finalizing the changes to measure Q413 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1122] Esenwa, C., & Gutierrez, J. (2015). Secondary Stroke Prevention: Challenges and Solutions. *Vascular Health and Risk Management*, *11*, 437–450. https://doi.org/10.2147/VHRM.S63791.

[1123] Medical News Today. (2023). Recurrent Strokes: What to Know. https://www.medicalnewstoday.com/articles/recurrent-strokes.

D.44. Osteoporosis Management in Women Who Had a Fracture

Category	Description
CBE # / eCQM CBE #:	0053 / N/A
Quality #:	418
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure Specifications / MIPS CQM Specifications
Current Measure Description:	The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**The measure description is revised to read: For all collection types:** The percentage of women 50-85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 180 days after the fracture. **Updated instructions: For all collection types: Revised:** from six months to 180 days. **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion. **The measure numerator is revised to read: For all collection types:** Patients who received either a bone mineral density test or a prescription for a drug to treat osteoporosis in the 180 days after the fracture.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to use both 6 months and 180 days within the measure denominator and numerator to allow for the appropriate time anchors. In the denominator, 6 months is used so that the measurement period to identify a fracture is always July 1 – June 30 (during the 6 months prior to the performance period through June 30 of the performance period). The numerator action of administration of a bone mineral density test or a prescription for a drug to treat osteoporosis within a specific number of days (180 days after the date of a fracture) rather than months with varying number of days (e.g., 28 – 31 days). We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66-80 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q418. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the frailty exclusion criteria to measure Q418: Osteoporosis Management in Women Who Had a Fracture. The removal of the encounter criteria will reduce reporting burden while still following through with the intent of the exclusion for patients with an indication of frailty.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62550), we are finalizing the changes to measure Q418 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.45. Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	420
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.
Substantive Change:	**Updated numerator definition: Added:** Varicose Veins Symptom Questionnaire (VVSymQ) and Venous Clinical Severity Score (VCSS).
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We proposed to revise the definition of an 'Outcome Survey' to include the VVSymQ and VCSS. These outcome surveys measure improvement for saphenous vein ablation and will allow clinicians more choices for meeting the numerator, which may encourage further adoption of this measure.[1124]

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62551), we are finalizing the changes to measure Q420 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1124] Paty, J., Turner-Bowker, D. M., Elash, C. A., & Wright, D. (2016). The VVSymQ® Instrument: Use of a New Patient-Reported Outcome Measure for Assessment of Varicose Vein Symptoms. *Phlebology*, *31*(7), 481–488. https://doi.org/10.1177/0268355515595193.

D.46. Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	432
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.

Substantive Change:	**The measure title is revised from Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair to:** Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair. **The measure description is revised to read:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bladder or bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery. **The measure instructions are revised to read:** This measure is to be submitted each time an anterior, posterior, or apical prolapse repair surgery is performed from December 1st of the previous performance period through November 30th of the current performance period. There is no diagnosis associated with this measure. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. This measure will be calculated with 2 performance rates: 1) Percentage of patients undergoing prolapse repair who sustain a bladder injury that necessitates repair either intraoperatively or within 30 days after surgery. 2) Percentage of patients undergoing prolapse repair who sustain a bowel injury that necessitates repair either intraoperatively or within 30 days after surgery. Submission of the two performance rates is required for this measure. A simple average, which is the sum of the performance rates divided by the number of the performance rates will be used to calculate performance. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients undergoing anterior or apical pelvic organ prolapse (POP) surgery who sustain a bladder injury. 2) All patients undergoing anterior, posterior, or apical pelvic organ prolapse (POP) surgery who sustain a bowel injury. This measure contains two submission criteria which together ensure that the proper evaluation and treatment is provided for patients who undergo pelvic organ prolapse repair. Submission Criteria 1 evaluates whether patients sustained a bladder injury intraoperatively or within 30 days after surgery. Submission Criteria 2 evaluates whether patients sustained a bowel injury intraoperatively or within 30 days after surgery. Patients who undergo a procedure that meets the denominator of both submission criteria should be included in both and assessed for each clinical outcome. **Updated denominator: Added:** SUBMISSION CRITERIA 2: All patients undergoing anterior, posterior, or apical pelvic organ prolapse (POP) surgery. **Updated denominator criteria: Added:** SUBMISSION CRITERIA 2: All patients, regardless of age AND Patient procedure during the denominator identification period WITHOUT Telehealth Modifier **Updated definition: Added:** SUBMISSION CRITERIA 1 & 2: Denominator identification period – the twelve month period in which eligible patients have a procedure, which December 1st of the previous performance period through November 30th of the current performance period. **Updated numerator:** **Revised:** SUBMISSION CRITERIA 1: Percentage of patients undergoing prolapse repair who sustain a bladder injury that necessitates repair either intraoperatively or within 30 days after surgery. **Added:** SUBMISSION CRITERIA 2: Percentage of patients undergoing prolapse repair who sustain a bowel injury that necessitates repair either intraoperatively or within 30 days after surgery. Update numerator instructions: Added: SUBMISSION CRITERIA 2: INVERSE MEASURE – A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control. **Updated numerator note: Added:** SUBMISSION CRITERIA 2:

Category	Description
	In order to meet the measure, bowel injury is sustained as a result of the prolapse surgery. **Updated numerator options: Added:** SUBMISSION CRITERIA 2: Performance Met: Patient sustained bowel injury at the time of surgery or discovered subsequently up to 30 days post-surgery OR Denominator Exception: Documented medical reasons for not reporting bowel injury (e.g. gynecologic or other pelvic malignancy documented, planned (e.g. not due to an unexpected bowel injury) resection and/or re-anastomosis of bowel, or patient death from non-medical causes not related to surgery, patient died during procedure without evidence of bowel injury) OR Performance Not Met: Patient did not sustain a bowel injury at the time of surgery nor discovered subsequently up to 30 days post-surgery
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed to revise this measure to add a submission criteria and performance rate for patients who retain a bowel injury at the time of any pelvic organ prolapse repair. We proposed to add submission criteria two to evaluate all patients undergoing anterior, posterior, or apical pelvic organ prolapse surgery who sustain a bowel injury. Previously, assessment of bowel injury outcomes for POP procedures was a separate measure. As both measures are assessing for adverse outcomes following POP procedures, these measures are being combined so that a full picture of adverse outcomes can be captured for this patient population. Additionally, by combining these measures, the denominator eligible patient population may increase allowing for more robust data for participating MIPS clinicians. We also proposed to add a definition for the denominator identification period of December 1st of the previous performance period through November 30th of the current performance period. In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair to include both bladder and bowel injury.

Response: We thank the commenter for supporting the substantive changes to this measure.

For the reasons stated above and in the proposed rule (89 FR 62552 through 62554), we are finalizing the changes to measure Q432 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.47. Appropriate Workup Prior to Endometrial Ablation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	448
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**Updated the instructions: Revised:** submission of the measure to once per performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to change the frequency of this measure from each time a procedure for endometrial ablation is performed to once per performance period, as this is more aligned with the clinical action being assessed for this measure.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62554), we are finalizing the changes to measure Q448 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.48. Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

Category	Description
CBE # / eCQM CBE #:	1858 / N/A
Quality #:	450
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated. **The measure denominator is revised to read:** All breast cancer patients aged 18 to 70 with pathologic stage I (T1c) – III HER2 positive breast cancer diagnosed between July 1st of the previous performance period through June 30th of the current performance period. **Updated denominator instructions: Added:** For the purposes of this measure, only pathologic staging and HER-2 testing performed between July 1st of the previous performance period through June 30th of the current performance period will be included in the denominator of this measure. **Updated denominator note: Added:** This measure includes both female and male breast cancers. While treatment recommendations for males have largely been extrapolated from results of clinical trials focused on breast cancer in females, management of breast cancer in males is similar in overall management to breast cancer in females. Consistent with guidance in National Comprehensive Cancer Network (NCCN) guideline recommendations for adjuvant systemic therapy, chemotherapy with/without HER2-targeted therapy should be recommended for males with breast cancer according to guidelines for females with breast cancer. **Updated denominator criteria: Revised:** Patients age 18-70 years on date of encounter **Added:** diagnosis codes for male breast cancer. **Added:** Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period. **Updated numerator note: Added:** The timeframe to identify the adjuvant treatment course is within six months of breast cancer pathologic staging. To satisfy the numerator, both chemotherapy and HER2-targeted therapy must occur within six months of pathologic staging.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update multiple components of this measure to ensure that all patients diagnosed with breast cancer are included in the measure's denominator. While treatment recommendations for males have largely been extrapolated from results of clinical trials focused on breast cancer in females,[1125] management of breast cancer in males is similar in overall management to breast cancer in females. Consistent with guidance in NCCN recommendations for adjuvant systemic therapy, chemotherapy with/without HER2-targeted therapy should be recommended for males with breast cancer according to guidelines for females with breast cancer.[1126] Additionally, revisions to the denominator definition will clarify the timeframe in which pathologic staging and HER-2 testing should be performed for patient to be included in the denominator. We also proposed revisions to the numerator note to further clarify definition of and timeframe for when adjuvant treatment, for the purposes of this measure, should occur relative to pathologic staging.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62555), we are finalizing the changes to measure Q450 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1125] Hassett, M. J., Somerfield, M. R., & Giordano, S. H. (2020). Management of Male Breast Cancer: ASCO Guideline Summary. *JCO Oncology Practice*, *16*(8), e839–e843. https://doi.org/10.1200/JOP.19.00792.

[1126] Gradishar, W. J., Moran, M. S., Abraham, J., Abramson, V., Aft, R., Agnese, D., Allison, K. H., Anderson, B., Burstein, H. J., Chew, H., Dang, C., Elias, A. D., Giordano, S. H., Goetz, M. P., Goldstein, L. J., Hurvitz, S. A., Jankowitz, R. C., Javid, S. H., Krishnamurthy, J., Leitch, A. M., … Kumar, R. (2023). NCCN Guidelines® Insights: Breast Cancer, Version 4.2023. *Journal of the National Comprehensive Cancer Network: JNCCN*, *21*(6), 594–608. https://doi.org/10.6004/jnccn.2023.0031.

D.49. RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

Category	Description
CBE # / eCQM CBE #:	1859 / N/A
Quality #:	451
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator instructions: Added:** The denominator of this measure is intended to capture newly diagnosed stage IV patients or patients who have distant metastases at the time of colon cancer diagnosis. For the purposes of this measure, the patient's initial diagnosis may occur between December 1 of the prior year through November 30 of the performance period, and anti-EGFR monoclonal antibody therapy may occur between December 1 of the prior year through December 31 of the performance period.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to add denominator instructions to clarify that only patients who have been newly diagnosed with Stage IV colorectal cancer or patients who have distant metastases at the time of colon cancer diagnosis are to be captured in the denominator of the measure. This will ensure that the appropriate patient population is assessed for the numerator action.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62556), we are finalizing the changes to measure Q451 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.50. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	462
CMS eCQM ID:	CMS645v8
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**The measure denominator is revised to read:** Patients with a qualifying encounter in the measurement period AND with a diagnosis of prostate cancer AND with an order for ADT or an active medication of ADT with an intent for treatment greater than or equal to 12 months during the measurement period AND order for ADT in 3 months before to 9 months after the start of the measurement period.
Measure Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to expand the denominator to include all patients regardless of gender. This revision broadens the denominator population to capture all patients with a diagnosis of prostate cancer who are receiving androgen deprivation therapy and ensure a bone density evaluation is completed prior to the start of treatment. As significantly lower PSA screening rates were seen among transgender individuals for ages 40-54 and 55-69, but higher rates within the age group 70-80 (P.ß<.ß.001 for all),[1127] broadening the denominator will ensure these patient populations are being screened in accordance with current clinical guidelines.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62557), we are finalizing the changes to measure Q462 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1127] Premo, H., Gordee, A., Lee, H. J., Scales, C. D., Moul, J. W., & Peterson, A. (2023). Disparities in Prostate Cancer Screening for Transgender Women: An Analysis of the MarketScan Database. *Urology*, *176*, 237–242. https://doi.org/10.1016/j.urology.2023.03.016.

D.51. Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0657 / N/A
Quality #:	464
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**The measure instructions are revised to read:** This measure is to be submitted once for each occurrence of otitis media with effusion (OME) in children seen during the performance period. Each unique occurrence starts with the onset of OME symptoms and concludes with the resolution of OME or after 90 days if a resolution of OME symptoms is not documented. If multiple encounters are documented within an occurrence, Merit-based Incentive Payment System (MIPS) eligible clinicians should submit the most recent encounter during that occurrence. A new occurrence of OME cannot start until the previous occurrence during the performance period has concluded.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the measure instructions to clarify what constitutes an occurrence for the purposes of this measure. This additional guidance will further clarify how patients are attributed to the denominator of this measure for each eligible occurrence. This change will ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62558), we are finalizing the changes to measure Q464 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.52. Functional Status After Primary Total Knee Replacement

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	470
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR. tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator note: Revised:** list of situations that denote performance not met.
Measure Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We proposed to revise the numerator note by clarifying that if a tool other than the Oxford Knee Score (OKS) or Knee injury/Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) is used to assess a patient's functional status for this measure, it will result in a performance not met. The requirements for meeting this measure require use of the specific tools referenced in the measure specification, as they have been tested, validated, and determined to be most appropriate for capturing the numerator action.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q470: Functional Status After Primary Total Knee Replacement. The commenter requested clarification if a tool other than the Oxford Knee Score (OKS) or Knee injury/Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) is used to assess a patient's functional status, this should result in a performance not met.

Response: We thank the commenter for supporting the substantive changes to this measure. Currently this measure is prescriptive as to the tools that can be utilized to meet performance; however, we encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62558), we are finalizing the changes to measure Q470 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.53. Psoriasis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	485
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The percentage of patients aged 8 years and older, with a diagnosis of psoriasis where at an initial (index) visit have a patient-reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow-up visit.
Substantive Change:	**Updated denominator note: Added:** The initial (index) visit assessment and the follow-up visit for assessment must occur during the performance period. The initial (index) visit is the first encounter with the patient during the performance period. Every visit after the initial (index) visit during the performance period is a follow-up visit. An assessment should be completed at each visit. **Updated numerator instructions: Removed:** If a patient has multiple follow-up visits within the measurement period, the last (most recent) visit should be used.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-reported Outcome-based Performance Measure
Rationale	We proposed to update the denominator note to clarify encounter timing by including language outlining that a patient's first visit during the measurement period is considered the initial (index) encounter. Each visit after the initial (index) visit during the measurement period will be deemed a follow-up visit used to determine the outcome of the measure. This change will ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q485: Psoriasis – Improvement in Patient-Reported Itch Severity.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62559), we are finalizing the changes to measure Q485 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.54. Dermatitis – Improvement in Patient-Reported Itch Severity

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	486
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The percentage of patients aged 8 years and older, with a diagnosis of dermatitis where at an initial (index) visit have a patient-reported itch severity assessment performed, score greater than or equal to 4, and who achieve a score reduction of 3 or more points at a follow-up visit.
Substantive Change:	**Updated denominator note: Added:** The initial (index) assessment and the follow-up visit for assessment must occur during the performance period. The initial (index) visit is the first encounter with the patient during the performance period. Every visit after the initial (index) visit during the performance period is a follow-up visit. An assessment should be completed at each visit. **Updated numerator instructions: Removed**: If a patient has multiple follow-up visits within the measurement period, the last (most recent) visit should be used.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-based Performance Measure
Rationale	We proposed to update the denominator note to clarify encounter timing by including language outlining that a patient's first visit during the measurement period is considered the initial (index) encounter. Each visit after the initial (index) visit during the measurement period will be deemed a follow-up visit used to determine the outcome of the measure. This change will ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q486: Dermatitis – Improvement in Patient-Reported Itch Severity.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62559), we are finalizing the changes to measure Q486 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.55. Kidney Health Evaluation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	488
CMS eCQM ID:	CMS951v3
Current Collection Type:	eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients aged 18-75 years with a diagnosis of diabetes who received a kidney health evaluation defined by an Estimated Glomerular Filtration Rate (eGFR) AND Urine Albumin-Creatinine Ratio (uACR) within the measurement period.
Substantive Change:	**Updated description: For all collection types: Revised:** patients aged 18-85 years. **Updated denominator: For all collection types: Revised:** patients aged 18-85 years. **Updated denominator criteria: For the MIPS CQM Specifications collection type: Revised:** patients aged 18-85 years.
Measure Steward:	National Kidney Foundation
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the age from 18-75 to 18-85 years of age for denominator eligibility. Based on information from National Institutes of Health states, "A high proportion of older CKD patients are usually affected by multimorbidity, polypharmacy, frailty, functional and cognitive impairment, and disability."[1128] "The benefits of preventing/slowing the progression of CKD has the potential to impact different social and health domains, for example, reducing the need for long-term care and the cost related to caregiving."[1129] Increasing the denominator age criteria support the reporting of clinicians currently screening a broader elderly population for this preventable disease.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to adjust the upper age range from 75 to 85 years old to promote screening for a broader elderly population to measure Q488: Kidney Health Evaluation. Kidney heath evaluation, which begins with appropriate, clinically adherent screening, is essential to identifying CKD at early stages and increases the likelihood of successful intervention.

Response: We thank the commenter for supporting the substantive changes to this measure.

Comment: One commenter opposed the age extension from 75 to 85 years to measure Q488. The commenter stated most older adults, with or without diabetes mellitus, will have annual serum creatinine assessments due to their frequent contact with the healthcare system and ubiquitous blood testing, including the basic and comprehensive metabolic panels. Therefore, this measure specification change effectively impacts the addition of annual urine microalbumin creatinine ratio (uMAC) testing. Due to abundant serum creatinine testing, clinicians and patients are likely to be aware of renal decline in those 76 to 85 years of age and beyond, without a uMAC result. The commenter indicated that this proposed change would force clinicians to order and communicate the results of a test that in most cases they should not order or act on.

Response: We appreciate the concerns expressed by the commenter. The extension of the age to 85 years will encourage annual kidney health evaluations in older adults with diabetes to assess for kidney function and kidney damage. These recommended blood and urine kidney tests forge an intentional focus on early detection and improved kidney care. The National Kidney Foundation recommends annual testing for patients with certain risk factors, including diabetes and being over the age of 60.[1130]

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62560), we are finalizing the changes to measure Q488 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1128] Corsonello, A., Freiberger, E., & Lattanzio, F. (2020). The Screening for Chronic Kidney Disease Among Older People across Europe (SCOPE) Project: Findings from Cross-Sectional Analysis. *BMC Geriatrics*, *20*(Suppl 1), 316. https://doi.org/10.1186/s12877-020-01701-w.

[1129] See footnote Corsonello et al., 2020.

[1130] National Kidney Foundation. (2023). Urine Albumin-Creatinine Ratio (uACR). https://www.kidney.org/kidney-topics/urine-albumin-creatinine-ratio-uacr#:~:text=The%20recommended%20frequency%20ranges%20from,been%20diagnosed%20with%20kidney%20disease.

D.56. Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	490
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of cancer, on immune checkpoint inhibitor therapy, and grade 2 or above diarrhea and/or grade 2 or above colitis, who have immune checkpoint inhibitor therapy held and corticosteroids or immunosuppressants prescribed or administered.
Substantive Change:	**Updated denominator definition: For the MIPS CQM Specifications collection type: Added:** immune checkpoint inhibitors Lag-3 inhibitor drug: Relatlimab; and Tremelimumab to CTLA-4 inhibitor drugs.
Measure Steward:	Society for Immunotherapy of Cancer (SITC)
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator definition to add new Food and Drug Administration (FDA) approved checkpoint inhibitors, Relatlimab and Tremelimumab. These inhibitors are clinically appropriate to include in the denominator of this measure.[1131] [1132]

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (89 FR 62561), we are finalizing the changes to measure Q490 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1131] FDA. (2022). FDA Approves Tremelimumab in Combination with Durvalumab and Platinum-based Chemotherapy for Metastatic Non-small Cell Lung Cancer. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tremelimumab-combination-durvalumab-and-platinum-based-chemotherapy-metastatic-non.

[1132] FDA. (2022). FDA Approves Opdualag for Unresectable or Metastatic Melanoma. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-opdualag-unresectable-or-metastatic-melanoma.

D.57. Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	492
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Substantive Change:	**Updated: Reporting Requirements: Removed:** individual reporting.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale	We proposed a substantive change to this measure that will be applied retroactively starting with the CY 2023 performance period/2025 MIPS payment year. In the CY 2023 PFS final rule, we inadvertently specified the measure was available at the individual clinician level. The inclusion of the availability of the measure at the individual clinician level is a misrepresentation and erroneously conveys to MIPS eligible clinicians reporting at the individual clinician level that the measure is available to meet the minimum required number of measures to report under traditional MIPS or an MVP. The measure was tested and developed for implementation at the group, virtual group, subgroup via an MVP, and APM Entity levels. Thus, the measure is limited to groups, virtual groups, subgroups via an MVP, and APM Entities participating in MIPS. A failure to apply this substantive change retroactively will be contrary to the public interest. Prior to the finalization of this measure as a new measure available within the MIPS quality measure inventory in the CY 2023 PFS final rule, the measure was initially proposed as a new measure in the CY 2022 PFS proposed rule. Based on the public comments received in response to the initial proposal of this measure in the CY 2022 PFS proposed rule, there were concerns regarding the attribution of certain patients to clinicians, particularly the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. As a result, the measure was not finalized as part of the CY 2022 PFS final rule; however, we noted that we will continue to consider how to implement condition-specific measures such as this measure under MIPS (86 FR 65692 through 65694). In the CY 2023 PFS proposed rule, we re-proposed this measure, which mitigated the concerns regarding the attribution of such patients to clinicians by excluding patients at advanced stages of heart failure and requiring that a group, virtual group, subgroup via an MVP, and APM Entity to include at least 1 cardiologist (and a 21-patient case minimum); and subsequently, the measure was finalized in the CY 2023 PFS final rule (87 FR 70266) through 70271). The intent of the measure is for assessment of performance to be conducted at the group, virtual group, subgroup via an MVP, and APM Entity levels. The measure was not tested, developed, or implemented at the individual clinician level. In order for this measure to be available at the individual clinician level, the measure will need to be tested at the individual clinician level to establish validity, reliability, and risk adjustments at the individual clinician level. It is not appropriate for the measure to be available at the individual clinician level without further testing. Consequently, any assessment of data for this measure at the individual clinician level will produce invalid and unreliable results. By retroactively applying the substantive change to this measure (modifying the measure to remove the individual clinician level as an option) effective starting with the CY 2023 performance period/2025 MIPS payment year, the level of reporting available for the measure will align with the intent, implementation, and operationalization of the measure, and clarify that the measure is not available at the individual clinician level.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q492: Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System and was pleased that CMS acknowledged that this measure's application at the individual clinician level could result in invalid and unreliable results, given that it has not been tested. A second commenter supported the proposed substantive change as it ensures accuracy and validity by using the measure as intended. The change also aligns the measure's use with its tested and developed levels, namely groups, virtual groups, subgroups, and APM Entities.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62562), we are finalizing the changes to measure Q492 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.58. Adult Immunization Status

Category	Description
CBE # / eCQM CBE #:	3620 / N/A
Quality #:	493
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Substantive Change:	**Updated instructions: Revised:** pneumococcal vaccine on or after their 19th birthday. **Updated numerator: Revised:** Submission Criteria 4: pneumococcal vaccine on or after their 19th birthday.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the measure instructions and numerator to lower the minimum age from 60 years of age to 19 years of age. This revision aligns with the updated ACIP pneumococcal vaccination guidelines[1133] that recommend administering conjugate vaccines to all adults with certain underlying medical conditions. In the CY 2023 PFS final rule, this measure was finalized, and it was noted that the scoring of the measure will use a weighted average for the first 2 years of implementation; and starting with the CY 2025 performance period/2027 MIPS payment year, the measure will be scored as an all-or-none composite measure to ensure a more thorough assessment of a patient's vaccination status (87 FR 70272 through 70274). However, based upon an analysis of preliminary data submitted for the CY 2023 performance period, low measure adoption, and feedback received through Quality Payment Program Service Now tickets regarding burden of implementation and ability to meet performance on all four components, we proposed to maintain the weighted average analytic for the CY 2025 performance period and subsequent years as determined by CMS. The utilization of the weighted average metric/analytic beyond 2 years will provide clinicians with more time to prepare for the transition to a more stringent all-or-none metric/analytic, which will require a complete vaccination history to meet numerator compliance.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported revisions to measure Q493: Adult Immunization Status to align with ACIP recommendations, such as the proposal to update the numerator instructions lowering the minimum age for pneumococcal vaccinations. The commenter encouraged CMS to continue refinements of the Adult Immunization Status measure in accordance with up-to-date ACIP recommendations, and to create consistency of the measure specifications with updates made by the measure steward, NCQA, related to removing the herpes zoster live (ZVL) vaccine from the herpes zoster immunization indicator, and adding a hepatitis B immunization indicator.

The commenter indicated it is important for CMS to create consistencies of this measure in MIPS and across other reporting structures, given the broad uptake of this measure in quality reporting programs and MVPs. The commenter also acknowledged the challenges some clinicians have faced in meeting the performance requirements for all four vaccine indicators under measure Q494 and suggested tracking individual vaccine performance under this measure.

Response: We thank this commenter for supporting the substantive changes to this measure. We appreciate the commenters feedback. We strive to align measures across quality reporting programs as much as possible and encourage measure stewards to propose refinements to keep the measures up to date. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years, such as tracking individual performance under this measure. This measure will retain its weighted average analytic as we are delaying the transition to an all-or-none analytic to a future year.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62563), we are finalizing the changes to measure Q493 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1133] Kobayashi, M., Pilishvili, T., Farrar, J. L., Leidner, A. J., Gierke, R., Prasad, N., Moro, P., Campos-Outcalt, D., Morgan, R. L., Long, S. S., Poehling, K. A., & Cohen, A. L. (2023). Pneumococcal Vaccine for Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023. *MMWR. Recommendations and Reports: Morbidity and Mortality Weekly Report. Recommendations and Reports*, *72*(3), 1–39. https://doi.org/10.15585/mmwr.rr7203a1.

D.59. Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	497
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Substantive Change:	**Updated instructions: Updated:** Percentage of patients 65 years of age or older who received a pneumococcal vaccination on or after their 19th birthday. **Updated denominator exclusion: Removed:** (Submission Criteria 3 and Submission Criteria 4): specific encounter requirements from the frailty/advanced illness exclusion. **Updated denominator criteria: Added:** (Submission Criteria 7) coding for nutrition/dietitian clinician type. **Updated numerator definition: Revised:** intervals for rescreening for first and second hypertensive BP readings.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the measure instructions for patients 65 years of age and older who have received a pneumococcal vaccination on or after their 19th birthday. This update will allow for the identification of patients 65 years of age and older who may have a clinical condition that will make them a candidate to receive the pneumococcal vaccine prior to 65 years of age.[1134] We proposed to add encounter codes for nutrition therapy to the denominator criteria as this is an appropriate setting to identify people who may have elevated blood pressure (BP) readings. Nutritional approaches play a pivotal role in helping to reduce the risk of hypertension or control blood pressure in people with hypertension.[1135] We proposed to remove the minimum timeframe for follow-up screenings for patients with elevated BP readings. This change allows clinician discretion to recommend a follow-up plan based on the patient's current health status. Additionally, this supports stability of this measure component, as the frequency is each visit, within the specification over time, while still maintaining consistency with the current guidelines.[1136] We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator for submission criteria 3 and submission criteria 4 of measure Q497.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the frailty exclusion criteria to measure Q497: Preventive Care and Wellness (composite). The removal of the encounter criteria will reduce reporting burden while still following through with the intent of the exclusion for patients with an indication of frailty.

Response: We thank the commenter for supporting the substantive changes to this measure

Comment: One commenter appreciated that measure Q497 was updated to improve data capture and ensure that it is aligned with evidence but remained concerned on the complexity of the measure and its inclusion in MIPS.

Response: We thank the commenter for supporting the substantive changes to this measure. By setting a more stringent performance standard through use of a single composite measure compared to the prior framework, under which each quality action was reported through a separate quality measure, we will gain a better picture of overall preventive care practices as each

[1134] See footnote Kobayashi et al., 2023 in Table D.58 of this Appendix.
[1135] See footnote Physicians Committee for Responsible Medicine, 2023 in Table D.28 of this Appendix.
[1136] See footnote Whelton et. al., 2018 in Table D.28 of this Appendix.

component is important to either prevention of or early detection of disease (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678940/*). We maintained two of the component measures, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention and Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, in select specialty measure sets due to the importance of those clinical concepts to specialties where the composite measure would not be applicable, and we maintained measure Q493: Adult Immunization Status for use within traditional MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62564), we are finalizing the changes to measure Q497 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.60. Connection to Community Service Provider

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	498
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percent of patients 18 years or older who screen positive for one or more of the following health related social needs (HRSNs): food insecurity, housing instability, transportation needs, utility help needs, or interpersonal safety; and had contact with a Community Service Provider (CSP) for at least 1 of their HRSNs within 60 days after screening.
Substantive Change:	**Updated denominator criteria: Added:** coding for Dentistry, Emergency Medicine, Inpatient, Nuclear Medicine, Interventional Radiology, Psychiatry, Mental and Behavioral Health, Nephrology, Nutrition/Dietician, Obstetrics/Gynecology, Ophthalmology, Otolaryngology, Physical Therapy/Occupational Therapy, Home Care and Skilled Nursing.
Measure Steward:	OCHIN
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to update the denominator criteria to include coding for multiple patient services as this measure is applicable to the scope of care associated with these services. Clinicians treating patients within these services have an opportunity for screening for HRSNs and connecting with an appropriate CSP. Addressing the social determinants is an important and emerging area of practice that entails starting earlier and broadening the scope of interventions, thus making entire families and communities healthier.[1137]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to include medical nutrition therapy codes in the denominator criteria to measure Q498: Connection to Community Service Provides that underscores the crucial role RDNs play in screening for health-related social needs and connecting patients with appropriate community service providers. One commenter appreciated the addition of coding for physical therapy. Two additional commenters supported the proposed substantive changes to measure Q498.

Response: We thank the commenters for the supporting substantive changes to this measure.

Comment: One commenter did not support expanding the measure's coding to measure Q498 to be attributed to the additional specialties under the substantive change. The commenter supported the measure's intent, but continued to oppose its inclusion in MIPS, stating that measures must be evidence-based and facilitate improvements in patient care. The commenter continued to see a lack of any evidence supporting the measure, or any testing been provided to demonstrate the measure's reliability and validity. By expanding to additional specialties without sufficient testing at the individual clinician level, the commenter believed that CMS increases the potential for unintended negative consequences, and as a result, the commenter did support the measure or this expansion in MIPS or MVPs.

The commenter remained concerned that clinicians will be unable to address their patient needs due to the lack of resources and tools that are widely and readily available to clinicians and practices. The availability of resources will also be dependent on the patient's locality and the type of service needed. The commenter expressed that the measure should continue to align with the work of the HL 7 Gravity Project and the United States Core Data for Interoperability (USCDI). The commenter also voiced that to continue to include social needs-related measures in MIPS along with all the CMS quality programs without a comprehensive strategy on the best approach for physicians and clinicians to address the problem will exacerbate inequities and runs the risk of deteriorating the physician-patient relationship.

Response: We acknowledge the commenters concerns with this measure; however, we disagree with the commenter that this measure is not evidence-based. Studies have shown that social needs can create significant barriers to patients receiving and achieving high quality of care and can also contribute to poorer health.[1138] Systematically screening patients for social drivers of health and referring them to community-based resources as needed can result in improved health outcomes.[1139] Furthermore, improving the clinician's understanding of the social obstacles their patients face beyond the clinical realm – but which may

[1137] Andermann, A., & CLEAR Collaboration (2016). Taking Action on the Social Determinants of Health in Clinical Practice: A Framework for Health Professionals. *CMAJ: Canadian Medical Association Journal*, *188*(17-18), E474–E483. https://doi.org/10.1503/cmaj.160177.

[1138] Daniel, H., Bornstein, S. S., Kane, G. C., Health and Public Policy Committee of the American College of Physicians, Carney, J. K., Gantzer, H. E., Henry, T. L., Lenchus, J. D., Li, J. M., McCandless, B. M., Nalitt, B. R., Viswanathan, L., Murphy, C. J., Azah, A. M., & Marks, L. (2018). Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. *Annals of Internal Medicine*, *168*(8), 577–578. https://doi.org/10.7326/M17-2441.

[1139] See footnote Daniel et al., 2018.

affect their clinical outcomes – can provide critical insights, catalyze prevention and/or early identification and prompt referral, improve a patient's overall health and well-being.[1140]

While we agree availability of resources may be a challenge in some areas, with the increase in telehealth and virtual networking, the CSP need not be in the general area to provide assistance. Through different programs, CSPs can identify and work with the proper resources to reduce social stressors for patients and clinicians. We acknowledge that due to nuances in clinician specialization, scope of care, or regional location, not all measures within MIPS will be applicable or appropriate to all clinicians within that specialty set umbrella. However, no measures within traditional MIPS are required. MIPS provides clinician choice to account for these nuances, while ensuring clinicians can choose measures that are most meaningful to their scope of care and patient case-mix.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62565), we are finalizing the changes to measure Q498 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1140] Billioux, A., K. Verlander, S. Anthony, and D. Alley. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. *NAM Perspectives.* Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/201705b.

D.61. Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	500
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 8 weeks.
Substantive Change:	**Updated denominator criteria: Added:** acute PVD. **Removed:** coding for non-acute disorders related to PVD.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the denominator criteria by removing diagnosis codes for non-acute PVD and adding acute PVD within the criteria of the denominator. The ICD-10-CM PVD diagnosis codes do not differentiate between acute and non-acute disorders of vitreous detachment; therefore, to ensure the intended patient population is identified, the denominator criteria must be specific to acute PVD.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter provided comments related to proposed substantive changes proposed to measure Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up and measure Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up (see Table D.62 of this Appendix). The commenter requested guidance on what specific coding will be added to indicate acute PVD. Currently, the measure specification for measure Q500 does not require a HCPCS code for acute PVD, while the measure specification for measure Q501 does. The commenter requested that the coding requirements be consistent for these two measures.

Currently, the 2024 measure specifications for measures Q500 and Q501 both have the following definition of acute PVD specified in the Denominator section "Acute PVD – For the purposes of this measure, acute PVD and vitreous hemorrhage is defined as recent onset of 30 days or less. For PVD, acute can be documented as new onset vitreous separation or vitreous detachment." This indicates these measures could be mapped to keywords for reporting, rather than relying on coding. The commenter requested that CMS allow providers to use either the HCPCS code or the field mapping to identify the patient population. Since a significant percentage of clinicians do not use the acute PVD HCPCS code, there will need to be significant education required to implement new practices should the code be required for these measures in 2025. Therefore, in addition to making the denominator requirements the same for measures Q500 and Q501, the commenter requested that CMS clarify and clearly communicate what the coding changes for these measures will be prior to December 2024. This would allow time to educate clients and members to ensure they are able to code appropriately for these measures for a full year starting on January 1, 2025.

Response: We thank the commenters for their feedback. The specific coding will be listed in the measure specifications along with the Single Source document which will be posted in December.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62566), we are finalizing the changes to measure Q500 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.62. Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	501
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of patients with a diagnosis of acute posterior vitreous detachment (PVD) and acute vitreous hemorrhage in either eye who were appropriately evaluated during the initial exam and were re-evaluated no later than 2 weeks.
Substantive Change:	**Updated denominator criteria: Removed:** coding for non-acute disorders related to PVD.
Measure Steward:	American Society of Retina Specialists
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to revise the denominator criteria by removing diagnosis codes for non-acute PVD and adding acute PVD within the criteria of the denominator. The ICD-10-CM PVD diagnosis codes do not differentiate between acute and non-acute disorders of vitreous detachment; therefore, to ensure the intended patient population is identified, the denominator criteria must be specific to acute PVD.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table D.61 of this Appendix, one commenter requested guidance on what specific coding will be added to indicate acute PVD to measures Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up and Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up.

Response: Please see our response to this commenter under Table D.61 of this Appendix.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62566), we are finalizing the changes to measure Q501 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.63. Gains in Patient Activation Measure (PAM®) Scores at 12 Months

Category	Description
CBE # / eCQM CBE #:	2483 / N/A
Quality #:	503
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	The Patient Activation Measure® (PAM®) is a 10- or 13- item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM® performance measure (PAM®-PM) is the change in score on the PAM® from baseline to follow-up measurement.
Substantive Change:	**Updated instructions: Revised:** follow-up PAM® survey collected on at least 25% of all eligible patients within 4 to 12 months of the baseline during the performance period. **The measure denominator is revised to read:** **For Submission Criteria 1:** Patients aged 14 years and older with at least two qualifying visits during the performance period. **For Submission Criteria 2, 3 & 4:** Patients aged 14 years and older with Performance Met for Submission Criteria 1 who had a baseline PAM® score and a second score within 4 to 12 month of baseline PAM® score and who were seen for a qualifying visit at least twice during the performance period. **Updated denominator criteria: Revised:** For Submission Criteria 2, 3, & 4: follow-up PAM® survey collected on at least 25% of all eligible patients within 4 to 12 months of the baseline during the performance period. **Updated denominator exception: Revised:** For Submission Criteria 1: to remove patients with excessive missing responses or patients who were not seen for the second PAM survey within 4 months of the baseline. **Updated denominator exclusion: Added:** For ALL Submission Criteria: Patients who died during the performance period. **Updated numerator: Revised:** for ALL Submission Criteria: timing of follow-up PAM® survey to occur 4 to 12 months after baseline. **Updated numerator definition: Added**: For Submission Criteria 1: clarification as to what denotes excessive missing responses for each PAM survey.
Measure Steward:	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale	We proposed to revise multiple components of this measure to allow re-administration of the PAM® survey no less than 4 months after the baseline survey is administered as opposed to 6 months. This change will allow a higher percentage of patients to complete the survey and be included in the measure denominator. In addition, we proposed to lower the minimum performance threshold for collected follow-up PAM® surveys from 50 percent to 25 percent and remove patients who were missing more than 3 responses on the PAM-10® surveys or more than 4 responses on the PAM-13® surveys. Revising the threshold for the collected follow-up PAM® survey reduces clinician burden by lowering the number of survey responses that need to be collected to meet the measure denominator. We also proposed to add a definition to clarify what denotes excessive for missing responses. Removing patients with excessive missing responses allows for a more complete assessment of an individual's knowledge, skills, and confidence for managing their health and health care. In addition, we proposed to increase the number of qualifying visits to two during the performance period and add an exclusion to remove patients who may have died during the performance period. These revisions to the denominator ensure a patient is established within that clinician's patient population which supports the completion of the baseline and follow-up of the survey.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed substantive changes to measure Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months. One of these commenters agreed with the proposal to lower the minimum performance threshold for collected follow-up PAM® surveys from 50 percent to 25 percent and supported the proposed modification to the denominator criteria to require two visits. This will ensure patients who are lost to follow-up do not count against a reporting clinician.

Response: We thank the commenters for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62567), we are finalizing the changes to measure Q503 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

D.64. Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	504
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM Specifications
Current Measure Description:	Percentage of adult aged 18 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older with suicidal ideation or behavior symptoms (based on results of a standardized assessment tool or screening tool) or increased suicide risk (based on the clinician's evaluation or clinician-rating tool) for whom a suicide safety plan is initiated, reviewed, and/or updated in collaboration between the patient and their clinician. **The measure denominator is revised to read:** For denominator submission criteria 1 & 2: Patients aged 12 years and older with a mental and/or substance use disorder with suicidal ideation and/or behavior symptoms or suicide risk at a clinical encounter during the denominator identification period.
Measure Steward:	American Psychiatric Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale	We proposed to revise the age from 18 years and older to 12 years and older for denominator eligibility as suicide risk assessment is an important part of child and adolescent mental health, as noted in an American Academy of Pediatrics publication.[1141] "Suicide is the second leading cause of death for 10- to 24-year-olds in the United States and is a global public health issue, with a recent declaration of a National State of Emergency in Children's Mental Health by the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and Children's Hospital Association."[1142]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to measure Q504: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk to include patients 12 years and older as part of data collection. However, the commenter recommended lowering the age to 10 years and older to capture the quality of care for a broader population of patients who are impacted by suicide.

Response: We thank the commenter for supporting the substantive changes to this measure and appreciate the feedback regarding lowering the age to 10. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62568), we are finalizing the changes to measure Q504 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

[1141] Hua, L. L., Lee, J., Rahmandar, M. H., Sigel, E. J., Committee on Adolescence, & Council on Injury, Violence, and Poison Prevention. (2024). Suicide and Suicide Risk in Adolescents. *Pediatrics*, *153*(1), e2023064800. https://doi.org/10.1542/peds.2023-064800.

[1142] See footnote Hua et al., 2024.

Table Group DD: Finalized Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112**:** Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128**:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79897 through 79902). We note that some MIPS quality measures available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP) and/or APP Plus, as finalized in section IV.A.4.c.(3) of this final rule. For such measures, the collection type applicable for purposes of the APP and/or APP Plus (Medicare CQM for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQM)) is also specified as a collection type available for such measures described in Table Group DD.

Table Group DD within this final rule provides substantive changes finalized for the CY 2025 performance period/2027 MIPS payment year for MIPS quality measures available only in a relevant MVP. Two of the aforementioned MIPS quality measures, Q112 and Q113, have substantive changes under Table Group DD. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2025 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2025 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2026. The 2025 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

Note: Electronic clinical quality measures (eCQMs) that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2025 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

We solicited comments on these substantive changes.

DD.1. Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of women 40 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications, and Medicare CQM Specifications (collection type available only in the APP and/or APP Plus). **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q112. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the frailty exclusion criteria to measure Q112: Breast Cancer Screening. The removal of the encounter criteria will reduce reporting burden while still following through with the intent of the exclusion for patients with an indication of frailty.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62570), we are finalizing the changes to measure Q112 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

DD.2. Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v13
Current Collection Type:	Medicare Part B Claims Measure Specifications / eCQM Specifications / MIPS CQM Specifications
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications, and Medicare CQM Specifications (collection type available only in the APP and/or APP Plus) **Updated denominator exclusion: For all collection types: Removed:** specific encounter requirements from the frailty/advanced illness exclusion.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale	We proposed to update the denominator exclusion by removing the requirement for patients to have had at least one inpatient or two outpatient encounters to recognize a diagnosis of advanced illness. The removal of this requirement within the denominator exclusion reduces the burden of identifying applicable encounters, while still identifying patients with an indication of frailty. This is particularly applicable for those patients seen outside of their reporting clinician's medical record. This revision will update the denominator exclusion to remove any patient 66 years of age and older who has a diagnosis of advanced illness during the measurement period or the year prior from the denominator of measure Q113. Decreasing complexity and burden of this element ensures consistent implementation allowing for more comparable data.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed substantive changes to the frailty exclusion criteria to measure Q113: Colorectal Cancer Screening. The removal of the encounter criteria will reduce reporting burden while still following through with the intent of the exclusion for patients with an indication of frailty.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (89 FR 62570), we are finalizing the changes to measure Q113 as proposed for the CY 2025 performance period/2027 MIPS payment year and future years.

APPENDIX 2: IMPROVEMENT ACTIVITIES

We refer readers to the CY 2025 Physician Fee Schedule (PFS) proposed rule (89 FR 62056 through 62057 and 89 FR 62571 through 62581), where we proposed for the CY 2025 performance period/2027 MIPS payment year and future years to add two new improvement activities, modify two previously adopted improvement activities, and remove eight previously adopted improvement activities. We refer readers to 89 FR 62056 of the CY 2025 PFS proposed rule for additional details on the Call for Improvement Activities process. In this final rule, for the CY 2025 performance period/2027 MIPS payment year and future years, we are adding **two** new improvement activities, modifying **one** previously adopted improvement activity, and removing **four** previously adopted improvement activities. These changes are discussed in section IV.A.4.e.(3)(b)(iii) of this final rule and in more detail below.

TABLE A: New Improvement Activities for the CY 2025 Performance Period/2027 MIPS Payment Year and for Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_PM_24**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake
Proposed Activity Description:	Establish a process or procedure to increase rates of lung cancer screening through one or more of the following interventions: • Implementation of protocols that support enhanced documentation methods to identify eligible patients for lung cancer screening. ++ Example: A practice could embed electronic health record (EHR) prompts to flag insufficient patient smoking history (for example, total pack-years) and increase practice awareness around patient eligibility for screening ++ Example: A practice could implement documentation processes or procedures (for example, retrospective chart review, lung cancer screening eligibility questionnaire) to improve patient lung cancer screening eligibility data in the medical record • Development of a patient outreach and activation plan consisting of educational materials and resources for patients at high-risk of lung cancer for improved patient engagement and decision-making. ++ Example: Providers or clinic staff could provide culturally and linguistically appropriate patient-directed educational or care navigation materials related to lung cancer screening, eligibility criteria for low-dose computed tomography (LDCT), and the purpose and benefits of screening ++ Example: Providers or clinic staff could provide tools to prepare patients for shared decision-making (SDM) clinical encounters and promote patient/provider communication on lung cancer screening decision-making • Establishment of a navigation program to improve uptake and adherence of lung cancer screening and increase rates of LDCT referral completion. ++ Example: A practice could designate and train existing clinic staff or hire an additional staff member to counsel patients on the importance of lung cancer screening and refer them to existing resources (for example, transportation assistance, translator, financial services, appointment scheduling) to support ability to obtain LDCT ++ Example: A practice could create a process to follow up with referred patients via telephone reminders or virtual notifications (for example, email, patient charts)
Rationale:	Lung cancer is a leading cause of cancer-related deaths (21%) in the U.S., more than colon and breast cancers combined.[1,2] While there are established guidelines for the targeted use of LDCT for eligible patients, including particular criteria for age and

smoking history[3,4], national lung cancer screening (LCS) rates are estimated at only 6.5% as of 2020, compared to 63% for colon and 64% for breast cancer screening in 2019.[5,6]

Evidence demonstrates that screening for lung cancer can improve patient outcomes. The implementation of protocols that support enhanced documentation methods to identify eligible patients for LCS has been found to increase early-stage lung cancer detection, in one study by 24 percent (Russel et al., 2022).[7] Other studies have also shown benefits from enhancing documentation to allow for more appropriate LCS:

- Following a retrospective chart review of existing patient smoking history and implementation of a notification system for primary care providers (PCPs), a community hospital identified 82 percent of patients who were eligible for LCS not yet referred for screening, and of that, 31 percent completed an LDCT referral.[8]
- Implementation of a clinical reminder system in an EHR to refer eligible patients to an LCS program, increased the number of LDCTs performed from 54 percent to 79 percent in one Veterans Affairs (VA) medical center.[9]
- EHR prompts generating a notification for providers to order LDCT screening for eligible patients, increased documentation of complete patient smoking history by 31 percent.[10]
- Updating patient pack-year data in the EHR through a patient questionnaire on smoking history and implementation of an EHR screen assessing pack-year data in alignment with evidence-based guidelines; development of a patient outreach and activation plan consisting of educational materials and resources for patients at high-risk of lung cancer for improved patient engagement and decision-making: among patients from a tobacco quit-line utilizing a video-based LCS decision aid, 50 percent reported feeling well-prepared to make screening decisions than with traditional materials and 68 percent reported being clear about their values related to the harms and benefits of screening. Additionally, patients using the decision-aid were more knowledgeable about LCS than participants using standard educational materials at each follow-up assessment.[11]
- A web-based tool developed for SDM led to improved patient engagement, knowledge of LDCT, and preparation for SDM discussions among veterans in a primary care setting.[12]
- A computer tailored decision-support tool developed in alignment with the U.S. Preventive Services Task Force (USPSTF) LCS guidelines, increased LCS knowledge scores (2.33 mean change) and patient-perceived self-efficacy and benefits of LCS in a community-based clinic.[13]

Evidence also demonstrates the outcomes-improvement potential of the establishment of a navigation program to improve uptake and adherence of LCS and to increase rates of LDCT referral completion:

- In a patient navigator-led program including patient outreach to determine LCS eligibility, SDM discussions, and appointment-scheduling with patient's PCPs, 23.5 percent of LDCTs were performed in the intervention group compared to 8.6 percent in the control group among high-risk current smokers across 5 community health centers.[14]
- An oncology nurse navigator-led provider education program resulted in improved provider knowledge of LDCT and documented tobacco cessation discussions, as well as increased LDCT ordering for eligible patients.[15]
- A nurse-practitioner-led LCS clinic observed a 60 percent increase in the total number of LDCTs conducted and 85 percent of stakeholder participants noted the clinic was effective at addressing barriers to LCS.[16]

Exemplifying the importance of efforts seeking to increase LCS and follow up, guidelines and recommendations on expanded LCS eligibility criteria and SDM requirements by the Centers for Medicare & Medicaid Services (CMS) have recently been implemented:

- In 2021, leading LCS clinical guideline developers, including USPSTF and the AAFP lowered the starting age of LCS with LDCT from 55 to 50 years and

	patient pack-year history from 30 to 20 years, resulting in a larger eligible screening population.[17,3] • In 2022, under the Medicare National Coverage Determination, CMS expanded LCS eligibility criteria for age and pack-year history for beneficiaries receiving LDCT in alignment with clinical guidelines (for example, USPSTF, AAFP). • In addition to the expanded eligibility criteria, CMS requires a counseling and SDM visit to be appropriately documented in a patient's medical record and be inclusive of determination of beneficiary eligibility and the use of one or more decision-aids.[18] There is also published evidence that cost-effectiveness of care can improve as a result of expanded eligibility screening. Research has found downstream effects linked to early detection and prevention in LCS to be associated with long-term cost-effectiveness in LCS care delivery: • In 2021, the USPSTF expanded screening recommendations to include individuals at an earlier age of 50 from 55 years, and minimum cumulative smoking exposure from 30 to 20 pack-years. An economic evaluation of this guideline change indicated that the updated recommendations were cost effective compared to the earlier recommendations, with a mean incremental cost-effectiveness ratio of $72,564 per quality-adjusted life-year (QALY) gained.[19] • One study demonstrates the cost-savings of earlier diagnosis of lung cancer. In a review of patients with non-small cell lung cancer (NSCLC), it was revealed that the total per-patient per-month health care costs after diagnosis were significantly higher among those diagnosed at a Stage IV and lower among those diagnosed at Stage I ($7,239 Stage I, $9,484 Stage II, $11,193 Stage IIIa, $17,415 Stage IIIb, and $21,441 Stage IV).[20] • One modeling study of costs and outcomes associated with lung cancer found that implementation of a patient navigation program is cost-effective for lung cancer patients in Medicare, including that the program was cost-effective at a probability of 0.91 at $100,000/QALY.[21] • Given the significant impact of lung cancer in the U.S.--and the effectiveness of LCS and related interventions--as noted above, this activity has a high likelihood of making a positive impact on outcomes for eligible clinicians' patients.
Comment & Response:	*Comment*: We received comments in support of this new activity, citing that this will promote increased utilization of these important screenings. *Response*: We appreciate the supportive comments regarding this new activity.
Final Action:	We are finalizing this new activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_PM_25**
Proposed Subcategory:	Population Management
Proposed Activity Title:	Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk
Proposed Activity Description:	Implement standardized, evidence-based cardiovascular disease risk assessment and care management for a defined population in the clinician's practice. The clinician or clinician group will apply standardized risk assessment and care management to a broad, clinician-defined patient population in the practice. The population can be defined by 1) patient age and/or atherosclerotic cardiovascular disease (ASCVD) risk factors; or 2) the constraints of the risk assessment tool (for example, the American College of Cardiology (ACC)/American Heart Association (AHA) ASCVD Risk Calculator is validated for patients over age 40). The results of screening and the plan for treatment and follow up will be documented using a standardized method in the patient's medical record. Care management plan and follow up intervals will be influenced by the degree of patient risk.

	Cardiovascular care management should be defined by risk assessment and lead to the development of individualized care plans with specific goals. Shared decision making should be part of the development of every patient care plan.
Rationale:	Heart disease is the leading cause of death in the United States. Stroke is the fifth most common cause of death in the United States.[22]This activity is informed by the results of the CMS Innovation Center Million Hearts Model, which included initial ASCVD assessment as well as cardiovascular care management. [23] The Million Hearts Model used the ACC/AHA ASCVD Risk Calculator: ASCVD Risk Estimator (acc.org). [24] The proposed new activity supports improved identification and treatment of patients at risk for ASCVD, and would expand on the work of the model in two ways: (1) increasing flexibility in requirements, allowing more clinician specialties to participate, along with increased flexibility in risk assessment to fit the needs of attesting clinicians and their patient populations; (2) requiring the use of structured documentation of risk factors and associated treatment plans with the aim of addressing all risk factors directly. This activity accommodates the use of any evidence-based approach to risk evaluation and patient care management that is implemented using standardized methods and across an entire patient population. The ASCVD Risk Estimator used by the Million Hearts Model is evidence based and simple to implement but may not be appropriate for every practice scenario or patient population. There is strong published evidence validating the ACC/AHA ASCVD Risk Calculator; describing optimal care for coronary artery disease (including making comparisons to European Union best practices); and providing guidelines for primary prevention of coronary artery disease.[25,26,27,28]
Comment & Response:	*Comment*: We received comments in support of this new activity, citing that this will promote increased utilization of these important screenings. *Response*: We appreciate the supportive comments regarding this new activity.
Final Action:	We are finalizing this new activity as proposed.

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[4] National Comprehensive Cancer Network. NCCN Guidelines for Patients. (2020) Lung Cancer Screening. https://www.nccn.org/patients/guidelines/content/PDF/lung_screening-patient.pdf.

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TABLE B: Changes to Previously Adopted Improvement Activities for the CY 2025 Performance Period/2027 MIPS Payment Year and for Future Years

In this final rule, we are modifying **one** previously finalized improvement activity for the CY 2025 performance period/2027 MIPS payment year and future years. This change is discussed in section IV.A.4.e.(3)(b)(iii) of this final rule and in more detail below.

Current Improvement Activity	
Current Activity ID:	**IA_ERP_6**
Current Subcategory:	Emergency Response & Preparedness
Current Activity Title:	COVID-19 Vaccine Achievement for Practice Staff
Current Activity Description:	Demonstrate that the MIPS eligible clinician's practice has maintained or achieved a rate of 100 percent of office staff staying up to date with COVID vaccines according to the Centers for Disease Control and Prevention.[29] Please note that those who are determined to have a medical contraindication specified by CDC recommendations are excluded from this activity.
Current Weighting:	Medium
Proposed Activity ID:	**IA_PM_26**
Proposed Subcategory:	Population Management
Proposed Revised Activity Title:	Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B
Proposed Revised Activity Description:	Demonstrate that the MIPS eligible clinician's practice has achieved and/or maintained a vaccination rate of 60 percent of clinical practice staff for COVID-19, and 80 percent for influenza. Demonstrate vaccination, immunity, or non-responder status to hepatitis B for 95 percent of clinical practice staff. Vaccination recommendations are from Centers for Disease Control and Prevention; staff with contraindications to the vaccinations, as determined by the CDC, are excluded from the requirements. Vaccines and Immunizations CDC.
Proposed Change and Rationale:	Adjusting the target goals for this activity would align with the latest CDC recommendations and feedback received indicates that the proposal could increase the activity's utilization. Additionally, we are expanding the focus of this activity to include influenza and hepatitis B to highlight the importance of staff vaccination for vaccine-preventable diseases prevalent today. We also proposed a change in this activity's subcategory, from Emergency Response & Preparedness to Population Management, to emphasize that staff vaccination is a long-term strategy in reducing morbidity and mortality rates for these diseases.
Comment & Response:	*Comment*: We received comments in general support of this activity modification. One commenter pointed out that this revised activity will promote workforce safety from serious illness, enabling clinicians to continue providing essential long-term patient care, as well as limiting the potential spread of diseases to vulnerable patients. *Response*: We appreciate the supportive comments regarding this activity modification, and we will continue with our approach of reviewing, assessing, and refining each activity on a regular basis for relevance and effectiveness in promoting clinical practice improvement.
Final Action:	We are finalizing this activity modification as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_4**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of patients through implementation of improvements in patient portal
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal

	include but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Current Weighting:	Medium
Proposed Activity ID:	**IA_BE_4**
Proposed Subcategory:	Beneficiary Engagement
Proposed Revised Activity Title:	Engagement of Patients through Implementation of New Patient Portal
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must implement and provide access to a new patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to, the following: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; and/or any relevant acute or chronic disease management.
Proposed Change and Rationale:	We proposed to modify this activity's description and its validation criteria to specify the implementation of a new patient/caregiver portal by clinicians who were not previously using a patient portal. This activity was originally created during a time of transition to EHRs to encourage electronic information exchange. It has become standard practice to use patient portals; therefore, the activity is likely no longer driving improvement among clinicians who have already implemented a patient portal. This activity has been highly utilized year over year and continues to be in the top ten activities reported. Limiting the activity to clinicians that implement new patient portals in practices that previously did not use them would refocus the measure on its original purpose and encourage clinicians who have previously implemented patient portals to report other improvement activities that may offer meaningful opportunities for improvement.
Comment & Response:	*Comment*: Several commenters supported our Inventory changes as proposed. *Response*: We appreciate commenters' support as well as suggestions on ways to maintain an Inventory of activities that are diverse, robust, and meaningful. *Comment*: Multiple commenters did not support this modification to limit this activity to new patient portal users. A few commenters argued that maintaining an established patient portal and deploying new functionalities demonstrates a continued commitment to quality improvement and a significant financial investment, and that current clinicians who regularly use a patient portal should also be able to attest to this improvement activity. *Response*: We disagree with the commenters that stated the activity should remain available for the maintenance of a patient portal. The implementation of a patient portal is a specific action that promotes clinical improvement. While maintaining and updating an existing patient portal is an integral part of supporting patient engagement and health information exchange, it does not improve clinical care relative to the prior year. *Comment*: Several commenters requested that CMS give a one-year notice before modifying this activity so that practices have enough time to plan for changes.

	Response: In response to comments received requesting a one-year notice before modifying this activity, we are delaying implementation of this activity modification to give clinicians additional time to prepare to report alternate activities.
Final Action:	We are delaying implementation of this activity modification. It will be effective beginning with the CY 2026 performance period/2028 MIPS payment year.

[29]Centers for Disease Control and Prevention (2024). Stay Up to Date with COVID-19 Vaccines. Last Updated April 25, 2024. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html

TABLE C: Improvement Activities Being Removed for the CY 2025 Performance Period/20267MIPS Payment Year and for Future Years

In this final rule, we are removing **four** previously finalized improvement activities beginning with the CY 2025 performance period/2027 MIPS payment year. These changes are discussed in section IV.A.4.e.(3)(b)(iii) of this final rule and in more detail below; activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_ EPA_1**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Current Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent care (for example, MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record for example, coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (for example, senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Current Weighting:	High
Removal Rationale:	We proposed to remove this activity under removal factor seven, activity is obsolete; this activity was created, in part, to incentivize utilization of EHRs to increase access to clinicians in off hours and decrease emergency room (ER) visits. Today, EHRs are highly utilized, and this activity has become standard of care. This is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized and that the clinical practice improvement promoted by the activity has been achieved. We proposed the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Comment & Response:	*Comment*: We received comments expressing broad support for this activity removal. *Response*: We appreciate the supportive comments. *Comment*: Several commenters expressed concern about removing this activity, citing the importance of clinicians' having continual access to their patient medical records. One commenter suggested that, rather than removing the activity, it should be limited to newly established access to patient medical records. A few commenters requested that CMS give a one-year notice before removing or modifying an activity so that practices have enough time to plan for changes. *Response*: We also acknowledge commenters' expressions of concern about this removal. The establishment of expanded hours of access to patient medical records, alternative methods for accessing patient information, and/or a process for providing rapid access to patient information during urgent care or transition management are specific actions that promote clinical improvement. While maintaining 24/7 access to patient records for clinicians is an integral part of health information exchange, maintaining this access does not improve care relative to the prior year. More broadly, this improvement activity is obsolete because there has been widespread adoption of EHR systems that provide 24/7 access to and health exchange of patient data for clinicians and groups.

Final Action:	We are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PM_12**
Current Subcategory:	Population Management
Current Activity Title:	Population empanelment
Current Activity Description:	Empanel (assign responsibility for) the total population, linking each patient to a MIPS eligible clinician or group or care team. Empanelment is a series of processes that assign each active patient to a MIPS eligible clinician or group and/or care team, confirm assignment with patients and clinicians, and use the resultant patient panels as a foundation for individual patient and population health management. Empanelment identifies the patients and population for whom the MIPS eligible clinician or group and/or care team is responsible and is the foundation for the relationship continuity between patient and MIPS eligible clinician or group /care team that is at the heart of comprehensive primary care. Effective empanelment requires identification of the "active population" of the practice: those patients who identify and use your practice as a source for primary care. There are many ways to define "active patients" operationally, but generally, the definition of "active patients" includes patients who have sought care within the last 24 to 36 months, allowing inclusion of younger patients who have minimal acute or preventive health care.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor seven, activity is obsolete; this activity was designed in the early years of the MIPS program to highlight the importance of patient population empanelment to drive patient-centered care and, over time, to drive quality improvement. Empanelment is now more widely accepted and/or used as an option to drive and/or measure comprehensive care, and this activity has no requirement for implementation or improvement beyond the empanelment; therefore, we are recommending its removal.
Comment & Response:	*Comment*: Several commenters supported our Inventory changes as proposed. A few commenters did not support this removal, arguing that panel management is a critical, ongoing activity that requires regular monitoring to adjust for patient acuity and clinician workloads. One commenter suggested that, rather than removing the activity, it should be limited to new reporters for a finite number of years. *Response*: We appreciate commenters' suggestions. This improvement activity is obsolete because the establishment of empanelment processes has been widely achieved and annual maintenance, while integral, does significantly improve clinical care relative to the prior year. *Comment*: A few commenters requested that CMS give a one-year notice before removing or modifying an activity so that practices have enough time to plan for changes. *Response*: In response to comments received requesting a one-year notice before removing this activity, we are delaying implementation of this activity removal to give clinicians additional time to prepare to report alternate activities.
Final Action:	We are delaying implementation of this activity removal. It will be effective beginning with the CY 2026 performance period/2028 MIPS payment year.
Current Improvement Activity	
Current Activity ID:	**IA_CC_1**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of use of specialist reports back to referring clinician or group to close referral loop
Current Activity Description:	Performance of regular practices that include providing specialist reports back to the referring individual MIPS eligible clinician or group to close the referral loop or where the referring individual MIPS eligible clinician or group initiates regular inquiries to

	specialist for specialist reports which could be documented or noted in the EHR technology.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor one, this activity is duplicative, and factor five, this activity does not align with the quality, cost, or Promoting Interoperability performance categories. This activity provides credit for ensuring that consultation reports are communicated between an ordering and a consulting provider, and this is now standard of care. Also, this concept is redundant with some quality and Quality Clinical Data Registry (QCDR) measures, including QM#374. Our recommendation for removal is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized and that the clinical practice improvement promoted by the activity has been achieved. We proposed the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Comment & Response:	*Comment*: Several commenters supported our Inventory changes as proposed. A few commenters did not support this removal because supporting electronic referral loops contributes to delivering well-coordinated, patient-centered care. *Response*: We appreciate commenters' feedback. The practice of closing the referral loop among specialists and referring clinicians has been widely achieved and credit for completing this action is already being offered in other performance categories, making this activity duplicative of and out of alignment with the quality measures performance category. *Comment*: Several commenters requested that CMS give a one-year notice before removing this activity so that practices have enough time to plan for changes. *Response*: In response to comments received requesting a one-year notice before removing this activity, we are delaying implementation of this activity removal to give clinicians additional time to prepare to report alternate activities.
Final Action:	We are delaying implementation of this activity removal. It will be effective beginning with the CY 2026 performance Period/2028 MIPS payment year.
Current Improvement Activity	
Current Activity ID:	**IA_CC_2**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of improvements that contribute to more timely communication of test results
Current Activity Description:	Timely communication of test results defined as timely identification of abnormal test results with timely follow-up.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor seven, activity is obsolete. This activity was created, in part, to encourage strategies for timely communication and to improve upon those strategies. This process has become widely used with the use of EHRs and the adoption of patient portals and is now standard of care. This is supported by the fact that this activity continues to be in the top ten activities reported, indicating that it is overutilized. We proposed the removal of this activity in the context of our regular review of the Inventory. In conducting this review recently, we concluded that the goal of this activity has been widely achieved by eligible clinicians and practices.
Comment & Response:	*Comment*: Several commenters supported our Inventory changes as proposed. A few commenters did not support this removal, arguing that timely communication of test results is an ongoing activity. One commenter suggested that, rather than removing the activity, it should be limited to new reporters for a finite number of years. A few commenters requested that CMS give a one-year notice before removing or modifying an activity so that practices have enough time to plan for changes.

	Response: We appreciate commenters' suggestions. This improvement activity is obsolete because the establishment of processes to support timely communication of results has been widely achieved, and maintenance, while integral, does not significantly improve clinical care relative to the prior year. In response to comments received requesting a one-year notice before removing this activity, we are delaying implementation of this activity removal to give clinicians additional time to prepare to report alternate activities.
Final Action:	We are delaying implementation of this activity removal. It will be effective beginning with CY 2026 performance period/2028 MIPS payment ear.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_4**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	Implementation of a Personal Protective Equipment (PPE) Plan
Current Activity Description:	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients. In accordance with guidance from the Centers for Disease Control and Prevention (CDC) the PPE plan should address: • Conventional capacity: PPE controls that should be implemented in general infection prevention and control plans in healthcare settings, including training in proper PPE use. • Contingency capacity: actions that may be used temporarily during periods of expected PPE shortages. • Crisis capacity: strategies that may need to be considered during periods of known PPE shortages. The PPE plan should address all of the following types of PPE: • Standard precautions (for example, hand hygiene, prevention of needle-stick or sharps injuries, safe waste management, cleaning and disinfection of the environment) • Eye protection • Gowns (including coveralls or aprons) • Gloves • Facemasks • Respirators (including N95 respirators)
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor seven, activity is obsolete; since the COVID-19 pandemic, most clinicians are well prepared in PPE safety, as PPE enhancements have been made throughout patient care settings. It is unlikely that this activity will drive new improvements. We acknowledge the ongoing importance of PPE, and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of PPE protocols are reflected in MIPS.
Comment & Response:	*Comment*: We received comments expressing general support for this activity removal. Two commenters expressed concern about the removal of this activity, citing that maintaining a plan for PPE will be essential for any future pandemics as well as everyday functioning of the health care system. A few commenters requested that CMS give a one-year notice before modifying or removing this activity so that practices have enough time to plan for changes. *Response*: We appreciate commenters' suggestions. The implementation of PPE plans has been widely achieved. We will consider comments received urging CMS to develop and may propose through rulemaking an improvement activity that promotes a comprehensive approach to long-term sustenance of PPE protocols.
Final Action:	We are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_5**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	Implementation of a Laboratory Preparedness Plan
Current Activity Description:	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public

	health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities. For laboratories without a preparedness plan, MIPS eligible clinicians would meet with stakeholders, record minutes, and document a preparedness plan, as needed. The laboratory must then implement the steps identified in the plan and maintain them. For laboratories with existing preparedness plans, MIPS eligible clinicians should review, revise, or update the plan as necessary to meet the needs of the current PHE, implement new procedures, and maintain the plan. Maintenance of the plan in this activity could include additional hazard assessments, drills, training, and/or developing checklists to facilitate execution of the plan. Participation in debriefings to evaluate the effectiveness of plans are additional examples of engagement in this activity.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor seven, activity is obsolete; since the COVID-19 pandemic, most clinicians are now well prepared in COVID-19-related patient safety and laboratory-preparedness enhancements have been made throughout patient care settings. It is unlikely that this activity will drive new improvements. We acknowledge the ongoing importance of laboratory preparedness, and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of lab preparedness protocols are reflected in MIPS.
Comment & Response:	*Comment*: We received comments expressing general support for this activity removal. Two commenters expressed concern about the removal of this activity, citing that maintaining a plan for laboratory preparedness will be essential for any future pandemics as well as everyday functioning of the health care system. A few commenters requested that CMS give a one-year notice before modifying or removing this activity so that practices have enough time to plan for changes. *Response*: We appreciate commenters' suggestions. The implementation of laboratory preparedness plans has been widely achieved. We will consider comments received urging CMS to develop and may propose through rulemaking an improvement activity that promotes a comprehensive approach to long-term sustenance of lab preparedness protocols.
Final Action:	We are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_8**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Electronic Health Record Enhancements for BH data capture
Current Activity Description:	Enhancements to an electronic health record to capture additional data on behavioral health (BH) populations and use that data for additional decision-making purposes (for example, capture of additional BH data results in additional depression screening for at-risk patient not previously identified).
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor two, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. This activity was created, in part, to assist in the transition from paper charts to EHRs. While the use of EHRs is now highly prevalent and has become part of current basic standards of care, there is still much progress to be made in terms of adoption and use of EHRs and other health information technologies in a behavioral health context. This activity, though, allows attestation with a low level of effort and with vague requirements related to clinical outcomes. Because there are other, more potentially impactful, behavioral health activities in the current Inventory, we are recommending that this activity be removed. IA_BMH_7, Implementation of Integrated Patient Centered Behavioral Health Model, which includes 'use of a registry or health information technology functionality to support active care management and outreach

	to patients in treatment,' is a strong alternative activity. We also intend, in future rulemaking, to develop a new activity (or to modify an existing activity) to promote the effective use of health information technologies in behavioral health.
Comment & Response:	*Comment*: Several commenters supported our Inventory changes as proposed. A few commenters did not support this removal, expressing concern that this sends a message that we are not prioritizing behavioral health. *Response*: We appreciate commenters' feedback. We are committed to promoting the use of health information technology and exchange in behavioral health, as evidenced by our ongoing efforts to refocus the improvement activity Inventory on more high-impact improvement activities in general, including behavioral health improvement activities. Please see more discussion regarding this at section IV.A.4.e.(3)(b)(iii) of this final rule. *Comment*: Multiple commenters requested that CMS give a one-year notice before removing or modifying an activity so that practices have enough time to plan for changes. *Response*: In response to comments received requesting a one-year notice before removing this activity, we are delaying implementation of this activity removal to give clinicians additional time to prepare to report alternate activities.
Final Action:	We are delaying implementation of this activity removal. It will be effective beginning with CY 2026 performance period/2028 MIPS payment ear
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_27**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Invasive Procedure or Surgery Anticoagulation Medication Management
Current Activity Description:	For an anticoagulated patient undergoing a planned invasive procedure for which interruption in anticoagulation is anticipated, including patients taking vitamin K antagonists (warfarin), target specific oral anticoagulants (such as apixaban, dabigatran, and rivaroxaban), and heparins/low molecular weight heparins, documentation, including through the use of electronic tools, that the plan for anticoagulation management in the periprocedural period was discussed with the patient and with the clinician responsible for managing the patient's anticoagulation. Elements of the plan should include the following: discontinuation, resumption, and, if applicable, bridging, laboratory monitoring, and management of concomitant antithrombotic medications (such as antiplatelets and nonsteroidal anti-inflammatory drugs (NSAIDs)). An invasive or surgical procedure is defined as a procedure in which skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice.
Current Weighting:	Medium
Removal Rationale:	We proposed to remove this activity under removal factor one, this activity is duplicative. We recommend removal of this activity as its focus is duplicative with IA_CC_15: PSH [Perioperative-Surgical Home] Care Coordination. IA_CC_15 requires coordination of patient care through the perioperative period and includes anticoagulant management as one part of its requirements. This activity, IA_PSPA_27, is more tightly focused in an area that is high risk and, therefore, is not likely changing clinical practice widely. We acknowledge the ongoing importance of care coordination and medication management, and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of anticoagulation medication management are reflected in MIPS.
Comment & Response:	*Comment*: We received comments expressing general support for this activity removal. Response: We appreciate the supportive comments.
l Action:	We are finalizing this activity removal as proposed.

APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs, including MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix contains two groups of MVP tables: Group A, which includes six new MVPs and Group B, which includes modifications to 16 previously finalized MVPs. We received comments on all Group A and Group B MVPs with the comment summaries and responses following each MVP set of tables.

Each MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category relevant to the clinical theme of the MVP. Each MVP also includes a foundational layer comprised of population health measures and Promoting Interoperability performance category measures.

MVP Development: Performance Category Sources

The MVP tables contain a set of MIPS quality measures, QCDR measures (as applicable), improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities considered in developing the MVP tables are as follows:

- Existing MIPS quality measures are in the 2024 MIPS Quality Measures List on the Quality Payment Program website.[1143] See Appendix 1: MIPS Quality Measures of this final rule for any additions (Table Group A), removals (Table Group C), or modifications to existing quality measures (Table Groups D and DD).
- Existing QCDR measures are based on the most recent publication of the 2024 QCDR Measure Specification file, located on the Quality Payment Program website.[1144] We plan to modify the list of 2025 QCDR measures around December 2024.
- Improvement activities are in the 2024 Improvement Activities Inventory and the 2024 MIPS Data Validation Criteria, located on the Quality Payment Program website.[1145] See Appendix 2: Improvement Activities of this final rule for any proposed additions (Table Group A), proposed modifications to existing improvement activities (Table Group B), or proposed removals (Table Group C).
- Existing cost measures are in the 2024 Cost Measures Inventory.[1146] See section IV.A.4.e.(2) of this final rule for any additions or modifications to existing cost measures.
- For further details on the population health measures (attributed to the Quality Performance Category) included in the foundational layer, see the CY 2022 PFS final rule (86 FR 65408 through 65409).
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located on the Quality Payment Program website.[1147] We did not propose, and are not finalizing, any policy updates to the Promoting Interoperability performance category or any new, modified, or removed Promoting Interoperability measures for the CY 2025 performance period/2027 MIPS payment year (see section IV.A.4.e. of this final rule).

MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity

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[1143] See the 2024 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2632/2024%20MIPS%20Quality%20Measures%20List.xlsx.*

[1144] See *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2617/2024%20QCDR%20Measure%20Specifications.xlsx* for QCDR measures.

[1145] See the 2024 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2644/2024ImprovementActivitiesInv.zip* and 2024 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2666/2024MIPSDataValidationCriteria.zip.* for improvement activity details.

[1146] See the 2024 Cost Measures Inventory: *https://qpp.cms.gov/mips/explore-measures?tab=costMeasures&py=2024.*

[1147] See the 2024 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2223/2024%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip* for Promoting Interoperability measure details.

- We proposed to eliminate the weighting from improvement activities and provide full credit for the improvement activities performance category when an MVP participant attests to one improvement activity option within the selected MVP. See section IV.A.4.e.(3)(b)(iv) of this final rule for detailed information regarding finalized proposals on the removal of weighting from improvement activities and for detailed information regarding finalized proposals on the reporting requirement changes for improvement activities.
- We proposed to modify IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff to expand the focus and importance of vaccination status to drive improvement across the practice. We proposed to add the proposed modified IA_ERP_6 to all new and previously finalized MVPs because of the importance of vaccination status in practice settings. See Appendix 2, Improvement Activities: Table B of this final rule for detailed information regarding finalized modifications to IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff, including the finalized activity ID and title update.

MVP Table Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in the Group A and Group B tables below:

● Quality measures, improvement activities, and cost measures proposed for addition to a previously finalized MVP are identified with a plus sign (+) within the Group B MVP tables in this appendix.

● New quality measures, improvement activities, and cost measures proposed for inclusion in MIPS beginning with the CY 2025 performance period/2027 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1, MIPS Quality Measures: Table Group A of this final rule for further information regarding new MIPS quality measures. See Appendix 2: Improvement Activities: Table A of this final rule for further information regarding new improvement activities. See section IV.A.4.e.(2)(a)(ii) of this final rule for further information regarding new cost measures.

● Existing measures and improvement activities with revisions are identified with a single asterisk (*). See Appendix 1, MIPS Quality Measures: Table Group D of this final rule for further information regarding proposed revisions to MIPS quality measures. See Appendix 2: Improvement Activities: Table B of this final rule for further information regarding proposed revisions to improvement activities. See section IV.A.4.e.(2)(a)(iii) of this final rule for further information regarding proposed revisions to cost measures. We intend to include existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions are finalized beginning with the CY 2025 performance period/2027 MIPS payment year.

● Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.

● Quality measures considered high priority (as defined in § 414.1305) are identified with a single exclamation point (!) while outcome measures (as defined in § 414.1305) are identified with a double exclamation point (!!). Further details of these types of measures are in the CMS Measures Management System Hub.[1148]

● Quality measures and improvement activities that include a health equity component are identified with a tilde (~) within the MVP table.

● Quality measure collection types are identified in parentheses after each quality measure title, and improvement activity medium/high weight designations are identified in parentheses after each improvement activity

[1148] See *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

Group A: New MVPs Proposed for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

A.1 Complete Ophthalmologic Care MVP

In the CY 2025 PFS proposed rule (89 FR 62583 through 62588), we proposed and solicited comments on the Complete Ophthalmologic Care MVP. The proposed Complete Ophthalmologic Care MVP focuses on assessing meaningful outcomes in cataract, glaucoma, retinal detachment, and broadly applicable ocular care. This MVP would be most applicable to clinicians who treat patients within the practice of ophthalmology and optometry. The summary of the public comments received and our responses for this MVP are included immediately after Table A.1b.

Quality Measures

We proposed to include 18 MIPS quality measures and 6 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of ocular care by assessing ocular health and treatment of disorders attributed to diabetes related disease, glaucoma, retinal detachment, and cataracts. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in ocular care:

- Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation: This MIPS quality measure evaluates changes in the optic nerve which define the progression and worsening of glaucoma disease status.
- Q019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: This MIPS quality measure focuses on the communication between the primary physician managing ongoing care and the physician performing the dilated macular or fundus exam on patients with diabetic retinopathy.
- Q117: Diabetes: Eye Exam: This MIPS quality measure supports eye screening for diabetic retinal disease.
- Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care: This MIPS quality measure focuses on glaucoma treatment and follow up, ensuring the IOP is within a range at which visual field loss is unlikely to significantly reduce a patient's health-related quality of life over their lifetime.
- Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: This MIPS quality measure evaluates visual acuity as a surgical outcome following cataract surgery.
- Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: This MIPS quality measure looks for improvement in visual function following cataract surgery.
- Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery: This MIPS quality measure assesses patient satisfaction following cataract surgery. Patient satisfaction is a valuable performance indicator for measuring quality of care delivered by clinicians providing cataract surgery. Patient satisfaction is an assessment of the patient's experience with the care process delivered by the clinician and health care services.
- Q384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery: This MIPS quality measure assesses for successful surgical procedures by evaluating if patients required a return to the operation room or not.
- Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery: This MIPS quality measure assesses for successful surgical procedures by evaluating if patients showed improvement of visual acuity following surgery as compared to their preoperative level.
- Q389: Cataract Surgery: Difference Between Planned and Final Refraction: This MIPS quality measure evaluates patients for achieving a final refraction within +/- 1.0 diopters of their planned (target) refraction following cataract surgery.
- Q499: Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy: This MIPS quality measure focuses on patient safety and ensures appropriate screening and plan of care for elevated intraocular pressure following treatment with intravitreal or periocular steroid.
- Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up: This MIPS quality measure evaluates patients following acute posterior vitreous detachment to ensure prompt and appropriate care to minimize potential for complications.
- Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up: This MIPS quality measure evaluates patients following acute posterior vitreous detachment and acute vitreous hemorrhage to ensure prompt and appropriate care to minimize potential for complications.
- IRIS2: Glaucoma – Intraocular Pressure Reduction: This QCDR measure focuses on glaucoma patients to assess management of their IOP by evaluating if it is below a threshold level based on severity of their glaucoma.
- IRIS13: Diabetic Macular Edema – Loss of Visual Acuity: This QCDR measure evaluates outcomes of treatment for diabetic macular edema by assessing for change in visual acuity after treatment.
- IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure: This QCDR measure assesses for successful treatment of patients with glaucoma who have undergone trabeculectomy or an aqueous shunt procedure by evaluating for intraocular pressure reduction.

- IRIS54: Complications After Cataract Surgery: This QCDR measure assesses for successful cataract surgeries by reviewing patients for complications within 90 days of the procedure.
- IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days: This QCDR measure assesses for successful vitrectomy procedure in patients with diabetic retinopathy by reviewing patients for complications within 120 days of the procedure.
- IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery: This QCDR measure evaluates visual acuity as a surgical outcome following cataract surgery and minimally invasive glaucoma surgery.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in ocular care. The quality measures below assess for age-specific screenings and the patients' understanding of engagement in their healthcare:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q374: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 14 improvement activities that reflect actions and processes undertaken by clinicians who specialize in ocular care, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_25: Drug Cost Transparency
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_10: Care transition documentation practice improvements
- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_13: Chronic care and preventative care management for empaneled patients
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of ocular care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in ocular care, specifically cataract removal, and aligns with other measures and activities within this MVP:

- Routine Cataract Removal with Intraocular Lens (IOL) Implantation: This MIPS episode-based cost measure assesses costs associated with routine cataract removal. The addition of this measure aligns with included quality measures, such as Q191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery and Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

We proposed to modify the Routine Cataract Removal with Intraocular Lens (IOL) Implantation cost measure, which included a measure title update to Cataract Removal with Intraocular Lens (IOL) Implantation. Please see section IV.A.4.e(2)(a)(iii) of this final rule for all finalized revisions to this cost measure.

Complete Ophthalmologic Care MVP Tables

Tables A.1a and A.1b serve to represent the measures and activities that are finalized within the Complete Ophthalmologic Care MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.1a: Complete Ophthalmologic Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM Specifications) **(*)(!) Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM Specifications) **(*) Q117:** Diabetes: Eye Exam (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(!!) Q141:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims Specifications, MIPS CQM Specifications) **(!!) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM Specifications, MIPS CQM Specifications) **(!!) Q303:** Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM Specifications) **(!) Q304:** Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM Specifications) **(*)(!) Q374:** Closing the Referral Loop: Receipt of Specialist Report	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_25:** Drug Cost Transparency **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **(~) IA_CC_10:** Care transition documentation practice improvements **IA_CC_13:** Practice improvements to align with OpenNotes principles **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients **IA_PM_16:** Implementation of medication management practice improvements **(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements	**(*) Cataract Removal with Intraocular Lens (IOL) Implantation**

Quality	Improvement Activities	Cost
(Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!!) Q384:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery (Collection Type: MIPS CQM Specifications) **(!!) Q385:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQM Specifications) **(!!) Q389:** Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **Q499:** Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy (Collection Type: MIPS CQM Specifications) **(*) Q500:** Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up (Collection Type: MIPS CQM Specifications) **(*) Q501:** Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **(!!) IRIS2:** Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR) **(!!) IRIS13:** Diabetic Macular Edema – Loss of Visual Acuity (Collection Type: QCDR) **(!!) IRIS39:** Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR) **(!!) IRIS54:** Complications After Cataract Surgery (Collection Type: QCDR) **(!!) IRIS58:** Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR) **(!!) IRIS61:** Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)		

TABLE A.1b: Complete Ophthalmologic Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience. One commenter supported the inclusion of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter was opposed to the inclusion of the population health measures in this MVP. The commenter does not believe claims-based population health measures are applicable to ophthalmologists. The commenter stated that administrative claims-based quality measures have a high potential for holding clinicians accountable for care they do not provide, meaning clinicians have limited ability to influence their performance on them.

Response: The population health measures are part of the foundational layer included in all MVPs. If the case minimum is not met for the population health measures, they will be excluded from scoring. For further details on the population health measures included in the foundational layer, see CY 2022 PFS final rule (86 FR 65408 through 65409).

Comment: One commenter recommended specialty groups be provided the opportunity to determine if the measures included in an MVP are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP

website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter recommended leveraging the IRIS Registry measures in supporting meaningful eye-care related MVPs. One commenter recommended a few improvement activities be added to this MVP: IA_AHE_7: Comprehensive Eye Exams, IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record, IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements, and IA_PSPA_2: Participation in MOC Part IV.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter stated that the measures in this MVP may disadvantage ophthalmic practices in MIPS by limiting the maximum Quality score achievable under this MVP. The commenter explained small and rural practices are less likely to have the resources available to adopt EHRs. These practices would be further disadvantaged under this MVP candidate as they would not be able to report eCQMs and, thus, would be limited to lower scoring manual measures. Moreover, due to the smaller number of patients seen, singular adverse events will have a substantially greater impact on small practices than large practices in this MVP because they will be unable to choose measures with less clustered performance rates.

Response: We acknowledge the commenters' concerns regarding quality scoring. There are currently 24 quality and QCDR measures available in the MVP, 17 of which have a benchmark and 4 showing a 7-point cap. While we endeavor to include measures that allow for maximum points, we want to ensure important aspects of care within the MVP clinical topic are represented. Currently, this MVP aligns with the Ophthalmology specialty measure set, excluding only two measures, and therefore, should not adversely affect those clinicians who choose to report the MVP versus traditional MIPS. However, as MVPs are optional and there is clinician choice allowed in quality performance reporting, we would encourage clinicians to review each MVP and the measures and activities within to ensure it is appropriate and applicable to them prior to reporting.

Comment: Several commenters expressed opposition to this MVP and stated that it would be appropriate to limit the first ophthalmic MVP to cataract surgery. Commenters stated their belief that the MVP is not feasible given the complexity of properly representing ophthalmic subspecialties in both the cost and quality performance categories. The commenters noted that the cost measure proposed in this MVP applies only to cataract surgery, putting cataract surgeons at a disadvantage compared to other ocular care clinicians.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting, which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all measures are applicable to all clinicians who would choose to report this MVP. However, this represents the foundation from which to build the most meaningful MVP addressing ophthalmologic care and allows for clinician choice in choosing quality measures that best represent their practice.

Currently, there are no additional applicable episode-based cost measures available for use in this MVP beyond the Cataract Removal with Intraocular Lens (IOL) Implantation cost measure. Should additional applicable cost measures become available for use in MVPs, interested parties are welcome to submit recommended changes to the MVP through the MVP Maintenance Process. Until such time, ophthalmologists can choose to report this MVP. If a clinician cannot be scored on any of the cost measures within an MVP they choose to report (see § 414.1380(b)(2)(v)), the cost performance category will be reweighted in alignment with existing MIPS scoring policies (§ 414.1380(c)) and the clinician will not be penalized if there is not a cost measure applicable to their clinical practice.

After consideration of public comments, we are finalizing the *Complete Ophthalmologic Care MVP* with modifications in Table A.1a and as proposed in Table A.1b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal.

A.2 Dermatological Care MVP

In the CY 2025 PFS proposed rule (89 FR 62588 through 62592), we proposed and solicited comments on the Dermatological Care MVP. The proposed Dermatological Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP will be most applicable to clinicians who treat patients within the practice of dermatology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.2b.

Quality Measures

We proposed to include 11 MIPS quality measures and 6 QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of dermatology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in dermatology:

- Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy: This MIPS quality measure ensures TB testing is completed prior to the first course of biologic and/or immune response modifier therapy.
- Q397: Melanoma Reporting: This MIPS quality measure assesses that the pathology report for primary malignant cutaneous melanoma includes reporting identifiers needed for microsatellitosis of invasive tumors.
- Q410: Psoriasis: Clinical Response to Systemic Medications: This MIPS quality measure ensures patients with psoriasis vulgaris who are being treated with systemic medications maintain disease control by evaluating documented body surface assessments meet at least one of the specified benchmarks.
- Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician: This MIPS quality measure ensures pathology reports diagnosing carcinoma or melanoma are communicated from the Pathologist/Dermatopathologist within 7 days from the Pathologist receiving the specimen.
- Q485: Psoriasis – Improvement in Patient-Reported Itch Severity: This MIPS quality measure evaluates patients with a diagnosis of psoriasis for a reduction in itch severity of 3 or more points at follow up visits.
- Q486: Dermatitis – Improvement in Patient-Reported Itch Severity: This MIPS quality measure evaluates patients with a diagnosis of dermatitis for a reduction in itch severity of 3 or more points at follow up visits.
- Q509: Melanoma: Tracking and Evaluation of Recurrence: This proposed MIPS quality measure ensures patients who undergo excisional surgery for melanoma or melanoma in situ within the previous 5 years have documentation that an exam for recurrence of melanoma was performed within the performance period and results captured.
- AAD6: Skin Cancer: Biopsy Reporting Time – Clinician to Patient: This QCDR measure ensures timely communication from the clinician to the patient when they have a positive finding for carcinoma, melanoma, or primary cutaneous malignancies.
- AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life: This QCDR measure ensures a patient- reported quality-of-life assessment is completed and recorded in the medical record with a plan of care at least once in the performance period.
- AAD12: Melanoma: - Appropriate Surgical Margins: This QCDR measure ensures the initial biopsy and surgical margins are documented in the medical record and are in compliance with the minimum margin recommended in the current National Comprehensive Cancer Network (NCCN) guideline.
- AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures: This QCDR measure assesses for the appropriate use of post operative antibiotics for patients with skin cancer undergoing an office-based closure or reconstruction procedure.
- AAD17: Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures: This QCDR measure assesses the percentage of patients who had their anticoagulation therapy continued prior to an in-office procedure for intermediate layer and/or complex linear closures OR reconstruction after skin cancer resection performed.
- AAD18: Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection: This QCDR measure identifies the number of patients diagnosed with skin cancer who were prescribed an opioid/narcotic therapy as a first line pain management option post-operative by the reconstructing surgeon.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in dermatology. The quality measures below assess for age-specific screenings, and follow-up actions for select measures:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in dermatology, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement

activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_1: Enhance Engagement of Medicaid and Other Underserved Populations
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_16: Implementation of medication management practice improvements
- IA_PSPA_8: Use of Patient Safety Tools

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which includes a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of dermatology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in dermatology, specifically melanoma resection, and aligns with other measures and activities within this MVP:

- Melanoma Resection: This MIPS episode-based cost measure assesses costs associated with excision procedures to remove a cutaneous melanoma. The addition of this measure aligns with Q397: Melanoma Reporting and Q509: Melanoma: Tracking and Evaluation of Recurrence.

Dermatological Care MVP Tables

Tables A.2a and A.2b serve to represent the measures and activities that are finalized within the Dermatological Care MVP.

Symbol Key:
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.2a: Dermatological Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) **Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) (*) **Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) (!) **Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM Specifications) (!!) **Q410:** Psoriasis: Clinical Response to Systemic Medications	(~) **IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations (~) **IA_AHE_6:** Provide Education Opportunities for New Clinicians **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **IA_EPA_2:** Use of telehealth services that expand practice access (**) **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient	**Melanoma Resection**

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQM Specifications) (!) **Q440:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM Specifications) (*)(!!) **Q485:** Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM Specifications) (*)(!!) **Q486:** Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM Specifications) (~)(!) **Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) (*)(!!) **Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) (^)(!) **Q509:** Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQM Specifications) (!) **AAD6:** Skin Cancer: Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR) (!) **AAD8:** Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR) (!!) **AAD12:** Melanoma: - Appropriate Surgical Margins (Collection Type: QCDR) (!) **AAD16:** Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures (Collection Type: QCDR) (!) **AAD17:** Continuation of Anticoagulation Therapy in the Office-based Setting for Closure and Reconstruction After Skin Cancer Resection Procedures (Collection Type: QCDR) (!) **AAD18:** Avoidance of Opioid Prescriptions for Closure and Reconstruction After Skin Cancer Resection (Collection Type: QCDR)	Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements (*) **IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_8:** Use of Patient Safety Tools	

TABLE A.2b: Dermatological Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(‼) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) (‼) **Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended the removal of the pathology specific quality measures from this MVP. The commenter stated their belief that evaluating pathologists solely on dermatology measures does not capture the extent of the practice of pathology and could lead to confusion among single specialty pathology practices. Furthermore, the presence of only two quality measures in the MVP prevents pathologists from fully participating.

Response: We appreciate the commenters concerns. The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care, such as dermatopathology. We understand that not all measures are applicable to all clinicians who would choose to report this MVP; however, reporting MVPs is voluntary at this time. We maintain that this represents the foundation from which to build the most meaningful MVP addressing dermatological care and allows for clinician choice in choosing quality measures that best represent their practice. For guidance, please note that as stated above, this MVP is most applicable to dermatologists and is not directed towards pathology alone.

Comment: Several commenters recommend narrowing the scope of this MVP to focus on skin cancer, a neoplastic disease, which has a cost measure and clinically relevant quality measures, allowing for meaningful measurement. One commenter stated their belief that the broad Dermatological Care MVP will inevitably lead to unfair comparisons among dermatologists with varying sub-specializations and patient populations. Another commenter expressed concerns with the MVP as proposed, particularly the singular cost outcome focused on melanoma resection which would be limited to those practices with a Mohs surgeon.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all measures are applicable

to all clinicians who would choose to report this MVP. However, this represents the foundation from which to build the most meaningful MVP addressing dermatological care and allows for clinician choice in choosing quality measures that best represent their practice.

Currently, there are no additional applicable episode-based cost measures available for use in this MVP beyond the Melanoma Resection cost measure. Should additional applicable cost measures become available for use in MVPs, interested parties are welcome to submit recommended changes to the MVP through the MVP Maintenance Process. Until such time, dermatologists can choose to report this MVP. We note that this cost measure assesses costs related to melanoma resection procedures but does not include Mohs procedures. If a clinician cannot be scored on any of the cost measures within an MVP they choose to report (see § 414.1380(b)(2)(v)), the cost performance category will be reweighted in alignment with existing MIPS scoring policies (§ 414.1380(c)) and the clinician will not be penalized if there is not a cost measure applicable to their clinical practice..

Comment: One commenter recommended specialty groups be provided the opportunity to determine if the measures included are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter recommended the inclusion of the following quality measures to provide participants with a full choice of potentially relevant measures: Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, Q374: Closing the Referral Loop: Receipt of Specialist Report, and Q498: Connection to Community Service Provider. In addition, the commenter recommended the inclusion of the following improvement activities to ensure broad, applicable improvement activities that reflect current clinical practice of dermatologic care: IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record, IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, IA_CC_2: Implementation of improvements that contribute to more timely communication of test results, IA_BMH_2: Tobacco use, IA_BE_1: Use of certified EHR to capture patient-reported outcomes, and IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We note that we proposed and finalized the removal of the following improvement activities recommended by the commenter: IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record and IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan. See Appendix 2, Table C for additional details.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Annual Call for Quality Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Annual Call for Quality Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs or claims-based to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Dermatological Care MVP* with modifications in Table A.2a and as proposed in Table A.2b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details.

A.3 Gastroenterology Care MVP

In the CY 2025 PFS proposed rule (89 FR 62593 through 62596), we proposed and solicited comments on the Gastroenterology Care MVP. The proposed Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP will be most applicable to clinicians who treat patients within the practice of gastroenterology, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.3b.

Quality Measures

We proposed to include 11 MIPS quality measures and 3 QCDR measures within the quality performance category of this MVP, which are specific to the clinical topic of gastroenterology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in gastroenterology:

- Q113: Colorectal Cancer Screening: This MIPS quality measure ensures appropriate screening of patients for colorectal cancer.
- Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use: This MIPS quality measure ensures appropriate follow-up, an interval of 3 or more years, for patients with a history of prior adenomatous polyp(s) in previous colonoscopy.
- Q275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: This MIPS quality measure requires patients with a diagnosis of inflammatory bowel disease (IBD) have Hepatitis B Virus (HBV) status assessed prior to initiating anti-TNF (tumor necrosis factor) therapy.
- Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients: This MIPS quality measure ensures appropriate follow-up for patients receiving a screening colonoscopy without biopsy or polypectomy.
- Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation: This MIPS quality measure requires patients have received a one-time screening for hepatitis C virus (HCV) infection as well as treatment initiation or referral if screening is positive.
- Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis: This MIPS quality measure ensures patients with a diagnosis of chronic Hepatitis C cirrhosis have appropriate surveillance imaging for hepatocellular carcinoma at least once during the performance period.
- GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy: This QCDR measure ensures appropriate follow-up consistent with US Multi-Society Task Force (USMSTF) recommendations based upon pathology findings from screening colonoscopy with biopsy or polypectomy documented in colonoscopy report.
- GIQIC26: Screening Colonoscopy Adenoma Detection Rate: This QCDR measure evaluates patients who had a screening colonoscopy and at least one conventional adenoma or colorectal cancer was detected.
- NHCR4: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation: This QCDR measure ensures patients with inadequate bowel prep receive a repeat screening or surveillance colonoscopy or an alternate tier 1 or tier 2 colorectal cancer screening modality within one year.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in gastroenterology. The quality measures below assess for age-specific screenings, and follow-up actions for select measures:

- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure bases performance on clinicians documenting the list of current medications using all immediate resources for capture of this important clinical topic.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q374: Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures report receival from the referred to clinician, closing the communication loop.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in gastroenterology, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_6: Provide Education Opportunities for New Clinicians
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_CC_7: Regular training in care coordination
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_10: Care transition documentation practice improvements

- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity. which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of gastroenterology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in gastroenterology, including colonoscopies and broader gastroenterology care, and align with other measures and activities within this MVP:

- Screening/Surveillance Colonoscopy: This MIPS episode-based cost measure assesses costs associated with screening or surveillance colonoscopy procedures. This measure aligns with quality measures such as Q113: Colorectal Cancer Screening or Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.
- Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers. Gastroenterologists are included in attribution for the TPCC measure as they may provide broad, ongoing care to their patients, which is in line with the intent of the TPCC measure.

Gastroenterology Care MVP Tables

Tables A.3a and A.3b serve to represent the measures and activities that are finalized within the Gastroenterology Care MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.3a: Gastroenterology Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*) Q113: Colorectal Cancer Screening (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q185:** Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (Collection Type: MIPS CQM Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) **Q275:** Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_CC_7:** Regular training in care coordination **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **(~) IA_CC_10:** Care transition documentation practice improvements **IA_CC_13:** Practice improvements to align with OpenNotes principles **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways	**Screening/Surveillance Colonoscopy** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(*)(!) Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (Collection Type: Medicare Part B Claims Specifications, MIPS CQM Specifications) **(*)(!) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **(!) GIQIC23:** Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR) **(!!) GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR) **(!) NHCR4:** Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation (Collection Type: QCDR)	**IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B	

TABLE A.3b: Gastroenterology Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter supported the inclusion of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP and a couple of commenters supported the inclusion of Q113: Colorectal Cancer Screening measure in this MVP. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience. Another commenter recommended including measures in this MVP for metabolic dysfunction–associated steatohepatitis (MASH), Metabolic dysfunction–associated steatotic liver disease (MASLD), or obesity.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A few commenters expressed concern that the measure set lacks the ability to measure and evaluate the full spectrum of care under the purview of gastroenterologists, particularly gastroenterologists who subspecialize. One commenter recommended narrowing the scope of this MVP to focus on colorectal cancer prevention.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all measures are applicable to all clinicians who would choose to report this MVP. However, this represents the foundation from which to build the most meaningful MVP addressing gastroenterology care and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: One commenter recommended specialty groups be provided the opportunity to determine if the measures included in an MVP are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: A few commenters expressed concern that specialty care is being assessed through the lens of quality measures and improvement activities that are intended for use by primary care clinicians. The commenters felt that measures like Q113: Colorectal Cancer Screening, Q374: Closing the Referral Loop: Receipt of Specialist Report, and Q487: Screening for Social Drivers of Health are not intended for gastroenterologists; instead, they are geared toward primary care physicians.

Response: We acknowledge that due to nuances in clinician specialization and subsequent scope of care, not all measures will be applicable or appropriate to all clinicians. However, the MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. While measures Q113: Colorectal Cancer Screening and Q487: Screening for Social Drivers of Health may be perceived as being only applicable to primary care physicians, it would be incumbent upon all clinicians treating each patient to ensure they are providing proper care and are able to support their healthcare journey, driving positive health outcomes. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP include at least six eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward for current measures not available as eCQMs to discuss revisions and possible implementation in futures years.

Comment: A couple of commenters are concerned with the inclusion of the TPCC measure in this MVP. One commenter suggested that if we do not remove the TPCC measure from MIPS, we should at a minimum remove the TPCC measure from all MVPs that include other episode-based cost measures. Another commenter stated their belief that there is an absence of strong clinical or patient-reported outcome performance measures for high-cost conditions treated by gastroenterologists, such as inflammatory bowel disease. They stated that, without correlating quality measures, there is a possibility that the inclusion of broad population-based cost measures, such as the TPCC measure, that incentivize reduced spending could lead to inappropriate care.

Response: We agree with the commenters that it is important to consider quality performance alongside cost performance. The quality and cost measures included in the Gastroenterology MVP are aligned to focus on screenings performed by gastroenterologists. In addition to the Screening/Surveillance Colonoscopy episode-based cost measure, which assesses costs of care for screening or surveillance colonoscopy procedures, the TPCC measure also captures costs related to ongoing care management provided by gastroenterologists, which align with the quality measures in the MVP that address colonoscopy, inflammatory bowel disease, and care for hepatic disease.

We disagree with the commenter that broad population-based cost measures, such as the TPCC measure, could lead to inappropriate care. The inclusion of broadly applicable measures, such as the TPCC measure, in MVPs encourages clinicians to coordinate with other clinicians in treating a patient to improve overall cost performance. By holding multiple clinicians accountable, this promotes shared responsibility for a patient's care across primary care and specialties who tend to provide ongoing care. Ultimately, cost measures aim to promote care coordination and can capture clinicians' cost savings through reduction of poor patient outcomes associated with high costs, such as potentially avoidable hospitalizations or complications.

After consideration of public comments, we are finalizing the *Gastroenterology Care MVP* with modifications in Table A.3a and as proposed in Table A.3b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details.

A.4 Optimal Care for Patients with Urologic Conditions MVP

In the CY 2025 PFS proposed rule (89 FR 62596 through 62600), we proposed and solicited comments on the Optimal Care for Patients with Urologic Conditions MVP. The proposed Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence,

bladder cancer, and prostate cancer. This MVP will be most applicable to clinicians who treat patients within the practice urology including general urologists, urology oncologists, and sub-specialists focused on urology care for women, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.4b.

Quality Measures

We proposed to include nine MIPS quality measures and five QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of urology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in urology:

- Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures patients have a documented plan of care for urinary incontinence at least once within 12 months.
- Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy: This MIPS quality measure ensures patients with prostate cancer currently on or starting androgen deprivation therapy (ADT), with an intent for treatment greater than or equal to 12 months, have a bone density evaluation prior to starting or within 3 months after the start of ADT.
- Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia: This MIPS quality measure assesses for improvement in urinary symptoms for patients with a diagnosis of benign prostatic hyperplasia based upon the International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI).
- Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer: This MIPS quality measure ensures patients initially diagnosed with non-muscle invasive bladder cancer have treatment initiated within 6 months of the cancer staging.
- AQUA8: Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy: This QCDR measure assesses the number of patients who have urinary retention, infection, or a new antibiotic prescription at least 24 hours after and within 30 days of a prostate biopsy or inpatient consultation or require hospitalization within 30 days of prostate biopsy.
- AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment: This QCDR measure assesses the number of patients who had a repeat shock wave lithotripsy procedure within the 6 months of the initial treatment.
- AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures: This QCDR measure ensures patients have a urinalysis or culture within 14 days prior to surgical stone procedures.
- AQUA16: Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease: This QCDR measure assesses the number of patients who undergo a second TURBT within 6 weeks of the initial procedure.
- MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed LowRisk Prostate Cancer Patients: This QCDR measure ensures newly diagnosed low-risk prostate cancer patients are managed via active surveillance or watchful waiting to maintain the patient's quality of life.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in urology. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q318: Falls: Screening for Future Fall Risk: This MIPS quality measure ensures patients are screened each performance period for future fall risk.
- Q321: CAHPS for MIPS Clinician/Group Survey: This survey provides direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.
- Q358: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures a personalized surgical risk assessment is completed on each patient using a validated risk calculator or multi-institutional clinical data prior to the surgery along with discussion of the identified risks with the surgeon.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 17 improvement activities that reflect actions and processes undertaken by clinicians who specialize in urology, as well as activities that promote patient

engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_6: Regularly Assess Patient Experience of Care and Follow Up on Findings
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care
- IA_CC_7: Regular training in care coordination
- IA_CC_13: Practice improvements to align with OpenNotes principles
- IA_CC_17: Patient Navigator Program
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_MVP: Practice-Wide Quality Improvement in MIPS Value Pathways
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_17: Participation in Population Health Research
- IA_PM_21: Advance Care Planning
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_12: Participation in private payer CPIA
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes
- IA_PSPA_21: Implementation of fall screening and assessment programs

Cost Measures

We proposed to include three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of urology. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in urology and align with other measures and activities within this MVP:

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients with urology-related conditions or procedures.
- Renal or Ureteral Stone Surgical Treatment: This MIPS episode-based cost measure assesses costs associated with surgical treatment for renal or ureteral stones. This also aligns with quality measures such as AQUA14: Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment or AQUA15: Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures.
- Prostate Cancer: This proposed MIPS episode-based cost measure will assess costs associated with prostate cancer. This also aligns with quality measures such as Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy or MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed LowRisk Prostate Cancer Patients.

Optimal Care for Patients with Urologic Conditions MVP Tables

Tables A.4a and A.4b serve to represent the measures and activities that are finalized within the Optimal Care for Patients with Urologic Conditions MVP.

Symbol Key:
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.4a: Optimal Care for Patients with Urologic Conditions MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM Specifications) **(!) Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CSV) **(!) Q358:** Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(!!) Q476:** Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM Specifications) **(!) Q481:** Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **(!!) AQUA8:** Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (Collection Type: QCDR) **(!!) AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (Collection Type: QCDR) **(!) AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (Collection Type: QCDR) **AQUA16:** Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 disease (Collection Type: QCDR) **(!) MUSIC4:** Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed LowRisk Prostate Cancer Patients (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **IA_CC_7:** Regular training in care coordination **IA_CC_13:** Practice improvements to align with OpenNotes principles **IA_CC_17:** Patient Navigator Program **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_17:** Participation in Population Health Research **IA_PM_21:** Advance Care Planning **(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements **IA_PSPA_12:** Participation in private payer CPIA **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes **IA_PSPA_21:** Implementation of fall screening and assessment programs	**Renal or Ureteral Stone Surgical Treatment** **Medicare Spending Per Beneficiary (MSPB) Clinician** **(^) Prostate Cancer**

TABLE A.4b: Optimal Care for Patients with Urologic Conditions MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience. A couple of commenters recommended the addition of two additional improvement activities related to bladder cancer care; IA_CC_12: Care Coordination Agreements that Promote Improvements in Patient Tracking Across Settings and IA_PSPA_8: Use of Patient Safety Tools.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP be modified to be more meaningful and directly beneficial to both physicians and their patients, reflecting the real-world clinical scenarios and challenges faced in practice.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing urological care and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: One commenter recommended specialty groups be provided the opportunity to determine if the measures included are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Guidance on how to submit recommended changes

to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter recommended this MVP include at least six eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: A couple of commenters recommended the removal of IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff from this MVP. The commenters stated their belief that a focus on this activity might shift focus from improvement activities that are more clinically relevant to urology and align more closely with the quality measures included in the MVP.

Response: We appreciate commenters' feedback. This activity was proposed for inclusion in all MVPs because of the importance of vaccination status in practice settings; we consider this activity to be of significant public-health importance.

Comment: A few commenters recommended the removal of the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure from this MVP. The commenters expressed concern about the potential attribution of cases to consultant urologists, even though they likely have little control over the cost of the hospital episodes.

Response: The MSPB Clinician cost measure is appropriate for use in this MVP, as it assesses costs associated with inpatient hospitalizations for urologic conditions, including those not captured by the episode-based cost measures we also proposed for inclusion in this MVP. The MSPB Clinician measure is designed to assess costs associated with inpatient hospitalizations that can be influenced by a clinician's care decisions, including urologists who practice in an inpatient setting and provide care such as bladder and urinary tract procedures.

Comment: A couple of commenters were opposed to the inclusion of the proposed, new Prostate Cancer episode-based cost measure in this MVP. One commenter is concerned the risk adjustment methodology for the proposed Prostate Cancer measure is insufficient to accurately account for variation in costs due to disease severity. Furthermore, commenters stated their belief that, without substantial measure testing to understand unintended consequences, they are concerned adoption of this measure could result in care stinting. These commenters stated that this is of particular risk for advanced prostate cancer, which may necessitate genetic or mutation testing, advanced imaging, or novel treatments.

Response: The new Prostate Cancer episode-based cost measure (which we are finalizing) is appropriate for use in this MVP, as it assesses costs associated with prostate cancer and aligns withs Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy and MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed LowRisk Prostate Cancer Patients. Additionally, we maintain that the measure appropriately accounts for disease severity identifiable in claims, as reflected in the measure's subgrouping and risk adjustment methodologies. We addressed the measure-specific feedback, regarding risk adjustment methodology, measure testing, and potential unintended consequences, in section IV.A.4.e.(2)(a)(ii)of this final rule in further detail.

After consideration of public comments, we are finalizing the *Optimal Care for Patients with Urologic Conditions MVP* as proposed in Tables A.4a and A.4b for the CY 2025 performance period/2027 MIPS payment year and future years.

A.5 Pulmonology Care MVP

In the CY 2025 PFS proposed rule (89 FR 62600 through 62603), we proposed and solicited comments on the Pulmonology MVP. The proposed Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP will be most applicable to clinicians who treat patients within the practice of pulmonology and sleep medicine, including nonphysician practitioners (NPPs) such as nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.5b.

Quality Measures

We proposed to include nine MIPS quality measures and one QCDR measure within the quality performance category of this MVP, which are specific to the clinical topic of pulmonology. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in pulmonology:

- Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation for Long-Acting Inhaled Bronchodilator Therapy: This MIPS quality measure ensures adults 18 and older diagnosed with COPD have spirometry results documented airflow obstruction confirming diagnosis and have been prescribed a long-acting bronchodilator to provide proper treatment if symptomatic.
- Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis: This MIPS quality measure ensures adults diagnosed with obstructive sleep apnea have an appropriate assessment completed and documented at the time of diagnosis or measured within 2 months of initial evaluation for suspected obstructive sleep apnea.
- Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy: This MIPS quality measure ensures patients with a diagnosis of obstructive sleep apnea (OSA) who were prescribed an evidence-based therapy with documentation that adherence to the therapy was assessed annually.
- Q398: Optimal Asthma Control: This MIPS quality measure assesses pediatric and adult patients to ensure their asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and not at risk for exacerbation.
- ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD: This QCDR measure ensures patients with asthma or COPD seen in the emergency department receive tobacco cessation if screened positive for tobacco use.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in pulmonology care. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a BMI documented with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.
- Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in pulmonology care, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_AHE_12: Practice Improvements that Engage Community Resources to Address Drivers of Health
- IA_BE_23: Integration of patient coaching practices between visits
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_13: Chronic care and preventative care management for empaneled patients
- IA_PM_16: Implementation of medication management practice improvements

Cost Measures

We proposed to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of pulmonology care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in pulmonology and align with other measures and activities within this MVP:

- Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation: This MIPS episode-based cost measure assesses costs associated with inpatient treatment for an acute exacerbation of COPD. This also aligns with quality measures such as Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation for Long-Acting Inhaled Bronchodilator Therapy.

- Asthma/Chronic Obstructive Pulmonary Disease (COPD): This MIPS episode-based cost measure assesses costs associated with medical care to manage and treat asthma or COPD. This also aligns with quality measures such as Q398: Optimal Asthma Control or ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD.

Pulmonology Care MVP Tables

Tables A.5a and A.5b serve to represent the measures and activities that are finalized within the Pulmonology MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.5a: Pulmonology Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM Specifications) **Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQM Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) **(*) Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM Specifications) **Q279:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQM Specifications) **(!!) Q398:** Optimal Asthma Control (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **ACEP25:** Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_23:** Integration of patient coaching practices between visits **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients **IA_PM_16:** Implementation of medication management practice improvements **(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B	**Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation** **Asthma/Chronic Obstructive Pulmonary Disease (COPD)**

TABLE A.5b: Pulmonology Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience. One commenter supported the inclusion of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP. Another commenter expressed support for the inclusion of Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis and Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea Therapy in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP be modified to be more meaningful and directly beneficial to both physicians and their patients, reflecting the real-world clinical scenarios and challenges faced in practice.

Response: We acknowledge the commenters concerns; however, the MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing pulmonology care and allows for clinician choice in choosing quality measures that best represent their practice. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended specialty groups be provided the opportunity to determine if the measures included are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: A few commenters are concerned this MVP is not a viable option for allergists, noting only three quality measures are regularly utilized by allergist. The commenters recommended the addition of Quality measure Q130: Documentation of Current Medications in the Medical Record, Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) Sinusitis, and Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) which are applicable to allergists.

Response: We acknowledge the commenters' concerns, and we may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Pulmonology MVP* as proposed in Tables A.5a and A.5b for the CY 2025 performance period/2027 MIPS payment year and future years.

A.6 Surgical Care MVP

In the CY 2025 PFS proposed rule (89 FR 62603 through 62606), we proposed and solicited comments on the Surgical Care MVP. The proposed Surgical Care MVP focuses on the clinical theme of surgery. This MVP will be most applicable to clinicians who treat patients within the surgical settings of general surgery, neurosurgery, cardiothoracic surgery, anesthesiologists, including nonphysician practitioners (NPPs) such as certified registered nurse anesthetists (CRNAs), nurse practitioners, and physician assistants. The summary of the public comments received and our responses for this MVP are included immediately after Table A.6b.

Quality Measures

We proposed to include 15 MIPS quality measures within the quality performance category of this MVP, which are specific to the clinical theme of surgery. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in surgery:

- Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation: This MIPS quality measure identifies patients who undergo an isolated CABG and require intubation > 24 hours following exit from the operating room.
- Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: This MIPS quality measure assesses patients for postoperative renal failure or who require dialysis after CABG.
- Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: This MIPS quality measure identifies patients who return to the operating room for surgical re-exploration following an isolated CABG surgery during the current hospitalization.
- Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer: This MIPS quality measure assesses the percentage of patients with a diagnosis of primary invasive breast cancer who undergo a sentinel lymph node procedure.
- Q354: Anastomotic Leak Intervention: This MIPS quality measure evaluates for anastomotic leak intervention following gastric bypass or colectomy surgery.

- Q355: Unplanned Reoperation within the 30-Day Postoperative Period: This MIPS quality measure evaluates for an unplanned reoperation within 30 days of a denominator eligible procedure.
- Q357: Surgical Site Infection (SSI): This MIPS quality measure evaluates for SSI within 30 days of a denominator eligible procedure.
- Q358: Patient-Centered Surgical Risk Assessment and Communication: This MIPS quality measure ensures a personalized surgical risk assessment is completed on each patient using a validated risk calculator or multi-institutional clinical data prior to the surgery along with discussion of the identified risks with the surgeon.
- Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG): This MIPS quality measure assesses patients undergoing isolated CABG for quality outcomes by identifying the percentage of patients who die, including all deaths occurring during CABG hospitalization and deaths occurring after discharge up to 30 days post CABG surgery.
- Q459: Back Pain After Lumbar Surgery: This MIPS quality measure evaluates patients for a decrease in back pain post lumbar surgery based upon predetermined benchmarks.
- Q461: Leg Pain After Lumbar Surgery: This MIPS quality measure evaluates patients for a decrease in leg pain post lumbar surgery based upon predetermined benchmarks.
- Q471: Functional Status After Lumbar Surgery: This MIPS quality measure evaluates patients for an increase in functional status post lumbar surgery based upon predetermined benchmarks.

The following broadly applicable MIPS quality measures are relevant to clinicians who treat patients in surgical settings. The measures assess for age-specific screenings, and follow-up actions for select measures, in addition to recommended vaccinations:

- Q047: Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.
- Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure ensures patients are screened for tobacco use and if screened positive receive tobacco cessation intervention.
- Q487: Screening for Social Drivers of Health: This MIPS quality measure ensures adults are screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Improvement Activities

We reviewed the Improvement Activities Inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 12 improvement activities that reflect actions and processes undertaken by surgical care clinicians, as well as activities that promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote Use of Patient-Reported Outcome Tools
- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_CC_15: PSH Care Coordination
- IA_CC_17: Patient Navigator Program
- IA_CC_18: Relationship-Centered Communication
- IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff (modified to IA_PM_26)
- IA_PCMH: Electronic submission of Patient Centered Medical Home accreditation
- IA_PM_11: Regular review practices in place on targeted patient population needs
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_8: Use of Patient Safety Tools

Cost Measures

We proposed to include six MIPS cost measures within the cost performance category of this MVP, which apply to the clinical theme of surgical care. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in surgical care and align with other measures and activities within this MVP:

- Colon and Rectal Resection: This MIPS episode-based cost measure assesses costs associated with colon or rectal resections for either benign or malignant indications.
- Femoral or Inguinal Hernia Repair: This MIPS episode-based cost measure assesses costs associated with surgical procedures to repair a femoral or inguinal hernia.
- Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels: This MIPS episode-based cost measure assesses costs associated with surgery for lumbar spine fusion. This also aligns with quality measures such as Q471: Functional Status After Lumbar Surgery or Q461: Leg Pain After Lumbar Surgery.
- Lumpectomy, Partial Mastectomy, Simple Mastectomy: This MIPS episode-based cost measure assesses costs associated with partial or total mastectomy for breast cancer.

- Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to clinicians providing care in inpatient hospitals, including those who treat patients within the surgical settings of general surgery, neurosurgery, and cardiothoracic surgery.
- Non-Emergent Coronary Artery Bypass Graft (CABG): This MIPS episode-based cost measure assesses costs associated with CABG. This also aligns with quality measures such as Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation or Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration.

Surgical Care MVP Tables

Tables A.6a and A.6b serve to represent the measures and activities that are finalized within the Surgical Care MVP.

Symbol Key:
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE A.6a: Surgical Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Specifications, MIPS CQM Specifications) **(!!) Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQM Specifications) **(!!) Q167:** Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQM Specifications) **(*)(!!) Q168:** Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQM Specifications) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQM Specifications) **Q264:** Sentinel Lymph Node Biopsy for Invasive Breast Cancer (Collection Type: MIPS CQM Specifications) **(!!) Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQM Specifications) **(*)(!!) Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQM Specifications) **(!) Q358:** Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM Specifications) **(!!) Q445:** Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQM Specifications) **(!!) Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQM Specifications) **(!!) Q461:** Leg Pain After Lumbar Surgery (Collection Type: MIPS CQM Specifications) **(!!) Q471:** Functional Status After Lumbar Surgery (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **IA_BE_12:** Use evidence-based decision aids to support shared decision-making **IA_CC_15:** PSH Care Coordination **IA_CC_17:** Patient Navigator Program **IA_CC_18:** Relationship-Centered Communication **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs **(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements **IA_PSPA_8:** Use of Patient Safety Tools	**Colon and Rectal Resection** **Femoral or Inguinal Hernia Repair** **Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels** **Lumpectomy, Partial Mastectomy, Simple Mastectomy** **Medicare Spending Per Beneficiary (MSPB) Clinician** **Non-Emergent Coronary Artery Bypass Graft (CABG)**

TABLE A.6b: Surgical Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP as proposed. One commenter recommended the inclusion of more patient-centered measures in the MVP. For example, measures vetted by the Core Quality Measures Collaborative (CQMC) with consumer input, measures of patient outcomes, patient-reported measures, as well as new approaches to the evaluation of patient experience. One commenter supported the inclusion of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: Several commenters expressed opposition to this MVP as they believed the MVP is too broad to provide a meaningful pathway for specialists to be measured and meet the stated MVP goals as they relate to vascular surgeons and other surgical specialists. A couple of commenters believed the MVP is limiting for many surgical specialties. Other commenters believed the MVP includes measures across distinct populations without consideration of how these populations are treated in practice and does not allow for significant comparison or quality improvement. Another commenter believed there's a lack of benchmarks for certain measures, such as those quality measures related to CABG, which they feel may discourage meaningful participation and hinder the MVP's effectiveness. One commenter recommended the development of a Geriatric Surgery MVP instead of this MVP. The commenter believed a Geriatric Surgery MVP could align physician reporting with the Age Friendly Hospital measure that will be required for hospital reporting under the Hospital Inpatient Quality Reporting (IQR) program in 2025. They suggested that an MVP on this topic could focus on the unique needs of older adults as they move through the phases of surgical care. If aligned with the Hospital IQR program measure, hospitals could show their commitment to improving care for older adults, while also aligning metrics to achieve attestations and track performance for multiple programs. One commenter questioned combining measures from disparate surgical specialties that have little to no overlap in team-based care. The commenter stated the inclusion of measures relevant to spine surgery, cardiothoracic surgery, breast surgery, and general surgery appears arbitrary and disconnected from actual clinical practice.

Response: This MVP was intentionally made broad to allow for multiple surgical specialties the option of reporting an MVP as we move towards the sunsetting of traditional MIPS. While we understand this MVP covers multiple surgical specialties, this is due to limited measure inventory which does not allow for the creation of individual robust, meaningful MVPs for each surgical specialty. Clinicians who choose to report this MVP would still report data based upon the measures that are most applicable to their scope of care, allowing for an alternate option to traditional MIPS especially when choosing subgroup reporting with MVPs.

We acknowledge the commenters' concerns regarding benchmarks. While we endeavor to include measures that allow for maximum points, we want to ensure important aspects of care within the MVP clinical topic are represented. While we recognize that some of the quality measures don't have sufficient adoption to create a benchmark under traditional MIPS, we expect the move to MVP reporting, including subgroup reporting, will drive adoption of those measures as CABG is one of the most commonly performed procedures on Medicare beneficiaries.

We acknowledge the recommendation for a geriatric surgery MVP. Due to nuances between different CMS programs including Hospital IQR Program and MIPS, full alignment is not always possible, however, we continue to strive for alignment as feasible. Currently, the MIPS quality measure inventory does not contain surgical measures that are specific to the geriatric population. We encourage the commenter to submit quality measures to the Annual Call for Quality Measures for potential inclusion in future years. We will continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter requested clarification on why this MVP focuses on specific types of surgery but excludes others for which MIPS measures currently exist. For example, the commenter questioned why measures related to hip/knee surgery are not included in this MVP.

Response: We thank the commenter for their feedback. This MVP was intentionally made broad to allow for surgical specialties the option of reporting an MVP. While we understand this MVP covers multiple surgical specialties, the intent was to not overlap with currently available MVPs, such as the Improving Care for Lower Extremity Joint Repair MVP. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters expressed frustration regarding the construction of this MVP. They stated their belief that affected surgical specialties were not included in developing the MVP to assess the appropriateness of this strategy. One commenter recommended specialty groups be provided the opportunity to determine if the measures included in the MVP are appropriate and operationally reasonable.

Response: We post MVP candidates to the QPP website for public feedback for up to a 45-day window to further engage with interested parties on MVP candidates prior to rulemaking. In addition, interested parties are welcome to submit recommended changes to an MVP on an ongoing basis through the MVP Maintenance Process. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. We will also continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter recommended moving the CABG measures to the Advancing Care for Heart Disease MVP for this MVP to make more clinical sense and be more representative of team-based care.

Response: We thank the commenters for their general feedback on the CABG measures. We maintain that the Non-Emergent CABG episode-based cost measure is appropriate for use in the Surgical Care MVP, as it assesses costs associated with cardiothoracic surgery and aligns with Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation, Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure, and Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration. We may consider the inclusion of additional measures and improvement activities in this and other MVPs through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended refinements to the MVP to make it more accessible to CRNAs or to encourage subgroup reporting. The commenter noted that only one of the quality measures, Q164: Coronary Artery Bypass Graft: Prolonged Intubation, is directly attributable to CRNAs.

Response: We acknowledge the commenters' concerns. While this MVP focuses on the clinical theme of promoting quality care provided by surgeons, CRNAs and other applicable surgical clinicians play a vital role and positively influence the outcomes of several other quality measures within this MVP. Recognizing the MIPS quality measures inventory contains a limited number of measures that are specific to CRNAs, the Patient Safety and Support of Positive Experiences with Anesthesia MVP may be more in alignment with the scope of care provided by CRNAs. We would encourage the commenter to submit quality measures to the Annual Call for Quality Measures for potential inclusion in future years. We will continue to monitor this MVP and make revisions as appropriate based upon interested party feedback and MIPS quality measure inventory changes.

Comment: One commenter is opposed to the use of Q459: Back Pain After Lumbar Surgery in this MVP since improving back pain is typically not the primary goal of lumbar fusion surgery.

Response: We acknowledge the commenters' concerns. Low back pain is a common, disabling symptom driving patients to seek medical care. The benchmark of change (5.0) utilized within the measure was derived from years of data obtained by the measure steward. While we recognize that spine surgical interventions rarely eliminate back pain, assessing the percentage of patients achieving an "acceptable symptom state" may be an indicator of surgical success.

Comment: A couple of commenters believed there are limitations to measures Q355: Unplanned Reoperation within the 30-Day Postoperative Period and Q357: Surgical Site Infection. Although the title and description of these two measures seem to suggest that they are broadly applicable across surgical specialties, the denominator codes are almost exclusively focused on general surgery.

Response: We acknowledge the commenters' concerns and appreciate the feedback. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter believed there are limitations related to the spine measures included in this MVP. For example, for Q471: Functional Status After Lumbar Surgery, the only acceptable functional assessment tool that can be used to satisfy the measure is the Oswestry Disability Index. The commenter stated their belief that there are more appropriate functional outcome measures from tools such as PROMIS® (Patient-Reported Outcomes Measurement Information System) that should be included. The commenter was also concerned that all three spine surgery measures included in this MVP continue to lack a benchmark.

Response: We encourage the commenter to reach out to measure developers/stewards to develop additional measures utilizing the PROMIS tool for submission to the Annual Call for Quality Measures for possible future implementation. We may consider the inclusion of QCDR measures that meet the inclusion criteria and address a measurement gap through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Many of these measures currently lack a benchmark due to substantive changes made in previous years with the goal of creating a more robust set of measures leading to benchmark creation.

Comment: One commenter recommended the removal of IA_CC_15: PSH Care Coordination as they believed that the improvement activity is not multidisciplinary and does not necessarily involve CRNAs.

Response: We appreciate the feedback received. Upon reflection and to allow for clinician choice in choosing improvement activities that best represent their practice, we are going to retain this activity in this MVP.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: One commenter expressed uncertainty about how the quality measures related to Coronary Artery Bypass Grafting (CABG) surgery align with the corresponding cost measure for non-emergent CABG procedures. The commenter stated that, while the MVP's quality measures primarily focus on clinical outcomes, they indirectly influence the cost-effectiveness of CABG surgery. The commenter suggested that, however, clinical outcomes alone may not provide a comprehensive picture of resource utilization or costs, as factors like hospital length of stay and equipment usage significantly impact costs but may not be adequately captured by these measures. The commenter stated that, as with any of the cost measures, the focus on cost containment may inadvertently incentivize clinicians to limit necessary care or select patients based on cost considerations, potentially compromising patient outcomes or access to care. A couple of commenters are concerned that there is a lack of internal consistency between the quality and cost measures included in this MVP related to lumbar fusion. For example, quality measures Q461: Leg Pain After Lumbar Surgery, Q471: Functional Status After Lumbar Surgery and Q459: Back Pain After Lumbar Surgery each capture lumbar fusion or discectomy/laminectomy without fusion. On the other hand, the cost measure, Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels, only focuses on fusions. Furthermore, the lumbar fusion quality measures are evaluated at one-year post-operation, whereas the lumbar fusion acute episode cost measure ends at 90 days post-operation. As a result, the commenter stated their belief is that these quality and cost measures are misaligned, do not evaluate the same patient populations in the same manner, and will not result in accurate assessments of value. The commenter suggested this disparity creates an incentive to delay care, such as physical therapy, until after the acute cost measurement episode has ended.

Response: We agree with the commenters that it is important to consider quality performance alongside cost performance. The quality and cost measures included in the Surgical Care MVP are aligned to focus on the same clinical subgroupings, such as cardiothoracic and neurosurgery, as well as to cover similar patient populations. Both the Non-Emergent CABG and the Lumbar Spine Fusion for Degenerative Disease cost measures use similar service and diagnoses codes to their quality measure counterparts to identify the patient populations. The MVP also includes additional quality measures and improvement activities to collectively assess the overall value of surgical care. Additionally, the quality measures assess clinical outcomes which utilize different timeline criteria, based upon guidelines and best practices, for the purposes of assessing the quality action.

We also disagree with commenters that the inclusion of cost measures in the MVP do not adequately capture costs of resource utilization and incentivize care stinting. Cost measures encompass costs of all clinically related services furnished during an episode, including hospital stays, treatment and diagnostic services, ancillary items, services directly related to treatment, and those furnished as a consequence of care (for example, complications, readmissions, unplanned care, and emergency department visits). Cost measures aim to promote care coordination and can capture clinicians' cost savings through reduction of poor patient outcomes associated with higher-than-expected episode costs, such as potentially avoidable hospitalizations or complications.

After consideration of public comments, we are finalizing the *Surgical Care MVP* as proposed in Tables A.6a and A.6b for the CY 2025 performance period/2027 MIPS payment year and future years.

Group B: Modifications to Previously Finalized MVPs for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

In the CY 2025 PFS proposed rule (89 FR 62607 through 62609), we proposed and solicited comments on the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. Tables B.1a and B.1b represent the measures and activities that were finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP in (88 FR 88029 through 80032) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.1b.

Quality Measures

We proposed to modify the previously finalized Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP to remove one MIPS quality measure as it is a process measure and has become standard of care, based upon MIPS performance data showing continued high performance.

- Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Improvement Activities

For the reasons stated in the introduction of this appendix[1149], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Tables

Tables B.1a and B.1b serve to represent the measures and activities that are finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

[1149] See *Improvement Activity Policy Update and Global Inclusion of an Improvement A*ctivity.

TABLE B.1a: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(!) Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQM Specifications) **(!) Q321:** CAHPS for MIPs Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM Specifications) **(!) Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (Collection Type: MIPS CQM Specifications) **(!) Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(!!) ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR) **(!) ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain (Collection Type: QCDR) **(!) ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (Collection Type: QCDR) **(!) HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BMH_12:** Promoting Clinician Well-Being **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements **IA_PSPA_15:** Implementation of an Antimicrobial Stewardship Program (ASP)	**Emergency Medicine**

TABLE B.1b: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP.

Response: We thank the commenters for their support.

Comment: One commenter questioned why the Emergency Medicine MVP does not align with the Emergency Medicine specialty set.

Response: As we move to sunset traditional MIPS, MVPs are not intended to be duplicative of specialty measure sets but rather create a connected set of quality measures, cost measures and improvement activities to promote quality care within Emergency Medicine.

Comment: One commenter expressed concern that the MVP does not offer a broad enough inventory of CQMs to reflect the diversity of emergency medicine patient populations and the considerable expense of investing in a Qualified Clinical Data Registry (QCDR). The commenter recommended the addition of the following CQMs to the MVP; Q066: Appropriate Testing for Pharyngitis, Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy, and Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP* with modifications in Table B.1a and as proposed in Table B.1b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_CC_2: Implementation of improvements that contribute to more timely communication of test results. See Appendix 2, Table C for additional details.

B.2: Advancing Cancer Care MVP

In the CY 2025 PFS proposed rule (89 FR 62609 through 62613), we proposed and solicited comments on the previously finalized Advancing Cancer Care MVP. Tables B.2a and B.2b represent the measures and activities that were finalized within the Advancing Cancer Care MVP in (88 FR 80008 through 80011) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.2b.

Quality Measures

We proposed to modify the previously finalized Advancing Cancer Care MVP within the quality performance category of this MVP to include six additional MIPS quality measures and one additional QCDR measure that address appropriate cancer care treatment. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians providing care to patients with cancer:

- Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: This MIPS quality measure assesses overuse of bone scans for patients with prostate cancer with low incidence of recurrence receiving treatment.
- Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy: This proposed MIPS quality measure ensures timely biomarker testing for patients with a diagnosis of metastatic non-small cell lung cancer or squamous cell carcinoma of head and neck on first-line immune checkpoint inhibitor (ICI) therapy.
- Q507: Appropriate Germline Testing for Ovarian Cancer Patients: This proposed MIPS quality measure assesses patients with a diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer for completion germline testing within 6 months of diagnosis.
- TBD: Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer: This proposed MIPS quality measure assesses pain interference following chemotherapy administered with curative intent to adult patients with breast cancer.
- TBD: Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer: This proposed MIPS quality measure assess fatigue following chemotherapy administered with curative intent to adult patients with breast cancer.
- PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure): The intent of this QCDR measure is to assess prophylactic use of granulocyte colony stimulating factor (G-CSF) when it is not indicated for low-risk chemotherapy and is not restricted to metastatic colorectal cancer.

In addition, we proposed the following broadly applicable MIPS quality measure, which is relevant to patients receiving cancer care and their experience of their health care treatment journey:

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams are actively engaged to ensure patients are understood in a significant and empowering way.

We proposed to modify the previously finalized Advancing Cancer Care MVP to remove two MIPS quality measures as they are duplicative in concept to current MIPS quality measures and are being proposed for removal from MIPS:

- Q144: Oncology: Medical and Radiation - Plan of Care for Pain
- Q452: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

We are also proposing to remove one QCDR measure which will be replaced by PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure), which has a broader denominator and is not restricted to metastatic colorectal cancer.

- PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer

Improvement Activities

For the reasons stated in the introduction of this appendix[1150], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add an additional improvement activity that addresses maintenance requests from the public, as well as addresses priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

For the reasons stated in the introduction of this appendix, we proposed the following: remove the weights associated with the improvement activities contained in this MVP; and remove three improvement activities being proposed for removal from MIPS:

- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_ERP_4: Implementation of a Personal Protective Equipment (PPE) Plan

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of cancer care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in cancer care and aligns with other measures and activities included within this MVP:

- Prostate Cancer: This proposed MIPS episode-based cost measure will assess costs associated with prostate cancer. This also aligns with quality measures such as Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.

Advancing Cancer Care MVP Tables

Tables B.2a and B.2b serve to represent the measures and activities that are finalized within the Advancing Cancer Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.2a: Advancing Cancer Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **(+)(!) Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan	**(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care	**(^)(+) Prostate Cancer** **Total Per Capita Cost (TPCC)**

[1150] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q143**: Oncology: Medical and Radiation – Pain Intensity Quantified (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(!) Q144:** Oncology: Medical and Radiation - Plan of Care for Pain (Collection Type: MIPS CQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **(*)(!) Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQM Specifications) **(*) Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQM Specifications) **(!) Q453:** Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQM Specifications) **(!) Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQM Specifications) **(*) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*) Q490:** Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQM Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **(+)(^)(!) Q506:** Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy	**IA_BE_24:** Financial Navigation Program **IA_BMH_12:** Promoting Clinician Well-Being **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop **IA_CC_13:** Practice Improvements to align with OpenNotes principles **IA_CC_17:** Patient Navigator Program **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients **IA_PM_15:** Implementation of episodic care management practice improvements **IA_PM_16:** Implementation of medication management practice improvements **IA_PM_21:** Advance Care Planning **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs **IA_PSPA_28**: Completion of an Accredited Safety or Quality Improvement Program	

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQM Specifications) **(+)(^) Q507:** Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQM Specifications) **(!) PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to Start of Targeted Therapy (Collection Type: QCDR) **(+)(^)(!)PIMSH17:** Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)		

TABLE B.2b: Advancing Cancer Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter appreciated the focus on screening measures in this MVP. One commenter supported the addition of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP. A couple of commenters supported the inclusion of the Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure in this MVP. One commenter supported the inclusion of Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients. One commenter expressed support for retaining the following quality measures: Q450: Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer, Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy, and PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to Start of Targeted Therapy in this MVP. One commenter expressed support for the addition of the following new MIPS quality measures: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy and Appropriate Germline Testing for Ovarian Cancer Patients in this MVP. A couple of commenters supported the removal of the improvement activity weights from all activities and the updated requirement for MVP reporting requiring attestation to only one improvement activity.

One commenter suggested Q112: Breast Cancer, Q309 Cervical Cancer, and Q226 Preventative Care and Screening for Tobacco Care will be better for this MVP than the proposed new quality measure additions. They believed that these measures would support reporting of the MVP by both radiation oncology and medical oncology. A couple of commenters encouraged expanding this MVP to capture non-patient-facing clinicians who are integral to cancer care. Other commenters supported the removal of PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer and replacing it with PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure), which has a broader denominator and is not restricted to metastatic colorectal cancer. A couple of commenters recommended the inclusion of PIMSH15 and PIMSH16 to this MVP. One commenter recommended the inclusion of PIMSH4. One commenter encouraged expanding this MVP to capture non-patient-facing clinicians who are integral to cancer care.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on

an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter believed this MVP fails to recognize the complexity of cancer care that frequently involves the services of a surgical oncologist, a medical oncologist and a radiation oncologist. Another commenter noted the MVP is predominantly focused on medical oncology and would not be meaningful for radiation oncologists.

Response: We recognize the three main areas of oncology care and work to ensure the MVPs are broad to allow for comprehensive reporting within the MVP topic. We include measures that represent different aspects of care; however, we are limited to the current MIPS quality measure inventory and encourage interested parties to develop quality measures pertinent to their scope of care for potential consideration of implementation in MIPS. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing oncology care and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: A few commenters opposed the removal of Q144: Oncology: Medical and Radiation – Plan of Care for Pain from the MVP. They asserted that this measure is not duplicative of, but rather paired with Q143: Oncology: Medical and Radiation – Pain Intensity Quantified and that the measures should be implemented sequentially to achieve a comprehensive clinical quality outcome, with Q143 confirming that the patient's pain was evaluated and Q144 validating that a patient care plan for pain was developed based on that assessment. They stated that the intent is for applicable clinicians to report on both measures as a unit, while resulting in individual measure scores.

Response: Based on comments received, Q144 will be maintained in MIPS therefore it will be maintained in this MVP.

Comment: A couple of commenters believed the quality measures in this MVP should align with the measures included in the "oncology/hematology specialty set".

Response: As we move towards sunsetting traditional MIPS, MVPs are not intended to be duplicative of specialty measure sets but rather create a connected set of quality measures, cost measures and improvement activities to promote quality care for cancer patients.

Comment: One commenter recommended this MVP include at least six eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: A couple of commenters opposed the addition of the new, proposed Prostate Cancer cost measure to this MVP. The commenters stated that they do not believe the measure accurately reflects appropriate and expected cost variation based on disease severity and patient needs and may, in fact, create unintended disincentives that would limit provision of appropriate, high-quality care.

Response: The Prostate Cancer episode-based cost measure is appropriate for use in this MVP, as it assesses costs associated with prostate cancer and aligns with Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients. Additionally, we maintain that the measure appropriately accounts for disease severity identifiable in claims, as reflected in the measure's subgrouping and risk adjustment methodologies. We have addressed this measure-specific feedback under section IV.A.4.e.(2)(a)(ii)of this final rule in further detail.

Comment: A couple of commenters advocated for the removal of the Total Per Capita Cost (TPCC) measure from the MVP. One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Cancer Care MVP* with modifications in Table B.2a and as proposed in Table B.2b for the CY 2025 performance period/2027 MIPS payment year and future years. The following measures are not being finalized in MIPS and therefore are not being finalized in this MVP, TBD: Patient-Reported Pain

Interference Following Chemotherapy among Adults with Breast Cancer and TBD: Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer. See Appendix 1, Table B.27a for additional details. Based on comments received, we are not finalizing the removal of quality measure Q144: Oncology: Medical and Radiation - Plan of Care for Pain. The measure steward is evaluating respecifying measures Q143: Oncology: Medical and Radiation – Pain Intensity Quantified and Q144: Oncology: Medical and Radiation – Plan of Care for Pain into a single, combined measure and requested that both measures be retained at this time. See Appendix 1, Table C.3 for additional details. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. We are delaying the removal of IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop. See Appendix 2, Table C for additional details.

B.3: Advancing Care for Heart Disease MVP

In the CY 2025 PFS proposed rule (89 FR 62613 through 62616), we proposed and solicited comments on the previously finalized Advancing Care for Heart Disease MVP. Tables B.3a and B.3b represent the measures and activities that were finalized within the Advancing Care for Heart Disease MVP in (88 FR 80022 through 80025) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.3b.

Quality Measures

We proposed to modify the previously finalized Advancing Care for Heart Disease MVP within the quality performance category of this MVP to include one additional broadly applicable MIPS quality measure relevant to patients receiving care for heart disease. We reviewed the quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

Improvement Activities

For the reasons stated in the introduction of this appendix[1151], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

Cost Measures

We did not propose to modify the MIPS cost measures included within the cost performance category of this previously finalized Advancing Care for Heart Disease MVP by proposing to add or remove cost measures from the MVP.
However, we proposed to modify the ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI) cost measure, which included a proposed measure title update to Inpatient (IP) Percutaneous Coronary Intervention (PCI). Please see section IV.A.4.e.(2)(a)(iii) of this final rule for all finalized revisions to this cost measure.

Advancing Care for Heart Disease MVP Tables

Tables B.3a and B.3b serve to represent the measures and activities that are finalized within the Advancing Care for Heart Disease MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.3a: Advancing Care for Heart Disease MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **Heart Failure**

[1151] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy (Collection Type: MIPS CQM Specifications) **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%) (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤40%) (Collection Type: MIPS CQM Specifications) **(**) Q128**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(!) Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQM Specifications) **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM Specifications) **(!) Q377:** Functional Status Assessments for Heart Failure (Collection Type: eCQM Specifications) **(!!) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_12:** Use evidence-based decision aids to support shared decision-making **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **IA_BE_24:** Financial Navigation Program **IA_BE_25:** Drug Cost Transparency **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements	**(*) Inpatient (IP) Percutaneous Coronary Intervention (PCI)** **Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQM Specifications) **(*)(!!) Q393:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQM Specifications) **(!!) Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*)(!!) Q492:** Risk-Standardized Acute Cardiovascular-Related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (Collection Type: Administrative Claims) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications)		

TABLE B.3b: Advancing Care for Heart Disease MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP. Another commenter supported the inclusion of the Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure in this MVP. One commenter recommended Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease be added to this MVP. The commenter also recommended the inclusion of the new improvement activity for clinicians to assess and manage patients at risk of ASCVD. Another commenter recommended the inclusion of the newly proposed Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk improvement activity.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter was concerned with the inclusion of Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood noting the measure is not the best fit for interventional cardiologists attempting to report this MVP.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing cardiology care and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* as proposed in Tables B.3a and B.3b for the CY 2025 performance period/2027 MIPS payment year and future years.

B.4: Advancing Rheumatology Patient Care MVP

In the CY 2025 PFS proposed rule (89 FR 62616 through 62619), we proposed and solicited comments on the previously finalized Advancing Rheumatology Patient Care MVP. Tables B.4a and B.4b represent the measures and activities that were finalized within the Advancing Rheumatology Patient Care MVP in (88 FR 80026 through 80029) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.4b.

Quality Measures

We proposed to modify the previously finalized Advancing Rheumatology Patient Care MVP within the quality performance category of this MVP to include one additional MIPS quality measure and two QCDR measures that are relevant to patients receiving rheumatology care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measures proposed within this MVP provide address appropriate clinical care for patients with rheumatological conditions:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.
- UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy: This QCDR measure assesses patients newly diagnosed with ankylosing spondylitis for appropriate pharmacologic therapy by ensuring a course of NSAIDs is prescribed before initiation of biologics during the first six months of treatment.
- UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older: This QCDR measure identifies male patients who have ever had a central dual-energy X-ray absorptiometry (DXA) to screen for osteoporosis to identify osteoporotic risk for fracture.

Improvement Activities

For the reasons stated in the introduction of this appendix[1152], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activities being proposed for removal from MIPS:

- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to add one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of rheumatology care. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who specialize in rheumatology care and aligns with the other measures and activities included within this MVP:

- Rheumatoid Arthritis: This proposed MIPS episode-based cost measure will assess costs associated with medical care to manage and treat rheumatoid arthritis. This also aligns with quality measures such as Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity or Q178: Rheumatoid Arthritis (RA): Functional Status Assessment.

[1152] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Advancing Rheumatology Patient Care MVP Tables

Tables B.4a and B.4b serve to represent the measures and activities that are finalized within the Advancing Rheumatology Patient Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.4a: Advancing Rheumatology Patient Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specification) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM Specifications) **(*) Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQM Specifications) **(*) Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQM Specifications) **(*) Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **ACR12:** Disease Activity Measurement for Patients with PsA (Collection Type: QCDR) **(!!) ACR14:** Gout: Serum Urate Target	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes **IA_BE_4**: Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **IA_BE_24:** Financial Navigation Program **IA_BE_25**: Drug Cost Transparency **IA_BMH_2:** Tobacco use **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program	**(^)(+) Rheumatoid Arthritis** **Total Per Capita Cost (TPCC)**

Quality	Improvement Activities	Cost
(Collection Type: QCDR) **(!) ACR15:** Safe Hydroxychloroquine Dosing (Collection Type: QCDR) **(+)(!) UREQA2:** Ankylosing Spondylitis: Appropriate Pharmacologic Therapy (Collection Type: QCDR) **(+) UREQA9:** Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR) **(!!) UREQA10:** Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)		

TABLE B.4b: Advancing Rheumatology Patient Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter supported the inclusion of Q493: Adult Immunization Status measure in MVPs with a broad clinical reach such as this MVP. Another commenter supported the addition of the following quality measures: Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age, UREQA2: Ankylosing Spondylitis: Appropriate Pharmacologic Therapy, and UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older.

Response: We thank the commenters for their support.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: One commenter encouraged retaining IA_EPA_1 in MIPS and this MVP for at least one additional year given its wide use across multiple specialties, so practices have a greater duration of time to review all improvement activities to identify and plan for more meaningful activities for the 2026 performance year.

Response: We appreciate the commenter's feedback. Upon careful consideration, we are proceeding with removal of this activity under removal factor seven, activity is obsolete: this activity was created, in part, to incentivize utilization of EHRs to increase access to clinicians in off hours and decrease emergency room (ER) visits. Today, EHRs are highly utilized, and this activity has become standard of care.

Comment: One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Advancing Rheumatology Patient Care MVP* with modifications in Table B.4a and as proposed in Table B.4b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details.

B.5: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

In the CY 2025 PFS proposed rule (89 FR 26219 through 62622), we proposed and solicited comments on the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. Tables B.5a and B.5b represent the measures and activities that were finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP in ((88 FR 80039 through 80041) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.5b.

Quality Measures

We proposed to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP to include one additional broadly applicable MIPS quality measure relevant to patients receiving stroke care and their experience of their health care treatment journey. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

We also proposed to modify the previously finalized Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP to remove one MIPS quality measure as this measure is proposed for removal from MIPS:

- Q409: Clinical Outcome Post Endovascular Stroke Treatment

We proposed to modify the Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this final rule for all finalized revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1153], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Tables

Tables B.5a and B.5b serve to represent the measures and activities that are finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP.

Symbol Key:

[1153] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with proposed revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.5a: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQM Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Collection Type: MIPS CQM Specifications) **(*)(!!) Q344:** Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM Specifications) **(*)(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM Specifications) **Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(+)(!!) Q495**: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM Specifications)	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes **IA_BE_4**: Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_24:** Financial Navigation Program **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results **IA_CC_13:** Practice improvements to align with OpenNotes principles **IA_CC_17:** Patient Navigator Program **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_13:** Chronic care and preventative care management for empaneled patients **IA_PM_15:** Implementation of episodic care management practice improvements **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B	**Intracranial Hemorrhage or Cerebral Infarction**

TABLE B.5b: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP. Another commenter supported the inclusion of the Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* with modifications in Table B.5a and as proposed in Table B.5b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_CC_2: Implementation of improvements that contribute to more timely communication of test results. See Appendix 2, Table C for additional details.

B.6: Focusing on Women's Health MVP

In the CY 2025 PFS proposed rule (89 FR 62622 through 62625), we proposed and solicited comments on the previously finalized Focusing on Women's Health MVP. Tables B.6a and B.6b represent the measures and activities that were finalized within the Focusing on Women's Health MVP in (88 FR 79981 through 79986) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.6b.

Quality Measures

We proposed to modify the previously finalized Focusing on Women's Health MVP within the quality performance category of this MVP to include one additional MIPS quality measure that is relevant to women's health. We reviewed the MIPS quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

The following quality measure proposed within this MVP provides a meaningful and comprehensive assessment of the clinical care for clinicians providing women's health care to patients:

- Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age: This MIPS quality measure assesses women who have ever received a dual-energy x-ray absorptiometry (DXA) test to evaluate for the disease osteoporosis.

We are also proposing to modify the previously finalized Focusing on Women's Health MVP to remove one MIPS quality measure as it is a process measure that has become standard of care, based on MIPS performance data as demonstrated by the measure's high performance in the PY2024 MIPS Historical Quality Benchmarks file, as well as previous year's benchmark data, and is being proposed for removal from MIPS:

- Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

We proposed to modify the Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this final rule for all finalized revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1154], we proposed the following: add the modified proposed IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Focusing on Women's Health MVP Tables

Tables B.6a and B.6b serve to represent the measures and activities that are finalized within the Focusing on Women's Health MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.6a: Focusing on Women's Health MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+) Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specification)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations **(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Total Per Capita Cost (TPCC)**

[1154] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM Specifications) **(*)(**) Q112:** Breast Cancer Screening (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **Q309:** Cervical Cancer Screening (Collection Type: eCQM Specifications) **Q310:** Chlamydia Screening in Women (Collection Type: eCQM Specifications) **(!!) Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQM Specifications) **(*)(!) Q336:** Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQM Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM Specifications) **(!) Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM Specifications) **(*)(!!) Q432:** Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQM Specifications) **(*)(!) Q448:** Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQM Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health	**(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_4**: Engagement of patients through implementation of improvements in patient portal **(~) IA_BE_16:** Promote Self-management in Usual Care **(~) IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice **(~) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities **(~) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B	

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQM Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQM Specifications) **Q496:** Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQM Specifications) **(!!) UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)		

TABLE B.6b: Focusing on Women's Health MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for this MVP. One commenter supported the inclusion of Q493: Adult Immunization Status measure in MVPs with a broad clinical reach such as this MVP. And another commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP. One commenter suggested the addition of the Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services improvement activity to this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter expressed continued opposition to this MVP and recommended an MVP be developed that focused on gynecologic health and maternity care separately with the input of specialty societies.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing women's health and allows for clinician choice in choosing quality measures that best represent their practice.

After consideration of public comments, we are finalizing the *Focusing on Women's Health MVP* with modifications in Table B.6a and as proposed in Table B.6b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details.

B.7: Improving Care for Lower Extremity Joint Repair MVP

In the CY 2025 PFS proposed rule (89 FR 62626 through 62628), we proposed and solicited comments on the previously finalized Improving Care for Lower Extremity Joint Repair MVP. Tables B.7a and B.7b represent the measures and activities that were finalized within the Advancing Improving Care for Lower Extremity Joint Repair MVP in (88 FR 80033 through 80035) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.7b.

Improvement Activities

For the reasons stated in the introduction of this appendix[1155], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add an additional improvement activity that addresses maintenance requests from the public, as well as addresses priority areas including food insecurity and the incorporation of patient voices into health care decision making:

- IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

In addition, we proposed the following: remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_PSPA_27: Invasive Procedure or Surgery Anticoagulation Medication Management

Improving Care for Lower Extremity Joint Repair MVP Tables

Tables B.7a and B.7b serve to represent the measures and activities that are finalized within the Improving Care for Lower Extremity Joint Repair MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.7a: Improving Care for Lower Extremity Joint Repair MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(+)(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols (Medium Weight)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**

[1155] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(**) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(!) Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (Collection Type: MIPS CQM Specifications) **(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQM Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (Collection Type: eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQM Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications)	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_12** Use evidence-based decision aids to support shared decision-making **IA_CC_7:** Regular training in care coordination **(~) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans **IA_CC_13:** Practice improvements to align with OpenNotes principles **IA_CC_15:** PSH Care Coordination **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements **(~) IA_PSPA_18:** Measurement and improvement at the practice and panel level	

TABLE B.7b: Improving Care for Lower Extremity Joint Repair MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter expressed support for the modifications proposed to this MVP. Another commenter supported the addition of the Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols improvement activity in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* as proposed in Tables B.7a and B.7b for the CY 2025 performance period/2027 MIPS payment year and future years.

B.8: Optimal Care for Kidney Health MVP

In the CY 2025 PFS proposed rule (89 FR 62628 through 62631), we proposed and solicited comments on the previously finalized Optimal Care for Kidney Health MVP. Tables B.8a and B.8b represent the measures and activities that were finalized within the Optimal Care for Kidney Health MVP in (88 FR 80012 through 80015) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.8b.

Quality Measures

We proposed to modify the previously finalized Optimal Care for Kidney Health MVP within the quality performance category of this MVP to include three additional broadly applicable MIPS quality measures that are relevant to patients receiving care for kidney health. We reviewed the quality measure inventory and considered feedback received during the 2025 MVP maintenance period to determine which quality measures to include in this MVP.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.
- Q510: First Year Standardized Waitlist Ratio (FYSWR): This MIPS quality measure measures number of incident (newly initiated on dialysis) patients in a practitioner (inclusive of physicians and advanced practice providers) groups who were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis.
- Q511: Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW): This MIPS quality measure tracks dialysis patients who at a practitioner group practice who were on the kidney or kidney-pancreas transplant waitlist (all patients or patients in active status).

We proposed to modify the Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) quality measure, which includes a proposed measure title update. Please see Appendix 1: MIPS Quality Measures, Table Group D of this final rule for all finalized revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1156], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Cost Measures

We proposed to add three MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of kidney health. We reviewed the MIPS cost measure inventory and considered feedback received from interested parties through the MVP maintenance process to determine the cost measures to include in this MVP. The following proposed new cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in kidney care and align with the other measures and activities included within this MVP and are described in section IV.A.4.e(2)(a)(ii) of this final rule:

- Chronic Kidney Disease (CKD): This proposed MIPS episode-based cost measure will assess costs associated with medical care to manage and treat stage 4 or 5 chronic kidney disease.
- End-Stage Renal Disease (ESRD): This proposed MIPS episode-based cost measure will assess costs associated with medical care to manage ESRD.
- Kidney Transplant Management: This proposed MIPS episode-based cost measure will assess costs associated with medical care related to kidney transplant, beginning no sooner than 90 days post-transplant.

Optimal Care for Kidney Health MVP Tables

Tables B.8a and B.8b serve to represent the measures and activities that are finalized within the Optimal Care for Kidney Health MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.8a: Optimal Care for Kidney Health MVP Measures and Improvement Activities

[1156] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(!!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*) Q488:** Kidney Health Evaluation (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQM Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications) **(+)(^) Q510:** First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQM Specifications) **(+)(^) Q511:** Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) (Collection Type: MIPS CQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **(~) IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **(~) IA_BE_16:** Promote Self-management in Usual Care **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results **IA_CC_13:** Practice improvements to align with OpenNotes principles **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_16:** Implementation of medication management practice improvements **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs	**Acute Kidney Injury Requiring New Inpatient Dialysis (AKI)** **(^)(+) Chronic Kidney Disease (CKD)** **(^)(+) End-Stage Renal Disease (ESRD)** **(^)(+) Kidney Transplant Management** **Total Per Capita Cost (TPCC)**

TABLE B.8b: Optimal Care for Kidney Health MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the modifications made to this MVP. A couple of commenters recommended the addition of Remote Monitoring [remote physiological monitoring (RPM) and remote therapeutic monitoring (RTM)]. One commenter expressed support for the inclusion of the First Year Standardized Waitlist Ratio measure or the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter did not support the inclusion of the First Year Standardized Waitlist Ratio measure or the Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW) measure as they feel these measures are largely outside of nephrologists' ability to influence.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing kidney health and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: One commenter recommended this MVP include at least six eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to

reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs.. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Optimal Care for Kidney Health MVP* with modifications in Table B.8a and as proposed in Table B.8b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_CC_2: Implementation of improvements that contribute to more timely communication of test results. See Appendix 2, Table C for additional details.

B.9: Patient Safety and Support of Positive Experiences with Anesthesia MVP

In the CY 2025 PFS proposed rule (89 FR 62631 through 62633), we proposed and solicited comments on the previously finalized Patient Safety and Support of Positive Experiences with Anesthesia MVP. Tables B.9a and B.9b represent the measures and activities that were finalized within Patient Safety and Support of Positive Experiences with Anesthesia MVP in (88 FR 80036 through 80038) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.9b.

Improvement Activities

For the reasons stated in the introduction of this appendix[1157], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

Patient Safety and Support of Positive Experiences with Anesthesia MVP Tables

Tables B.9a and B.9b serve to represent the measures and activities that are finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.9a: Patient Safety and Support of Positive Experiences with Anesthesia MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!!) Q404: Anesthesiology Smoking Abstinence (Collection Type: MIPS CQM Specifications) **(!!) Q424:** Perioperative Temperature Management	**IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_22:** Improved practices that engage patient's pre-visit	**Medicare Spending Per Beneficiary (MSPB) Clinician**

[1157] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(Collection Type: MIPS CQM Specifications) **(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (Collection Type: MIPS CQM Specifications) **(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (Collection Type: MIPS CQM Specifications) **(!) Q477:** Multimodal Pain Management (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(!) ABG44:** Low Flow Inhalational General Anesthesia (Collection Type: QCDR) **(!!) AQI48:** Patient-Reported Experience with Anesthesia (Collection Type: QCDR) **(!!) EPREOP31:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: QCDR)	**IA_BMH_2:** Tobacco use **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results **IA_CC_15:** PSH Care Coordination **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs	

TABLE B.9b: Patient Safety and Support of Positive Experiences with Anesthesia MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter appreciates our effort in ensuring nurse practitioners (NPs) are eligible to participate in all the currently developed MVPs. Another commenter expressed support for all proposed changes to the improvement activity performance category in this MVP. Several commenters specifically supported the removal of the improvement activity weights from all activities and the updated requirement for MVP reporting requiring attestation to only one improvement activity. One commenter supported the inclusion of Q487: Screening for Social Drivers of Health improvement activity in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* with modifications in Table B.9a and as proposed in Table B.9b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the removal of IA_CC_2: Implementation of improvements that contribute to more timely communication of test results. See Appendix 2, Table C for additional details.

B.10: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

In the CY 2025 PFS proposed rule (89 FR 62633 through 62636), we proposed and solicited comments on the previously finalized Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. Tables B.10a and B.10b represent the measures and activities that were finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP in (88 FR 79991 through 79995) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.10b.

Quality Measures

We did not propose to modify the previously finalized Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP within the quality performance category of this MVP by proposing to add or remove quality measures from the MVP. However, we proposed to modify the Q340: HIV Medical Visit Frequency quality measure, which includes a proposed measure title update to HIV Annual Retention in Care. Please see Appendix 1: MIPS Quality Measures, Table Group D of this final rule for all finalized revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1158], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove one improvement activity being proposed for removal from MIPS:

- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups who Have Real-Time Access to Patient's Medical Record

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Tables

Tables B.10a and B.10b serve to represent the measures and activities that are finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.10a: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(!) Q065: Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specification) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health	**Total Per Capita Cost (TPCC)**

[1158] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q240:** Childhood Immunization Status (Collection Type: eCQM Specifications) **Q310:** Chlamydia Screening in Women (Collection Type: eCQM Specifications) **(!!) Q338:** HIV Viral Suppression (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q340:** HIV Annual Retention in Care (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q387:** Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQM Specifications) **Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM Specifications) **Q401:** Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*) Q493:** Adult Immunization Status (Collection Type: MIPS CQM Specifications)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs **(~) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients **(~) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support	

TABLE B.10b: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange

Population Health Measures	Promoting Interoperability
	OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter supported the inclusion of Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services IA in this MVP. One commenter supported the inclusion of Q493: Adult Immunization Status measure in MVPs with a broad clinical reach such as this MVP.

Response: We thank the commenters for their support.

Comment: One commenter continued to oppose the inclusion of the Total Per Capita Cost (TPCC) measure in this MVP. The commenter believed this measure captures aspects of care that infectious disease physicians do not have direct control over, and it provides little meaningful or actionable data to help clinicians understand what they can do to lower costs and improve the value of care. Importantly, for their specialty, is the failure of the measure to account for short-term investments that might result in savings and higher-quality care over the long term. One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP* with modifications in Table B.10a and as proposed in Table B.10b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details.

B.11: Quality Care for Patients with Neurological Conditions MVP

In the CY 2025 PFS proposed rule (89 FR 62636 through 62639), we proposed and solicited comments on the previously finalized Optimal Care for Patients with Episodic Neurological Conditions and the Supportive Care for Neurodegenerative Conditions MVPs proposal to consolidate the two MVPs into a single consolidated neurological MVP titled Quality Care for Patients with Neurological Conditions. Tables B.11a and B.11b represent the measures and activities that were finalized within the Optimal Care for Patients with Episodic Neurological Conditions MVP (88 FR 80015 through 80018) and the Supportive Care for Neurodegenerative Conditions MVP (88 FR 80019 through 80021) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.11b.

Quality Measures

We proposed to modify the previously finalized neurology MVPs within the quality performance category of this MVP to include two additional broadly applicable MIPS quality measures relevant to patients receiving care for neurodegenerative disorders. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

- Q155: Falls: Plan of care: This MIPS quality measure ensures adult patients, with a history of falls, have a plan of care for falls.

- Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood: This MIPS quality measure ensures palliative care clinicians and/or teams empathize to ensure patients are understood in a significant and empowering way.

We proposed to modify the previously finalized MVPs to remove six QCDR measures no longer being supported by Axon Registry QCDR:

- AAN5: Treatment Prescribed for Acute Migraine Attack
- AAN9: Querying and Follow-Up About Symptoms of Autonomic Dysfunction for Patients with Parkinson's Disease
- AAN22: Quality of Life Outcome for Patients with Neurologic Conditions
- AAN31: Acute Treatment Prescribed for Cluster Headache
- AAN32: Preventive Treatment Prescribed for Cluster Headache
- AAN34: Patient reported falls and plan of care

Improvement Activities

For the reasons stated in the introduction of this appendix[1159], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove three improvement activities being proposed for removal from MIPS:

- IA_BMH_8: Electronic Health Record Enhancements for BH data capture
- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Quality Care for Patients with Neurological Conditions MVP Tables

Tables B.11a and B.11b serve to represent the measures and activities that are finalized within the Quality Care for Patients with Neurological Conditions MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.11a: Quality Care for Patients with Neurological Conditions MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!) Q047: Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **(*)(!) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM Specifications, MIPS CQM Specifications) **(+)(*)(!) Q155:** Falls: Plan of Care (Collection Type: MIPS CQM Specifications) **(*)(!) Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q268:** Epilepsy: Counseling for Women of	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **(~) IA_BE_16:** Promote Self-management in Usual Care **IA_BE_24:** Financial Navigation Program **IA_BMH_4:** Depression screening	**Medicare Spending Per Beneficiary (MSPB) Clinician**

[1159] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
Childbearing Potential with Epilepsy (Collection Type: MIPS CQM Specifications) **(*) Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM Specifications) **(*) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM Specifications) **(*)(!) Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM Specifications) **(*)(!) Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM Specifications) **(*) Q290:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease (Collection Type: MIPS CQM Specifications) **(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQM Specifications) **(*)(!) Q293:** Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQM Specifications) **(*)(!) Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM Specifications) **(!) Q419:** Overuse of Imaging for the Evaluation of Primary Headache (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(+)(!!) Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM Specifications) **(*)(!!) Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM Specifications)	**IA_BMH_8:** Electronic Health Record Enhancements for BH data capture **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs **IA_PM_16:** Implementation of medication management practice improvements **IA_PM_21:** Advance Care Planning **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_21:** Implementation of fall screening and assessment programs	

TABLE B.11b: Quality Care for Patients with Neurological Conditions MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information

Population Health Measures	Promoting Interoperability
	Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the consolidation of the Optimal Care for Patients with Episodic Neurological Conditions and Supportive Care for Neurodegenerative Conditions MVPs. One commenter supported the inclusion of the Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure in this MVP. One commenter recommended the addition of Q182: Functional Outcome Assessment in this MVP. The commenter believed this measure would provide a broader functional status measure with flexibility for selecting standardized PROM tools, allowing clinicians evaluating patients with a broad range of neurological conditions, including rare diseases such as myasthenia gravis, to evaluate functionality and be measured under MIPS . A couple of commenters recommended additional eCQM collection types for Quality measures in this MVP.

Response: We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that all collection types for each MIPS quality measure finalized through rulemaking will be available for use within the MVP.

Comment: One commenter believed the current iteration of Quality Care for Patients with Neurological Conditions MVP does not meet its intended purpose of serving as a transition from MIPS into value-based care. The commenter appreciated the development of the current comprehensive MVPs but encouraged further development of quality and cost measures as well as care delivery models that are targeted and condition specific, while also serving as a meaningful on-ramp into participating in APMs.

Response: This MVP has a broad clinical focus and captures performance driving positive clinical outcomes by providing fundamental treatment and management of patients with neurological conditions. As we work through the transition from traditional MIPS to MVPs, we anticipate MIPS eligible clinicians/groups will continue to utilize traditional MIPS in the absence of an appropriate and applicable MVP; however, by utilizing reporting trends and focusing on more specialty-specific quality measures, the MVP works to capture more meaningful data to the clinician's scope of care. Moreover, it would not be expected for every aspect of a clinician's scope of care to be assessed, as the clinician would have choice in which quality measures, they find most meaningful and appropriate for their case-mix and practice. The intent is to provide clinicians flexibility and choice in reporting by allowing them to select a subset of measures and activities within an MVP based upon a clinical topic. We would encourage the commenter to submit quality measures to the Annual Call for Quality Measures for potential inclusion in future years. As MVPs continue from year to year, the MVP Maintenance Process can be utilized to update MVPs to ensure they represent priorities in care for the MVP topic and align with care being delivered by the clinicians reporting.

Comment: One commenter recommended this MVP include at least six eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to

reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Quality Care for Patients with Neurological Conditions MVP* with modifications in Table B.11a and as proposed in Table B.11b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_BMH_8: Electronic Health Record Enhancements for BH data capture and IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop. See Appendix 2, Table C for additional details.

B.12: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

In the CY 2025 PFS proposed rule (89 FR 62639 through 62641), we proposed and solicited comments on the previously finalized Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. Tables B.12a and B.12b represent the measures and activities that were finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP in (88 FR 79986 through 79990) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.12b.

Quality Measures

We proposed to modify the previously finalized Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP within the quality performance category of this MVP to remove two QCDR measures whose quality actions reflect a standard of care based upon clinical guidelines recognized as best practices by health care clinicians. Based upon MIPS performance data, AAO16 is high performing and AAO23 has had minimal variation in its historical benchmark. Though allergic rhinitis falls within the spectrum of care otolaryngologists provide, the complexity of caring for the condition is typically low. Many non-surgical clinician specialties, including primary care, treat allergic rhinitis regularly. Further, measure AAO23 requires the use of medications that all are available over the counter. Removal of AAO23 will encourage use of other measures within the MVP that represent the complexity of care otolaryngologists provide.

- AAO16: Age-Related Hearing Loss: Audiometric Evaluation
- AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines

Improvement Activities

For the reasons stated in the introduction of this appendix[1160], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Tables

Tables B.12a and B.12b serve to represent the measures and activities that are finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

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[1160] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

TABLE B.12a: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(**) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **(*) Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM Specifications) **(*)(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM Specifications) **(!) Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) (Collection Type: MIPS CQM Specifications) **(*)(!!) Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM Specifications) **(!!) Q357:** Surgical Site Infection (SSI) (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR) **AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (Collection Type: QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop **IA_CC_13:** Practice improvements to align with OpenNotes principles **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **IA_PM_16:** Implementation of medication management practice improvements **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements	**Medicare Spending Per Beneficiary (MSPB) Clinician**

TABLE B.12b: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP.

Response: We thank the commenters for their support.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

Comment: One commenter is opposed to the removal of IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record, AAO16: Age-Related Hearing Loss: Audiometric Evaluation, and AAO23: Allergic Rhinitis: Intranasal Corticosteroids or Oral Antihistamines. The commenter believed that the removal of the quality measures would eliminate nearly one quarter of the specialty-specific quality measures within the MVP, which could significantly affect the ability of otolaryngologists to participate in the MVP decreasing the opportunity to effectively evaluate and improve care for patients.

Response: Upon careful consideration, we are proceeding with removal of IA_EPA_1 under removal factor seven, activity is obsolete: this activity was created, in part, to incentivize utilization of EHRs to increase access to clinicians in off hours and decrease emergency room (ER) visits. Today, EHRs are highly utilized, and this activity has become standard of care.

We appreciate commenters' feedback on AAO16 and AAO23. Based upon MIPS performance data, AAO16 is high performing and AAO23 has had minimal variation in its historical benchmark. Though allergic rhinitis falls within the spectrum of care

otolaryngologists provide, the complexity of caring for the condition is typically low. Many non-surgical clinician specialties, including primary care, treat allergic rhinitis regularly.

After consideration of public comments, we are finalizing the *Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP* with modifications in Table B.12a and as proposed in Table B.12b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop. See Appendix 2, Table C for additional details.

B.13: Quality Care in Mental Health and Substance Use Disorders MVP

In the CY 2025 PFS proposed rule (89 FR 62641 through 62643), we proposed and solicited comments on the previously finalized Quality Care in Mental Health and Substance Use Disorders MVP. Tables B.13a and B.13b represent the measures and activities that were finalized within the Quality Care in Mental Health and Substance Use Disorders MVP in (88 FR 79986 through 80001) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.13b.

Improvement Activities

For the reasons stated in the introduction of this appendix[1161], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and remove the weights associated with the improvement activities contained in this MVP.

Quality Care in Mental Health and Substance Use Disorders MVP Tables

Tables B.13a and B.13b serve to represent the measures and activities that are finalized within the Quality Care in Mental Health and Substance Use Disorders MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.13a: Quality Care in Mental Health and Substance Use Disorders MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*) Q009: Antidepressant Medication Management (Collection Type: eCQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specification) **(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) **Q366:** Follow-Up Care for Children Prescribed ADHD Medication (ADD) (Collection Type: eCQM Specifications) **(!!) Q370:** Depression Remission at Twelve Months (Collection Type: eCQM Specifications, MIPS CQM Specification)	**(~) IA_AHE_1:** Enhance Engagement of Medicaid and Other Underserved Populations **(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_5:** MIPS Eligible Clinician Leadership in Clinical Trials or CBPR **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_12:** Use evidence-based decision aids to support shared decision-making. **(~) IA_BE_16:** Promote Self-management in Usual Care	**Medicare Spending Per Beneficiary (MSPB) Clinician** **Depression** **Psychoses and Related Conditions**

[1161] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
(!) Q382: Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM Specifications) **(*)(!!) Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQM Specifications) **(!) Q468:** Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(!!) Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQM Specifications) **(*)(!) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM Specifications) **(!!) Q505:** Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQM Specifications**)** **(!!) MBHR2:** Anxiety Response at 6-months (Collection Type: QCDR) **(!!) MBHR7:** Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	**IA_BE_23:** Integration of patient coaching practices between visits **IA_BMH_2:** Tobacco use **IA_BMH_5:** MDD prevention and treatment interventions **(~) IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model **(~) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults **IA_EPA_2:** Use of telehealth services that expand practice access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_6:** Use of toolsets or other resources to close healthcare disparities across communities **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support	

TABLE B.13b: Quality Care in Mental Health and Substance Use Disorders MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter supported the inclusion of IA_ERP_6: COVID-19 Vaccine Achievement for Practice Staff activity to this MVP. One commenter appreciated the continuation of Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) in this MVP. One commenter recommended the addition of Q493: Adult Immunization Status and other potentially relevant vaccination measures into this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter believed the data reportable for many of the measures in this MVP are not clinically meaningful for much of the treated patient population and are not tracked for clinicians.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting which would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all measures are applicable to all clinicians who would choose to report this MVP. However, this represents the foundation from which to build the most meaningful MVP addressing mental health and substance use disorder care and allows for clinician choice in choosing quality measures that best represent their practice.

After consideration of public comments, we are finalizing the *Quality Care in Mental Health and Substance Use Disorders MVP* as proposed in Tables B.13a and B.13b for the CY 2025 performance period/2027 MIPS payment year and future years.

B.14: Rehabilitative Support for Musculoskeletal Care MVP

In the CY 2025 PFS proposed rule (89 FR 62643 through 62646), we proposed and solicited comments on the previously finalized Rehabilitative Support for Musculoskeletal Care MVP. Tables B.14a and B.14b represent the measures and activities that were finalized within the Rehabilitative Support for Musculoskeletal Care MVP in (88 FR 80002 through 80007) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.14b.

Quality Measures

We proposed to modify the previously finalized Rehabilitative Support for Musculoskeletal Care MVP within the quality performance category of this MVP to include one additional MIPS quality measure and four QCDR measures that are relevant to patients receiving rehabilitative support for Musculoskeletal Care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2024 MVP maintenance period to determine which quality measures to include in this MVP.

- Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: This MIPS quality measure ensures that female patients with a diagnosis of urinary incontinence have a documented plan of care regarding rehabilitative treatment for urinary incontinence at least once within 12 months. A rehabilitation plan of care for these patients will address the musculoskeletal impairments of the pelvic floor related to urinary incontinence in women.
- MSK6: Patients Suffering From a Neck Injury who Improve Pain: This QCDR measure evaluates patients with a neck injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain: This QCDR measure evaluates patients with an upper extremity injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK8: Patients Suffering From a Back Injury who Improve Pain: This QCDR measure evaluates patients with a back injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.
- MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain: This QCDR measure evaluates patients with a lower extremity injury for achieving the minimal clinically important difference (MCID) improvement in pain by the end of treatment.

Improvement Activities

For the reasons stated in the introduction of this appendix[1162], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

Rehabilitative Support for Musculoskeletal Care MVP Tables

Tables B.14a and B.14b serve to represent the measures and activities that are finalized within the Rehabilitative Support for Musculoskeletal Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

TABLE B.14a: Rehabilitative Support for Musculoskeletal Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(+)(!) Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM Specifications) **(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_6:** Provide Education Opportunities for New Clinicians **(~) IA_AHE_9:** Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols	**Low Back Pain**

[1162] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

Quality	Improvement Activities	Cost
Measure Specifications, eCQM Specifications, MIPS CQM Specification) **(*)(!) Q155:** Falls: Plan of Care (Collection Type: MIPS CQM Specification) **(!!) Q217:** Functional Status Change for Patients with Knee Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q218:** Functional Status Change for Patients with Hip Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q219:** Functional Status Change with Lower Leg, Foot or Ankle Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q220:** Functional Status Change for Patients with Low Back Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q221:** Functional Status Change for Patients with Shoulder Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments (Collection Type: MIPS CQM Specifications) **(!!) Q478:** Functional Status Change for Patients with Neck Impairments (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(+)(!!) MSK6:** Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR) **(+)(!!) MSK7:** Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR) **(+)(!!) MSK8:** Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR) **(+)(!!) MSK9:** Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	**(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BMH_12:** Promoting Clinician Well-Being **(~) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults **IA_CC_1:** Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop **IA_CC_8:** Implementation of documentation improvements for practice/process improvements **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings **IA_EPA_2:** Use of telehealth services that expand practice access **(~) IA_EPA_3:** Collection and use of patient experience and satisfaction data on access **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs **IA_PSPA_21:** Implementation of fall screening and assessment programs	

TABLE B.14b: Rehabilitative Support for Musculoskeletal Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposed modifications of the Rehabilitative Support for this MVP. A few commenters supported the addition of MSK6: Patients Suffering From a Neck Injury who Improve Pain, MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain, MSK8: Patients Suffering From a Back Injury who Improve Pain, and MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain to this MVP. One commenter supported the addition of Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older. Another commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols in this MVP. Several commenters supported the removal of the improvement activity weights from all activities and the updated requirement for MVP reporting requiring attestation to only one improvement activity.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern with the limited nature of what can be reported in this MVP. The proposed measures to be added are pain measures, not functional measures; MSK6: Patients Suffering From a Neck Injury who Improve Pain, MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain, MSK8: Patients Suffering From a Back Injury who Improve Pain, and MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain. The commenters believed that the measures provide a poor measure of value for outpatient physical and occupational therapy clinicians.

Response: The MVPs are intentionally broad to allow for comprehensive reporting within the MVP topic and contain measures that represent different aspects of care. Rather than create an MVP for each subspecialty and/or setting that would create an overly complex MVP inventory state and increase administrative burden, these nuances may be captured within the MVP through different measures and activities representative of the reporting clinician's scope of care. We understand that not all measures are applicable to all clinicians who would choose to report this MVP. However, this represents the foundation from which to build the most meaningful MVP addressing rehabilitative support for musculoskeletal care and allows for clinician choice in choosing quality measures that best represent their practice.
Specifically, in addition to the MSK pain measures, this MVP does include seven MIPS CQMs that assess patient function and are applicable to most physical and occupational therapists. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing Rehabilitative Support for Musculoskeletal Care and allows for clinician choice in choosing quality measures that best represent their practice.

Comment: One commenter recommended adding functional measures to this MVP. A few commenters specifically requested the addition of MSK01: Patients Suffering From a Neck Injury who Improve Physical Function, MSK02: Patients Suffering From an Upper Extremity Injury who Improve Physical Function, MSK03: Patients Suffering From a Back Injury who Improve Physical Function, MSK04: Patients Suffering From a Lower Extremity Injury who Improve Physical Function, MSK05: Patients Suffering From a Knee Injury who Improve Physical Function and MSK10: Patients Suffering From a Knee Injury who Improve Pain. The commenter believed these measures would strengthen the MVPs ability to assess and report on quality in musculoskeletal rehabilitation and drive increased participation in the MVP and Quality Payment Programs.

Response: We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters stated their belief that the current functional measures (FOTO measures Q217: Functional Status Change for Patients with Knee Impairments, Q218: Functional Status Change for Patients with Hip Impairments, Q219: Functional Status Change with Lower Leg, Foot or Ankle Impairments, Q220: Functional Status Change for Patients with Low Back Impairments, Q221: Functional Status Change for Patients with Shoulder Impairments, Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments, and Q478: Functional Status Change for Patients with Neck Impairments) included in the MVP do not allow participation in the program with use of the PROMIS measures and are burdensome to collect and report if the therapist prefers to use the industry standard outcome measure tools. They asserted that this causes an additional burden on the clinician due to the absence of interoperability available for the FOTO measures to be integrated into other digital applications. One commenter recommended this MVP be expanded to include the complete MSK measure set.

Another commenter recommended the addition of several additional quality measures that would promote meaningful participation for physical therapists and other nonphysicians: Q182: Functional Outcome Assessment, Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention), and Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling. One commenter requested the inclusion of several additional improvement activities: IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care, IA_BE_16: Promote Self-management in Usual Care, IA_CC_9: Implementation of practices/processes for developing regular individual care plans, and IA_PM_13: Chronic care and preventative care management for empaneled patients.

Response: We acknowledge the commenters' concerns; however, the MIPS CQMs within this MVP are currently implemented and reported in MIPS. Specifically, the FOTO measures do not have to be reported within an existing digital application. The tools are publicly available for clinician and patient use and allows for a cross walk to several industry standard legacy tools. We understand that not all quality measures are applicable to all clinicians who would choose to report this MVP; however, this represents the foundation from which to build the most meaningful MVP addressing Rehabilitative Support for Musculoskeletal Care and allows for clinician choice in choosing quality measures that best represent their scope of care. Currently, we endeavor to not create overlap in quality/QCDR measure concepts. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will continue to evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Please note that all collection types for each MIPS quality measure finalized through rulemaking will be available for use within the MVP.

Comment: One commenter expressed concern with potential misalignment between the Low Back Pain cost measure and the quality measures included in this MVP. The commenter stated that most of the quality measures included in this MVP are not related to back pain and among the few that are, most lack a benchmark which means they are not being reported.

Response: We note that MIPS Q220: Functional Status Change for Patients with Low Back Impairments has a 2024 historical benchmark of 74.02% indicating that the measure is being reported and performance still indicates a gap. QCDR measure, MSK8: Patients Suffering From a Back Injury who Improve Pain is a new measure for the CY 2024 performance period, so would not yet have established a benchmark as reporting data would be submitted in early 2025. We maintain that the Low Back Pain episode-based cost measure is appropriate for use in this MVP, as described in the CY 2024 PFS proposed rule (88 FR 53164) and finalized in the CY 2024 PFS final rule (88 FR 80003 through 80007). We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter recommended this MVP include at least six eCQMs. One commenter is concerned that the MVP cannot be reported solely utilizing eCQMs. Another commenter stated their belief that quality measure reporting in an MVP should be available using a combination of claims-based reporting and eCQMs.

Response: We encourage the development of eCQMs as part of our overall strategy towards digital quality measures (dQMs); however, not all measures are submitted to the Call for Measures with an option for the eCQM collection type as this is not

currently a requirement for MIPS. We strive to include measures from different collection types to allow flexibility in reporting but are limited to how the measure is submitted by the measures steward to the Call for Measures. We encourage the commenter to reach out to the measure steward of current measures not available as eCQMs to discuss revisions for possible implementation in futures years.

After consideration of public comments, we are finalizing the *Rehabilitative Support for Musculoskeletal Care MVP* with modifications in Table B.14a and as proposed in Table B.14b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the removal of IA_CC_1: Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop. See Appendix 2, Table C for additional details.

B.15: Value in Primary Care MVP

In the CY 2025 PFS proposed rule (89 FR 62646 through 62648), we proposed and solicited comments on the previously finalized Value in Primary Care MVP. Tables B.15a and B.15b represent the measures and activities that were finalized within the Value in Primary Care MVP in (88 FR 80042 through 80047) with modifications proposed for the CY 2025 performance period/2027 MIPS payment year and future years. The summary of the public comments received and our responses for this MVP are included immediately after Table B.15b.

Quality Measures

We did not propose to modify the previously finalized Value in Primary Care MVP within the quality performance category of this MVP by proposing to add or remove quality measures from the MVP. However, we proposed to modify the Q001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) quality measure, which includes a proposed measure title update to Diabetes: Glycemic Status Assessment Greater Than 9%. Please see Appendix 1: MIPS Quality Measures, Table Group D of this final rule for all finalized revisions to this measure.

Improvement Activities

For the reasons stated in the introduction of this appendix[1163], we proposed the following: add the proposed modified IA_ERP_6 (modified to IA_PM_26) to all new and previously finalized MVPs because of the importance of vaccination status in practice settings; and add a proposed improvement activity that addresses risk for heart disease, the leading cause of death in the United States, as well as risk for stroke, which is the fifth most common cause of death. Promoting the implementation of standardized, evidence-based cardiovascular disease risk assessment and care management in the primary care setting has the potential to impact patient outcomes sizably and positively. This new activity, IA_PM_25, is based on the results of the CMS Innovation Center Million Hearts Model:

- IA_PM_25: Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

In addition, we proposed the following: remove the weights associated with the improvement activities contained in this MVP; and remove two improvement activities being proposed for removal from MIPS:

- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record

We proposed to modify the IA_BE_4: Engagement of patients through implementation of improvements in patient portal improvement activity, which included a proposed activity title update. Please see Appendix 2, Improvement Activities: Table Group B of this final rule for finalized revisions to this activity.

Value in Primary Care MVP Tables

Tables B.15a and B.15b serve to represent the measures and activities that are finalized within the Value in Primary Care MVP.

Symbol Key:
Plus sign (+): proposed additions of MIPS quality measures, improvement activities, or cost measures
Caret symbol (^): new proposed measures and improvement activities
Single asterisk (*): existing measures and improvement activities with revisions
Double asterisk (**): measures and improvement activities only available when included in an MVP
Single exclamation point (!): high priority measures
Double exclamation point (!!): outcome measures
Tilde (~): measures and improvement activities that include a health equity component

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[1163] See *MVP Development: Improvement Activity Policy Update and Global Inclusion of an Improvement Activity.*

TABLE B.15a: Value in Primary Care MVP Measures and Improvement Activities

Quality	Improvement Activities	Cost
(*)(!!) Q001: Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims Measure Specifications, MIPS CQM Specifications) **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQM Specifications) **(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM Specifications) **(!) Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CAHPS Survey Vendor) **Q438:** Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM Specifications, MIPS CQM Specifications) **Q475:** HIV Screening (Collection Type: eCQM Specifications) **(!!) Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) (Collection Type: MIPS CQM Specifications) **(~)(!) Q487:** Screening for Social Drivers of Health (Collection Type: MIPS CQM Specifications) **(*) Q493**: Adult Immunization Status (Collection Type: MIPS CQM Specifications) **(*) Q497:** Preventive Care and Wellness (composite) (Collection Type: MIPS CQM Specifications) **(*)(!) Q504:** Initiation, Review, And/Or Update To Suicide Safety Plan For Individuals With Suicidal Thoughts, Behavior, Or Suicide Risk (Collection Type: MIPS CQM Specifications)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools **(~) IA_AHE_9**: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols **(~) IA_AHE_12:** Practice Improvements that Engage Community Resources to Address Drivers of Health **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings **IA_BE_12:** Use evidence-based decision aids to support shared decision-making **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results **IA_CC_13:** Practice improvements to align with OpenNotes principles **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways **IA_PCMH:** Electronic submission of Patient Centered Medical Home accreditation **(~) IA_PM_11:** Regular review practices in place on targeted patient population needs **IA_PM_13:** Chronic care and preventative care management for empaneled patient **IA_PM_16:** Implementation of medication management practice improvements **(~) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services **(~) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines **(^)(+) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk **(+)(*) IA_PM_26:** Vaccine Achievement for Practice Staff: COVID-19, Influenza, and Hepatitis B	**Asthma/Chronic Obstructive Pulmonary Disease (COPD)** **Diabetes** **Depression** **Heart Failure** **Total Per Capita Cost (TPCC)**

TABLE B.15b: Value in Primary Care MVP Foundational Layer

Population Health Measures	Promoting Interoperability
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Systems (MIPS) Groups (Collection Type: Administrative Claims) **(!!) Q484:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Collection Type: Administrative Claims)	Security Risk Analysis High Priority Practices Safety Assurance Factors for EHR Resilience Guide (SAFER Guide) e-Prescribing Query of Prescription Drug Monitoring Program (PDMP) Provide Patients Electronic Access to Their Health Information Support Electronic Referral Loops By Sending Health Information AND Support Electronic Referral Loops By Receiving and Reconciling Health Information OR Health Information Exchange (HIE) Bi-Directional Exchange OR Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) Immunization Registry Reporting Syndromic Surveillance Reporting (Optional) Electronic Case Reporting Public Health Registry Reporting (Optional) Clinical Data Registry Reporting (Optional) Actions to Limit or Restrict Compatibility or Interoperability of CEHRT ONC Direct Review Attestation

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for this MVP. One commenter appreciated the focus on screening in this MVP. One commenter agreed that the measures reflected in this MVP are consistent with the focus of the APCM service requirements and practice capabilities for advanced primary care. Another commenter supported the inclusion of Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services IA in this MVP. A couple of commenters supported the inclusion of Q493: Adult Immunization Status measure in this MVP. Another commenter supported the inclusion of IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols in this MVP.

A couple of commenters recommended the addition of the following quality measures to this MVP as they provide additional collection types; Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up Plan, Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, Q309: Cervical Cancer Screening. Q238: Use of High-Risk Medications in Older Adults, Q472: Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture, and Q065: Appropriate Treatment for Upper Respiratory Infection (URI). One commenter urged us to consider the inclusion of the kidney health evaluation quality measure to promote screening and diagnosis of CKD for Medicare beneficiaries with diabetes in the primary care setting. One commenter recommended the inclusion of the new improvement activity for clinicians to assess and manage patients at risk of ASCVD. Another commenter recommended the addition of the proposed Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake activity in this MVP. One commenter recommended the addition of the Ambulatory Palliative Care Patients Experience of Feeling Heard and Understood measure in this MVP.

Response: We thank the commenters for their support. We may consider the inclusion of additional quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter suggested that, if we do not remove the TPCC measure from MIPS, then we should at a minimum remove the TPCC measure from all MVPs that include episode-based cost measures.

Response: The Total Per Capita Cost (TPCC) measure is appropriate for use in this MVP. We refer readers to the CY 2022 PFS proposed rule (86 FR 39881 through 39895), CY 2022 PFS final rule (86 FR 66001), CY 2023 PFS proposed rule (87 FR 46814 through 46828), and CY 2023 PFS final rule (87 FR 70038) for more information about why it is appropriate to include the TPCC measure in MVPs. We may consider the addition or removal of cost measures through future MVP maintenance and rulemaking processes. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Value in Primary Care MVP* with modifications in Table B.15a and as proposed in Table B.15b for the CY 2025 performance period/2027 MIPS payment year and future years. Based on comments received, we are delaying the proposed modification of IA_BE_4: Engagement of patients through implementation of improvements in patient portal. See Appendix 2, Table B for additional details. Based on comments received, we are delaying the removal of IA_CC_2: Implementation of improvements that contribute to more timely communication of test results. See Appendix 2, Table C for additional details.

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